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### ORIGINAL RESEARCH

### **Effectiveness of an Inpatient Smoking Cessation Program**

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**BACKGROUND:** Inpatient smoking cessation may increase the success of quitting smoking post-hospital discharge. **METHODS:** Using a quasiexperimental study design, use of cessation methods, mortality, self-reported abstinence, and quit status 6 months post-hospital discharge were measured to assess the effectiveness of an inpatient smoking cessation program. Subjects were interviewed by telephone 6 months post-hospital discharge. Outcomes for patients who were seen by the inpatient smoking cessation counselor were compared to consecutive patients who were not seen by the counselor. Electronic medical records (EMRs) and administrative data were used to construct baseline measures, comorbidity covariates, pharmaceutical use rates during hospitalization, readmission, and mortality outcomes. Multivariate methods included logistic regression and survival analysis.

**RESULTS:** At baseline, the study groups varied by mean age, length of stay (LOS), comorbidity index, cardiovascular diagnosis, and acuity. At 6 months post–hospital discharge, the intent to treat estimate for point prevalence abstinence was 16% in the intervention group compared to 10% in the comparison group (P = 0.02) while self-reported quit status in the intervention group was 44% vs. 30% in the comparison group (P = 0.00). The intervention group used more nicotine replacement therapy (NRT) than the comparison group both in-hospital and following discharge. Crude post–hospital discharge mortality was significantly less in the intervention group (0.02) than in the comparison group (0.04). A multivariate survival model, controlling for baseline imbalances, showed a significantly reduced mortality in the intervention group (hazard ratio [HR] = 0.37; P = 0.04).

**CONCLUSIONS:** Inpatient smoking cessation programs effectively improve quit outcomes, NRT use, and mortality post-hospital discharge. *Journal of Hospital Medicine* 2011;6:E1–E8. © 2010 Society of Hospital Medicine.

### KEYWORDS: effectiveness, inpatient counseling, post-hospital discharge mortality, smoking cessation.

In 1992, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) introduced standards to make hospital buildings smoke-free, resulting in the nation's first industry-wide ban on smoking in the workplace. This hospital smoking ban has led to increased smoking cessation among employees.<sup>1</sup> Since 2003, core measures from the Joint Commission and quality indicators from the Centers for Medicare and Medicaid Services have included inpatient smoking cessation counseling for acute myocardial infarction, pneumonia, and heart failure, as national guidelines strongly recommend smoking cessation counseling for patients with these diseases who smoke.<sup>2–5</sup>

The Department of Health and Human Services (DHHS) 2008 update on *Clinical Practice Guidelines for Treating Tobacco Use and Dependence*<sup>6</sup> recommends that clinicians use hospitalization as "an opportunity to promote smoking cessation" and "to prescribe medications to alleviate with-drawal symptoms." Hospitalization is an opportune time for smoking cessation because patients are restricted to a smoke-free environment in the hospital and, increasingly, on hospital campuses.<sup>6</sup> The illness leading to hospitalization

may be attributable, at least in part, to tobacco use, thereby increasing the patient's receptivity to cessation counseling. Last, medications used in-hospital to treat nicotine withdrawal symptoms may lead to continued or future use of these medications that, in turn, may ultimately lead to a successful quit attempt.

We report on the outcomes of our hospital's attempt to do this in the context of implementation of a smoke-free medical campus.<sup>7</sup> This study was designed to measure whether an inpatient smoking cessation intervention increases the likelihood of smoking cessation 6 months post-hospital discharge. Because effectiveness studies are the next step to improving translation of research into health promotion practice,<sup>8</sup> we set out to measure what the impact of this intervention would be in routine clinical practice as opposed to a carefully structured efficacy trial.

### Methods

#### Intervention

The Smoking Cessation service for inpatients began on April 3, 2006. Upon admission, all patients were screened

regarding their current smoking status. The nurse asked the patient if s/he currently smoked and then entered the responses into the hospital electronic medical record (EMR). A current smoker was defined as "smoking every day or some days within the past 30 days." A roster of newly admitted current smokers was electronically transmitted to the Respiratory Care office daily. Only current smokers received counseling. The Smoking Cessation Specialist (SCS) subsequently saw inpatients within a 24-hour time frame of admission, except for weekends and holidays. Each patient received 1 to 2 intensive follow-up counseling sessions during hospitalization. An average of 10 patients per day were seen.

