Title: Evaluating the Effectiveness of a Hospital-Based "Opt-Out" Tobacco Cessation Program: A Cohort Study

Running Title: Hospital-Based "Opt-Out" Tobacco Cessation Program

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ABSTRACT

Background: In 2014, the Medical University of South Carolina (MUSC) adopted a policy that all hospitalized patients who self-reported using tobacco be referred to a tobacco cessation program consistent with Joint Commission recommended tobacco treatment standards.

Objective: To evaluate the reach and impact of the "opt-out" tobacco cessation service.

Design: Cohort.

Setting: Hospital.

Patients: 42,061 adult (18 years or older) patients admitted to the MUSC Hospital between February 2014 and May 2015.

Intervention: All current cigarette smokers were referred to the tobacco cessation program, which consisted of a bedside consult and phone follow-up 3, 14 and 30 days after discharge using interactive-voice-recognition (IVR).

Measurements: The primary study outcomes were the proportion of 1) smokers reached by the bedside counselor and/or phone follow-up, 2) smokers who opted out; and 3) smokers who reported abstinence at any post-discharge phone call.

Results: Records identified 8,423 smokers, of whom 69.4% (n=5,843) where referred into the program after exclusions. One full-time bedside tobacco counselor was able to speak with 1,918 (32.8%) patients, of whom 96 (5%) denied currently smoking and 287 (14.9%) refused counseling. Re-contact at follow-up was achieved for 703 (55%) smokers who received bedside counseling and 1,613 (49%) who did not, yielding and overall follow-up reach rate of 60%. Of those reached by phone, 36.4% reported not smoking (51% versus 27% for those who did and did not receive bedside counseling, respectively). The overall intent-to-treat abstinence rate was 13.5%.

Limitations: Both enrollment in the program and abstinence from smoking were based on self-reported smoking behavior.

Conclusions: The findings demonstrate the feasibility of implementing an "opt-out" tobacco cessation service for hospitalized patients consisting of an inpatient bedside counselor and IVR follow-up after discharge.

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INTRODUCTION

In 2012, the Joint Commission (JC), which sets quality standards for hospitals in the United States, recommended that all current tobacco users identified upon hospitalization receive tobacco-cessation services as an inpatient and be followed up within 1-month after hospital discharge (1, 2). Studies have reported an increase in long-term quit rates when an in-hospital tobacco cessation intervention is combined with phone follow-up support after discharge (3-8). Despite evidence supporting the benefits of providing smoking cessation services to hospitalized patients, few hospitals have fully implemented the JC quality standards (2, 9). Most inpatient tobacco services rely on health care providers to refer patients into the service, with various strategies used to encourage providers to make referrals (e.g., in-service programs, prompts built into the electronic health records), however not all programs follow-up with patients after discharge from the hospital (2, 9). Unfortunately, evidence suggests that only a fraction of eligible smokers receive referral to evidence-based smoking cessation support, which has led some researchers and healthcare organizations to recommend the employment of an "opt out" referral system (10-12), in which patients are automatically enrolled unless they opt out of the service.

In 2014, the Medical University of South Carolina (MUSC) implemented a policy, consistent with the JC's recommendation, requiring that 1) all hospitalized patients be screened for tobacco use, 2) all patients who report current smoking receive referral to an evidence based tobacco cessation treatment service, with 3) phone follow-up cessation support for 30 days after hospital discharge. Unique to this program was the development of an "opt out" approach, where referrals to the cessation program occurred automatically without requiring any input or decision from either providers or patients. We report herein the reach and impact of the program over the first 15 months of implementation.

METHODS

The MUSC hospital inpatient tobacco cessation service is based in part upon the program previously implemented at the Ottawa Heart Institute which utilized bedside counseling and interactive voice recognition (IVR) follow-up calls to patients after hospital discharge (4, 13, 14). The MUSC service is unique because our treatment policy requires enrollment of all eligible

current smokers, defined as having smoked within 30 days of their hospitalization, as well as referral to phone follow-up whether or not the patients received a bedside consult. All current adult cigarette smokers are enrolled in the program with the following exclusions: 1) died during hospitalization; 2) receiving hospice care; 3) unable to communicate due to language or medical condition; 4) not discharged back home, and 5) patients without a phone number. Patients who were readmitted but had an active follow-up call schedule were also excluded. All eligible patients are automatically enrolled in the program, but are given the option to "opt out" of the service at any time.