The goal of the inpatient smoking cessation service was to counsel patients on the health effects of smoking, address nicotine withdrawal symptoms, explain the different pharmacotherapies available, advise on how to quit, give selfhelp materials, counsel family members, and refer to the New York State (NYS) Smokers' Fax-to-Quit program.<sup>9</sup> Following the consult, the SCS documented the encounter in the patient's chart, including recommendations for nicotine replacement therapy (NRT) or bupropion (varenicline was not addressed as it was not on the formulary). The chart documentation informed the physician and nursing staff of the intervention and included the date/time, stage of change, and support action taken.

The SCS was part-time, had nursing training, smoking cessation training,<sup>10</sup> and was also trained by the Seton Health Cessation Center in the "Butt Stops Here" Program.<sup>11</sup> She also implemented a performance improvement plan to increase the provision of smoking cessation counseling, increase NRT or bupropion prescriptions to smokers admitted to the hospital, and increase referrals to the NYS telephone quitline through the Fax-to-Quit program for outpatient resources and help following hospital discharge. The Fax-to-Quit program allows health care providers to refer patients to the NYS quitline via fax, with the patient's signature (patient permission) on the fax to quit form. After hospital discharge, the quitline then contacts the patient at a time that the patient requested.

The SCS visited patients with all admitting diagnoses on the medical, surgical, and special care units who were current smokers. Inpatients admitted to psychiatry, obstetrics, and the intensive care unit (ICU) were not seen by the SCS, except for ICU patients referred by a physician. Inpatients who had short stays or who were admitted and discharged in 1 day or during the weekend were not seen.

The intervention included either a brief 3-minute to 5minute intervention or a more intensive intervention, that required 10 to 20 minutes (18 minutes average). The length of the intervention was determined by how receptive the patient was to the intervention. All interventions began with patient identification, an introduction to the SCS, and an explanation of the purpose of the visit. The SCS then inquired about the patient's comfort level vis-a-vis nicotine withdrawal and if s/he was receiving any NRT while in the hospital (NRT on the inpatient formulary included the nicotine patch or gum). If the patient was receptive to counseling, the SCS then began to work through the 5 A's, as described in the 2000 DHHS Clinical Practice Guidelines.<sup>12</sup> The 2000 DHHS Clinical Practice Guidelines were used because the 2008 update had not been released at the time this study was initiated in 2006. These include: asking about smoking status, advising on how to quit, assessing readiness to quit, and assisting in arranging treatment options that include pharmacotherapy, counseling, as well as referral to the NYS Smokers' Quitline. A workbook was provided to reinforce counseling but was not necessarily used during counseling session. A compact disc (CD) with relaxation exercises<sup>5</sup> was provided to those inpatients who were interested in stress reduction. If family members were present, and were also smokers, they were included in the counseling session, if willing. Each patient was offered a referral via the Fax-to-Quit program to continue treatment on an outpatient basis.

If the patient was not motivated to quit or declined the consult, the visits were short and focused on the patient's experience with nicotine withdrawal. These patients were also given self-help materials and, if possible, the relevance of and roadblocks to quitting were reviewed. Patients were prompted to think about why quitting was relevant and often the reason for hospitalization was used to motivate the quitting process.

Upon hospital discharge, the patient's primary care provider was notified of the cessation intervention by a letter from the SCS. The letter described the intervention and stated whether or not the patient agreed to be referred to the Fax-to-Quit Program.

### **Study Participants**

Patients were recruited from July 1, 2006 (after the smoking ban went into effect) through June 1, 2008. Inpatients who currently smoked were informed of this study and were asked to sign informed consent to participate after they were seen by the SCS. Current smokers of all admitting diagnoses were recruited into the study. Patients provided informed consent for a telephone interview 6 months posthospital discharge. A written Health Insurance Portability and Accountability Act (HIPAA) release was obtained to allow access to an individual's specific EMR.