The MUSC inpatient tobacco cessation program includes 3 steps. In **step 1** (screening): all hospitalized patients are asked about whether or not they use cigarettes. Smoking status is identified through the electronic medical record (EMR). Only patients who self-identify as current smokers are referred to the tobacco cessation service. Most data are obtained from admission records, but in some instances smoking is identified using data obtained at patient discharge, the latter not seen by bedside counselor. We developed an explicit feature to allow patients who are identified as current smokers by the medical staff, but not through their EMR, to be manually referred to bedside consult. Patients reporting current smoking are identified and referred through a daily census to a certified tobacco treatment specialist, who then makes rounds throughout the hospital to engage all patients. In **step 2** (bedside counselling): The MUSC tobacco cessation service employs one full-time tobacco treatment specialist who provides bedside consults to as many patients as can be reached while hospitalized. The bedside consult (average of 15 minutes) includes obtaining a detailed tobacco history, assessment of nicotine dependence, readiness to quit, and an individualized tobacco treatment plan is developed consisting of counseling and nicotine replacement therapy (NRT) where appropriate. Information is captured on an electronic tablet (Table 1). The tablet generates an automated summary of the consult that includes the patient's smoking history and treatment plan. Recommendations for NRT are placed in the patient's chart to be acted upon by the attending physician during hospitalization and at discharge. In **step 3** (follow-up): All eligible patients, whether seen by the bedside counselor or not, are followed-up by IVR phone calls at 3, 14 and 30 days after discharge to assess their smoking status and provide additional support through a

direct referral to the South Carolina Quitline. At each of the three follow-up contact days, at least 6 callback attempts are made at multiple times of the day to maximize reach.

Data on all smokers are secured in a database that allows staff to track the status of patients enrolled into the service. A physician-led oversight committee meets monthly to track five quality indicators associated with the standards recommended by the JC: 1) the proportion of adult (18 years old and older) patients screened for tobacco use, 2) the proportion of current smokers reached by the bedside counselor, 3) the proportion of current smokers who receive pharmacotherapy support for their nicotine addiction, 4) the proportion of smokers reached by a follow-up call within a month after discharge, and 5) the proportion of smokers who report abstinence abstinent after discharge. The annual budget for the program which included expenses for the bedside counselor, printed materials, equipment, and the IVR system for making phone calls was approximately $170,000.

Data Sources

Data for this paper come from three sources: 1) electronic medical records (EMRs), 2) the bedside consult questionnaire (see table 1), and 3) the phone follow-up survey (copies of the follow-up surveys can be obtained from the corresponding author). EMRs contain information on the patients' admission and discharge dates and times, unit, demographics (age, race, sex, type of insurance), smoking status, and identifying information such as full name, address, and phone number. Data on daily admissions are extracted from EMRs and deposited via a secure, HIPAA-compliant transfer to TelASK Technologies (Ottawa, Canada) which identifies current smokers eligible for the tobacco cessation service. Each morning the list of inpatient smokers from the prior day's admissions is made available to the bedside counselor through a secure web-interface provided by TelASK that can be accessed using a desktop computer and a tablet. The interface loads each patient's identifying information to a task list that informs the bedside counselor where patients are located in the hospital. For patients seen by the bedside counselor, information on the consult is captured on the tablet and securely downloaded to the patient database system. Data from the EMRs received daily also allow the patient database system to detect smokers who have been discharged and are eligible to start receiving IVR calls, which are initiated 3 days after discharge. Based on the patient's hospital-assigned medical record number (MRN), the system identifies patients who have been readmitted to the hospital within 6-months

of the original admission, and excludes them from the program. Data from EMRs, bedside consult, and IVR calls are kept in separate databases and linked together for analysis via the patient's MRN and hospital admission date.

Statistical Analyses

We summarized data on the overall reach of the program, response to follow-up telephone calls, and self-reported smoking status 1-month after hospital discharge for patients hospitalized at MUSC between February 2014 and May 2015. Program reach was defined as eligible current cigarette smokers who received either a bedside consult and/or responded to at least one of the three follow-up callbacks after discharge from the hospital. Response to the telephone callback is defined as answering at least one of the three follow-up calls made 3, 14, and 30 days after hospital discharge. Self-reported smoking abstinence is measured as a response of not smoking to the most recent follow-up call completed after hospital discharge. When applying intent-to-treat (ITT) analysis of quit rates, all those not reached by phone were considered to be still smoking, allowing all eligible smokers to be included in the denominator and conservatively estimating overall quitting behavior. Frequencies and percentages were reported for categorical variables whereas medians and ranges, means and standard deviations (SD) were reported for continuously measured variables. All statistical analyses were performed in SAS 9.4 (SAS Institute, Cary, NC).