A comparison group of inpatients who were also current smokers, but who did not receive the intervention were also contacted six months after hospitalization. Reasons for not receiving the intervention included the fact the SCS was part-time and also took a leave of absence during the study and therefore could not see all inpatients who currently smoked. Other reasons for not receiving the intervention include too short a stay for the SCS to see the patient or the patient was out of the room for tests or procedures when the SCS was available. These patients provided informed consent to be interviewed 6 months after hospital discharge

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and HIPAA consent for access to their medical record. Not all inpatients in the comparison group provided written HIPAA release for use of their medical record; therefore, these patients were excluded because their baseline demographic and diagnostic data were missing.

Sample-size considerations were driven around having adequate numbers of subjects to measure the prevalence of smoking cessation at 6 months post-hospital discharge with an acceptable degree of precision. Prevalence estimates from previous studies for 6-month cessation typically range from 20% to 30%, with cessation rates as high as 67% (this estimate applies to post—myocardial infarction patients.)<sup>13</sup> For conservative estimation, we used 50% as the 6-month prevalence of cessation in the current study, which placed binomial variance at its theoretical maximum. In this case, a sample of 300 subjects provides a margin of error of  $\pm 0.058$  for a 95% confidence interval around this point estimate.

### **Data Sources**

The hospital EMR database was used to monitor several components of the program: nursing screening, smoking cessation counseling, and pharmacy dispensing of NRT and bupropion. The screening data were also used to monitor the proportion of current smokers admitted during the study period. Elements of the EMR were used to define the following covariates: patient age, gender, ethnicity, and the primary discharge diagnosis (via International Statistical Classification of Diseases and Related Health Problems, 9th edition [ICD9] codes) and readmission during the six month follow-up period. Mean length of stay (LOS) was computed. The Elixhauser Comorbidity Index that utilizes ICD9 codes was used for comorbidity risk adjustment.<sup>14</sup>

Study participants were contacted by phone 6 months post-hospital discharge. Data collection began July 1, 2006 and was completed January 1, 2009. The interview focused on self-reported point prevalence of smoking and 6-month quit status. The point prevalence for self-reported abstinence was derived from the question "Do you now smoke cigarettes every day, some days, or not at all?"15 Selfreported quit status was derived from question "Have you quit smoking since you were discharged from the hospital?" In addition, respondents were queried about their number of years smoked, post-hospital discharge number of quit attempts, and cessation efforts (NRT, self-help groups, quitline use, etc.). Last, they were surveyed about barriers to cessation (exposure to secondhand smoke, rules about smoking in the home or car), educational level, employment, and health ratings.

To determine the status of those lost to follow-up, administrative and EMR databases for appointments and follow-up visits were accessed to determine if the patient was alive during the 6 months between discharge and the follow-up call. To confirm mortality, we searched the Internet, Ancestry.com, and/or local newspaper obituaries for dates of death for all patients to validate that they had not died during the 6-month follow-up. World wide web searches can identify 97% of deaths listed in the Centers for Disease Control and Prevention (CDC)/National Death Index, which is considered the gold standard in epidemiologic studies.<sup>16</sup>

### Analysis

Univariate analysis of all covariates was completed to examine the normal distribution curves for these variables. Bivariate correlation analysis of all the independent variables by study group was performed to assess comparability of the study groups at baseline. The self-reported cessation outcomes were calculated by dividing the number of patients who said they were not using tobacco or had quit, at 6 months post–hospital discharge by the number of individuals in the study group at baseline minus those who had died. Both the intent to treat method, which assumes patients lost to follow-up were still smoking, and the responder method, which does not include nonresponders in the analysis, were used to adjust the denominators for these outcomes.

Multivariate regression analysis was then used to model receipt of the intervention as predictor of self-reported quit status adjusted for significant covariates. Statistical significance was defined by a P value of less than 0.05.

Survival analysis was employed to model differences in mortality between the study groups, controlling for any baseline imbalances (eg, comorbidity). Because baseline data were used in this model, the model includes only patients with signed a HIPAA release.

Internal review boards of our hospital and the NYS Department of Health reviewed and approved this study.

### Results

From January 1, 2007 to May 30, 2008, 660 inpatients who were current smokers were recruited into the study. Figure 1 summarizes patient flow through the study and explains the final sample size of 607. Exclusions include 52 inpatients from the study who completed the 6-month interview but who did not return a written HIPAA release. Without a HIPAA release to access the EMR, baseline comparison of the study groups and adjustment for comorbidity could not be completed for these patients. At 6 months post–hospital discharge, 53 subjects refused the interview when contacted by telephone.

As might be expected in a quasiexperimental design, the study groups were not equivalent at baseline (Table 1). The intervention and comparison groups differed with regard to age, length of stay (LOS), proportion of acute admissions, and the Elixhauser comorbidity index. These differences suggest that the intervention group was older, had a longer LOS, higher acuity at the time of admission, and more comorbidities. In addition, as a result of the intervention,

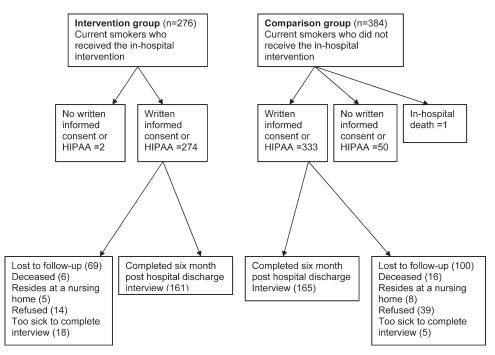


FIGURE 1. Study flow diagram. Abbreviation: HIPAA: Health Insurance Portability and Accountability Act.

the intervention group was more likely to receive NRT or bupropion in hospital and a Fax-to-Quit referral to the NYS Smokers' Quitline. In the intervention group, most patients received 1 visit from the SCS, only 2% received 2 visits. Family members were included in smoking cessation counseling for 58% of the intervention group.

As shown in Table 2, there was a significant amount of diagnostic heterogeneity in the discharge diagnoses codes of patients included in the study. However, there were significantly more patients in the intervention group with a first discharge diagnosis of cardiovascular disease (25%) compared to the comparison group (12%; P = 0.00).

Readmission outcomes based on EMR and administrative data were available for 607 inpatients with signed HIPAA releases. The readmission rate was higher for the intervention (41%) than the comparison group (20%). Despite a higher readmission rate, the crude mortality within the 6 months post–hospital discharge was lower for the intervention group, ie, 0.02 (6/276), than the comparison group, which had a crude mortality of 0.04 (16/384) during this period.

A multivariate survival model, controlling for age, sex, Elixhauser comorbidity index, LOS, and cardiovascular diagnosis, showed a significantly reduced mortality in the intervention group (hazard ratio [HR] = 0.37; P = 0.04). Although cardiac status (P = 0.09) and LOS (P = 0.15) were not significant in this model, they were retained because both of these variables showed significantly higher levels (along with the Elixhauser Index) at baseline in the intervention group, implying that the intervention group was sicker than the comparison group. The Elixhauser comorbidity index (HR = 1.42; P < 0.00) and age (HR = 1.07; P < 0.00) were

### TABLE 1. Baseline Demographic, Hospitalization, and Smoking Characteristics by Study Group

	$\begin{array}{l} \text{Intervention} \\ (n=275) \end{array}$	Comparison (n = 335) (P value)
Sex (% male)	51	51
Mean age (years)	51.4	48.5 (0.03)
Ethnicity (% white)	98	97
Marital status (% married)	48	47
Elective admission (vs. acute) (%)	25	31
Inpatient (vs. outpatient observation or outpatient surgical admission) (%)	86	68 (0.00)
LOS (days)	3.80	2.68 (0.00)
Elixhauser comorbidity index (mean)	1.66	1.17 (0.00)
Used NRT in hospital (%)	37	19 (0.00)
Used bupropion in hospital (%)	4	1 (0.00)
Referred to NYS Smokers' Quitline using Fax-to-Quit	10	0 (0.00)
Mean cigarettes per day*	17.7 (n = 213)	15.9 (n = 192)

Abbreviations: EMR, electronic medical record; LOS, length of stay; NRT, nicotine replacement therapy; NYS, New York State.

\*n differs due to missing data in the EMR.

the only other significant predictors of mortality in this model.