Role of the Funding source

MUSC Health provided the sole funding for the service reported. All co-authors are either employed or contracted by MUSC. MUSC Institutional Review Board (IRB) reviewed and approved the study.

RESULTS

Between February 2014 and May 2015 there were 42,061 adult admissions to the MUSC hospital, of who 8,423 (20%) reported current smoking (Figure 1). Of identified current smokers 69.4% (5,843/8,423) were deemed eligible for referral to the tobacco cessation program. The bedside counselor attempted to interview 2,941 patients of whom 1,918 were actually reached while in the hospital. Of those reached, 80% (1,535/1,918) were successfully counseled, 15%

(287/1,918) opted out of counseling, and 5% (96/1,918) denied using any tobacco within the past 30 days. Among patients not seen by the bedside counselor, 2,996 were eligible for enrollment in the follow-up IVR cessation program. Among the 5482 patients not seen by the bedside counselor, 2486 were deemed not eligible for phone follow-up due to not providing a phone number, having an ineligible discharge (e.g., discharged to hospice or prison), or being a psychiatric patient. We did not enroll psychiatric patients (Institute of Psychiatry - IOP) into the program until July 2014, which is one reason for the large number of excluded patients. Overall, a total of 5,400 patients were deemed eligible to receive phone follow-up calls.

Table 2 provides information on patient characteristics by smoking status. Current smoking was more common among males than females and those who were uninsured or on Medicaid than those with commercial insurance. Current smokers tended to be younger and have slightly longer lengths of stay in the hospital compared to former and never smokers. Current smoking was most common in those with a diagnosed psychiatric disorder (56.9%) and those treated for injury and poisoning (29.8%), but less prevalent among women giving childbirth (11.9%) and those with a diagnosis of cancer (13.9%) (data not shown).

Table 3 summarizes data for the 1,535 patients who completed the bedside consult and who partially comprise the sample eligible for IVR follow-up. Ninety-four percent of patients said that they were daily smokers, and most reported smoking their first cigarette within 5 minutes of waking up (79%). Few smokers (n=156; 11%) had tried to quit in the past year for at least 24-hours, and of those only 63% were successful in quitting for at least 1 day. About 40% had high intention for quitting smoking, but only 8% were very confident that they would remain smoke-free after discharge. Unassisted quitting (i.e., “cold turkey”) was the most common patient reported method of quitting followed by e-cigarettes. Approximately 44% experienced craving to smoking while hospitalized and the majority of those (81%) were interested in receiving NRT during their stay.

Of the 5,400 patients enrolled in the IVR follow-up calls, 42.8% (n=2,316) were reached at least once within 30 days post discharge. Of the 3,084 patients who did not respond to the follow-up calls 796 (25.8%) were mostly not reached because of wrong or nonworking numbers while the

balance (n=2,288, 74.2%), had apparently valid phone numbers but did not respond to any of the 18 callback attempts made to them and thus were classified as passively "opted out" of the program. Of the 2,316 individuals who responded to at least one of the phone follow-up calls only 18 (0.77%) affirmatively opted out of future calls. Combined, 60.4% (3,531/5,843) of the smokers were reached by the program, either by inpatient contact with the bedside counselor and/or by IVR follow-up calls.

Among those who were reached by phone at any call, 36.4% reported not smoking at the time of phone contact. Based on the intent-to-treat (ITT) method, 13.5% of patients were classified as not smoking based on their most recent follow-up call. Overall, of the 1,824 patients reach by phone and who acknowledged that they were smokers, 19.6% (n=357) selected the option of being transferred to the South Carolina Quitline to receive additional cessation support.

Table 4 compares outcomes for patients who received bedside counselling and post-discharge IVR phone follow-up calls and those who received post-discharge IVR calls only. Bedside tobacco cessation counseling was associated with a 13% increase in response to the follow-up calls, a 90% increase in reported tobacco abstinence, and an over two-fold increase in the reported use of stop smoking medications.

CONCLUSIONS

The findings from this study demonstrate the feasibility of implementing an opt-out tobacco cessation service for hospitalized patients that is consistent with the JC recommended standards for treating tobacco dependence (1). With one full-time bedside tobacco treatment specialist counselor and an automated IVR telephone support program, 60.4% of eligible patients received evidence-based cessation support. The majority of patients reached by phone within 30 days of hospital discharge reported that they had returned to smoking again, although abstinence rates were almost three-fold higher among those who had received a bedside consult while hospitalized. These findings are consistent with other studies which have reported that receiving an inpatient bedside tobacco treatment consult is associated with a greater likelihood of using stop smoking medications and refraining from smoking after discharge from the hospital (3-8). Other studies have suggested that IVR follow-up alone can also improve cessation outcomes (5, 13, 14).