Among those responding to the interview at 6 months post-hospital discharge (n = 326), there were no significant differences between the study groups with regard to age first started smoking, gender, educational level, employment status, ethnicity, or physical health status (data not shown). Table 3 summarizes the outcomes by the intervention and

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### TABLE 2. First Discharge Diagnosis Category Based on ICD-9 Code by Study Group

	Intervention $(n = 274)^*$ (%)	Comparison (n = 333)* (%)
Cardiovascular	25	$12^{\dagger}, P = 0.00$
Pulmonary	16	7
Orthopedics	12	12
Injury	10	15
GI	8	16
Cancer	6	8
GU	3	6
Endocrine	3	3
Other	17	21

Abbreviations: GI, gastrointestinal; GU, genitourinary; ICD-9, International Statistical Classification of Diseases and Related Health Problems, 9th edition.

\*Discharge diagnosis missing for 3 inpatients.

 $^{\dagger}P < 0.00$  in a dichotomous chi square analysis of cardiovascular vs. all other diagnoses.

comparison groups at 6 months post-hospital discharge. The point prevalence for abstinence was 27% in the intervention group compared to 19% in the comparison group (P = 0.09). Using the intent to treat analysis, the point prevalence for abstinence was 16% in the intervention group compared to 9.8% in the comparison group (P = 0.02). Self-reported quit status was 63% in the intervention group vs. 48% in the comparison group (P = 0.00). Using the intent to treat analysis, quit status was 44% in the intervention group vs. 30% in the comparison group (P = 0.00). Exclusion of the 52 patients without signed HIPAA releases (Figure 1) did not significantly alter these outcomes.

Patients who received the inpatient smoking cessation counseling were more likely to be called by or use the NYS Smokers' Quitline; however, these differences were not statistically significant. There was no difference between the study groups in awareness of the Quitline but the intervention group was more aware that free NRT was offered by the NYS Quitline. In terms of quit methods used during the 6month period (Table 4), NRT or bupropion use was higher in the intervention group. There were no other significant differences between the study groups, except for the use of acupuncture.

Multivariate analysis predicting quit status at 6 months post-hospital discharge included covariates controlling for age, sex, LOS, study group, and comorbidity. This analysis showed that patients with a cardiovascular discharge diagnosis were more likely to quit than patients who had other discharge diagnoses (odds ratio [OR], 3.02; 95% confidence interval [CI], 1.6–5.7; P = 0.00). Another statistically significant covariate in this model included sex (men were more likely to quit: OR, 0.61; 95% CI, 0.39–0.97; P = 0.04). Participating in the inpatient intervention group was marginally significant when controlling for these other variables (OR, 1.54; 95% CI, 0.98–2.45; P = 0.06). Hospital LOS, age, receipt of NRT in hospital, and the Elixhauser comorbidity index were not predictive of quit status at 6 months.

### TABLE 3. Self-Reported Outcomes 6 Months Post-Hospital D/C

	Intervention (n = 161)	Comparison (n = 165) (P value)
Self-reported now smoking "not at all" (%)	16	10 (0.02)
Self-reported quit within 6 months (%)	63	48 (0.00
Tried to quit (%)	68	62
Used NRT post-D/C (%)	26	17 (0.04)
Used other intervention (%)	21	14
Heard of the NYS Smokers' Quitline (%)	92	90
Aware that NYS Quitline offers NRT (%)	73	49 (0.00)
Received free NRT from NYS Smokers' Quitline (%)	9	6
Used NYS Smokers' Quitline (%)	15	9
Called by the NYS Smokers' Quitline (%)	11	5
Self-rated health status as fair or poor (%)	48	36
Another smoker living at home (%)	54	48
Mean hours spent in same room where someone else was smoking (n)	20	21 (0.04)
Households in which smoking is not	40	33
allowed in the home (%)		
Patients Still Smoking at the	Intervention	Comparison
6-Month Interview	(n = 118)	(n = 134)
Mean cigarettes currently smoked (n)	10.5	12.7
Mean quit attempts post-D/C (n)	3.2	3.5
Mean reduction in smoking* (cigarettes/day)	5.83	4.09

NOTE: Based on interview with those patients who had written informed consent and a HIPAA release on file; n = 326.

Abbreviations: D/C, discharge; NRT, nicotine replacement therapy; NYS, New York State. \*Baseline cigarettes/day minus 6-month cigarettes/day.

### Discussion

This study demonstrates how effective an inpatient smoking cessation program can be for increasing the success of quitting smoking after hospital discharge. At 6 months posthospital discharge, the intervention group had significantly higher intent to treat outcomes for point prevalence abstinence and quit status as well as lower crude and adjusted mortality than the comparison group.

Although at baseline the intervention group was older, had a longer LOS, more cardiovascular diagnoses, and higher comorbidity index, crude post-hospital discharge mortality was significantly less in the intervention group (0.02) than in the comparison group (0.04). This finding is more significant in light of the higher comorbidity and acuity of the intervention group at baseline. Our multivariate survival model that controlled for these imbalances at baseline demonstrated that the intervention group had significantly less mortality than the comparison group (HR = 0.37; P = 0.04). Reduction in mortality, as soon as 30 days after inpatient smoking cessation counseling, has been demonstrated post–myocardial infarction.<sup>17,18</sup> Intensive smoking cessation quit services were also linked with lower all cause mortality among cardiovascular disease patients 2 years

# TABLE 4. Quit Methods Used by Those Who Tried to QuitDuring the 6 Months Post-Hospital Discharge by StudyGroup

	Intervention $(n = 91)$	Comparisor (n = 93) (P value)
Got help from friends or family (%)	58	50
Used any medication to quit (%)	44	28 (0.02)
Used nicotine patch (%)	43	25 (0.00)
Used bupropion (%)	10	1 (0.00)
Used varenicline (%)	32	25
Cut back (%)	43	46
Quit with a friend (%)	20	13
Switched to lights (%)	18	13
Used print material (%)	14	16
Got help from the NYS Smokers' Quitline (%)	11	9
Called by the NYS Smokers' Quitline (%)	11	5 (0.09)
Counseling (%)	9	3
Acupuncture (%)	5	0 (0.02)
Switched to chew (%)	2	4
Attended classes (%)	3	1
Used NYS Smokers' Quitline website (%)	2	4

posthospitalization.<sup>19</sup> Our study, despite its relatively small sample size, demonstrates that the intervention retains its impact on mortality in real-world settings.

Following participation in an inpatient smoking cessation program, self-reported quit status at 6 months posthospital discharge in the intervention group was significantly higher in the intervention group (63%) than the comparison group (48%; P = 0.00). Using the intent to treat method, the differences between the study groups was still significant (44% in the intervention group, 30% in the comparison group; P = 0.00). Given the limitations of self-report and responder bias, the actual outcomes fall somewhere between these 2 estimates. In an effectiveness study of inpatient smoking cessation involving 6 hospitals in California, self-reported quit rates of 26% at 6 months were reported; however, different methods were used so the results are not strictly comparable.<sup>20</sup>

Our multivariate analysis suggests that patients with cardiovascular discharge diagnosis were more likely to quit than patients who had other discharge diagnoses (OR, 3.02; 95% CI, 1.6–5.7; P = 0.0007). This study extends findings of other studies that show that the success of smoking cessation may vary by diagnosis, particularly for smokers admitted for cardiovascular disease.<sup>21,22</sup> Other studies have shown that smoking cessation rates among patients post-myocardial infarction were higher in admitting facilities that had hospital-based smoking cessation programs and for those patients referred to cardiac rehabilitation.<sup>23</sup> Thus, the availability of a hospital-based smoking cessation program may

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be considered a "structural measure of health care quality" as suggested by Dawood et al.<sup>23</sup>

The use of NRT greatly increased in our hospital, coincident with the start of the inpatient cessation program<sup>7</sup> and, in this study, NRT use appears to continue after hospital discharge. Some studies show an additive effect of NRT combined with cessation counseling.<sup>24,25</sup> Although a Cochrane review did not find a statistically significant difference, there was a trend toward higher quit rates with the addition of NRT.<sup>21,22</sup>

Because hospitalized smokers may be more motivated to stop smoking, the updated 2008 DHHS clinical practice guidelines for *Treating Tobacco Use and Dependence* now recommend that all inpatients who currently smoke be given medications, advised, counseled, and receive followup after discharge.<sup>26</sup> Although our inpatient cessation program was started before these clinical practice guidelines were updated, we have had the opportunity to evaluate the recommended practice of inpatient tobacco cessation counseling. Compared to effects shown in efficacy studies, clinical interventions often lose effect size in daily practice and real-world settings.<sup>27,28</sup> It is reassuring that, in this effectiveness study, the impact of this intervention is still demonstrable.