The “opt-out” approach that we have used to deliver tobacco treatment was novel, particularly since nearly all of the published studies on hospital based cessation services rely on physician and/or patient self-referrals to trigger the delivery of tobacco cessation support (3-9). Our tobacco cessation service attempted to reach all smokers regardless of their motivation to quit. Consistent with other “opt-out” programs, we found that the vast majority of patients accepted the service when offered (12). For example, 80% (1,535/1,918) of hospitalized smokers who were approached by the counselor accepted the bedside consult. This percentage is slightly lower than what Warren et al. (12) found where over 90% of cancer patients accepted tobacco cessation treatment when offered. Less than 1% (n=18/4,112) of patients who were eligible to receive our automated follow-up calls explicitly asked to be removed from the program. These findings suggest that patient resistance to smoking cessation support may not be a significant barrier in hospitalized patients. These results significantly strengthen the argument to expand opt-out approaches for cessation support in both the inpatient and outpatient setting (10, 11). In this case, automated evidence-based cessation support was provided without any additional clinical burden on hospital staff or admission teams. Thus implementation was well received by both patients and clinicians.

Implementation of MUSCs opt out tobacco cessation service was not accomplished without overcoming some challenges. One of the challenges was developing an efficient HIPAA compliant strategy to that integrated with the hospital EMR system to consistently identify tobacco users admitted to the hospital on a daily basis. It took several months to develop and test a system that would reliably identify patient records and work out logistics for downloading, transferring, and reporting patient information in a way that was easily accessible by the bedside counselor and usable by the IVR phone follow-up system. This effort was further complicated by the MUSC’s implementation of a new EMR system in July 1st 2014. The switch to a new EMR system resulted in a brief interruption in our ability to identify records, which resulted in the suspension of the IVR follow-up calls for two months (i.e., on July and August, 2015). Moreover, while most of the 5,400 patients who were enrolled in the program had phones, about 8.5% of them were unreachable due to providing a wrong number on their medical record. Even

with these challenges, the opt-out approach to tobacco led to a significant proportion of patients receiving evidence-based cessation support.

This study has some important limitations that need to be acknowledged. First, because of the inconsistent way the EMR systems captured data on patients' use of other tobacco products, enrollment into the program was based only on those reporting current use of cigarettes. Second, there was no biochemical validation of smoking status to screen patients for enrollment into the program, or upon assessment of self-reported abstinence after hospital discharge. Prior studies suggest that smoking status tends to be under-reported by some categories of patients (15-17). We acknowledge that we likely missed some smokers by relying on self-reported smoking status identified via the EMR. In fact, the program did enroll about 150 tobacco-users who were not identified as current smokers by the EMR, but were referred into the program by medical staff (i.e., floor referrals). However, the overall prevalence of smoking for our hospitalized patient is consistent with the population survey for South Carolina. Though there may be value in using biochemical testing of patients to more accurately identify active tobacco users, this would add substantial clinical burden to hospital staff and patients.

Summary

With just one full-time bedside counselor and an automated IVR telephone follow-up system we were able to intervene with over 60% of eligible current smokers admitted to a large academic medical center, at a cost of about $36 per eligible patient. Having been seen by a bedside counselor while hospitalized was associated with an increased response to the post-discharge follow-up calls, self-reported use of stop smoking medications, and self-reported abstinence from tobacco.

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Conflict of Interest Statement

KMC has received grant funding from the Pfizer, Inc., to study the impact of a hospital based tobacco cessation intervention. He also receives funding as an expert witness in litigation filed against the tobacco industry. All other authors have no conflicts to report.

Figure 1. Flow of patients from screening to follow-up of adult admissions to the MUSC hospital Feb 2014-May 2015.