Provision of inpatient smoking cessation has been shown to be an effective smoking cessation intervention if combined with outpatient follow-up.29 Reviews by Rigotti et al.<sup>21,22</sup> recommend that inpatient "high-intensity behavioral interventions" should be followed by "at least 1 month of supportive contact after discharge to promote smoking cessation among hospitalized patients." In our study, specific cessation-related outpatient follow-up was not provided by our program. Although letters were sent to primary care providers describing the cessation service provided during the inpatient stay, our study could not ascertain what specific cessation service was offered by either primary-care or specialty-care providers during posthospitalization follow-up visits. An efficient alternative to outpatient visits may be follow-up delivered via a quitline. Follow-up in our study included referrals to the NYS Smokers' Quitline; however, only about 10% of inpatient reported using this service. While feasible, the effectiveness of quitline follow-up is as yet unknown.30

### Limitations

This study targets a later phase in research progression from hypothesis development, pilot studies, efficacy (empirically supported) trials, effectiveness trials (real-world settings), and dissemination studies.<sup>31</sup> Because this study addresses the effectiveness rather than the efficacy of inpatient smoking cessation counseling, the use of a quasiexperimental rather than randomized controlled clinical trial design led to measured differences in the study groups at baseline. An important imbalance arose in the intervention group that had twice the percentage of patients with cardiovascularrelated discharge diagnoses as the comparison group. While we were able to adjust for these differences in our analysis, there may be unmeasured differences due to the fact that the inpatients were not randomized to the study groups.

The outcomes of this study cannot be attributed to any one component of the intervention (eg, NRT) vs. the combined effect of the inpatient smoking cessation program. The program components were implemented simultaneously in order to maximize synergistic effects; therefore, the effects of program components are difficult to disaggregate.

The results are limited by the validity of self-report of smoking status. It is well known that research studies which validate smoking status biochemically have lower efficacy (OR, 1.44; 95% CI, 0.99–2.11) than those that do not validate smoking status (OR, 1.92; 95% CI, 1.26–2.93).<sup>32</sup> Although it was impractical in this effectiveness study to biochemically validate smoking status 6 months post–hospital discharge, we have documented a significant difference between the study groups that confirms the direction of the effect, if not the effect size.

Self-reports tend to underestimate smoking status in population studies<sup>33</sup>; however, the discrepancy between self-reported smoking and biochemical measurements among clinical trial participants is small.<sup>34</sup> However, a small but significant bias toward a socially desirable response in intervention groups compared to control groups of 3% with carbon monoxide and 5% for cotinine has been documented.<sup>35</sup> If social desirability bias is operative in this study, and if we apply the above correction factor of 4% to correct this classification error, then the difference between the intervention and comparison group would be 10 percentage points (40% in the intervention to treat estimates). That difference is still clinically relevant.

The observed difference between the intervention and comparison group is underestimated because the comparison group was exposed to smoking cessation as well both at the time of admission and following discharge (Table 4). The comparison group in this study could thus be viewed as a usual care group rather than a control group. That exposure does cloud the measurement of quit rates as the comparison group is "contaminated" to some degree by exposure to various cessation methods. The impact of this exposure is to reduce the effect size observed in this study or underestimate the effect of the inpatient smoking cessation counseling because the comparison group was exposed other cessation methods, although to a lesser extent.

The social desirability bias inherent in self-reported smoking status may increase the effect size while the use of comparison group that received usual care may decrease the effect size. Because neither of these biases could be measured in this study, it is impossible to say whether they negated each other.

As with any administrative database, use of EMR as a data source in this study led to missing data that precluded use of certain variables in the analysis. In addition, lack of

written and signed HIPAA releases also precluded inclusion of several inpatients, mostly in the comparison group, in the analytic database. However, it is reassuring that the results of the 6-month survey did not differ significantly when these individuals were included or excluded from a separate analysis of the survey data. Last, our study population is almost 100% Caucasian thus limiting how generalizable the results are to more heterogenous patient populations.

### Conclusions

This quasiexperimental effectiveness study showed that inpatient smoking cessation intervention improved smoking cessation outcomes, use of NRT, and was associated with a decreased mortality 6 months post-hospital discharge. The effectiveness of this inpatient intervention is maintained in real world settings but may be improved with post–hospital discharge follow-up.

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