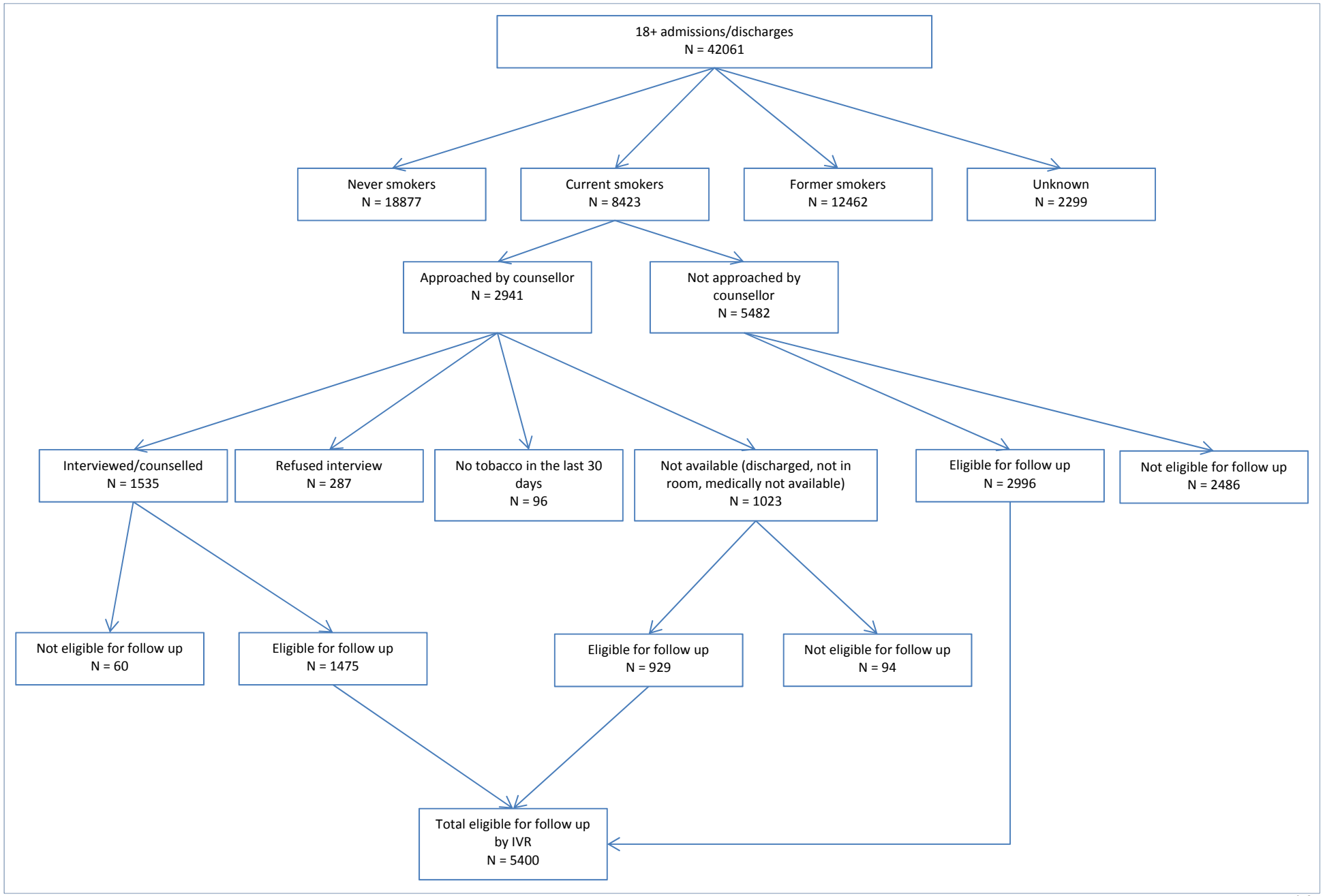

Table 1: Variables captured at the bedside consult

Demographics (variables obtained from the EMR)

- Medical record number and visit
- Full name
- Date of birth
- Admission date
- Admission unit
- Race

Tobacco use

- Tobacco (any type) use within 30 days
- Ever use of other tobacco products including (cigarettes, cigars, pipe, bidis, clove-cigarettes, oral, and e-cigarettes)
- 30-day use of ALL tobacco products
- Frequency and duration of use of ALL tobacco products
- Time to first cigarette in the morning
- Living with tobacco users

Quitting Tobacco

- Number and duration of past quitting attempts
- Methods assisting in quitting tobacco use
- Self-reported importance to quit and efficacy to remain quit
- Recommended cessation aid/medications during hospitalization including dosage

Follow-up

- Discharge facility and phone number
- Preferred contact method and time
- Consent to follow-up

Counselling Session

- Counselling duration
- Counselling outcome

Table 2. Patient characteristics by smoking status

Patient Characteristics	**Current Smokers (n=8,423, 20.0%)**	**Former Smokers (n=12,462, 29.6%)**	**Never Smokers (n=18,877, 44.9%)**	**Unknown status (n=2,299, 5.5%)**	**Total N=42,061**
Sex, n (%)‡					
Females	3761 (16.1)	5759 (24.7)	12559 (53.9)	1214 (5.2)	**23293**
Males	4661 (24.8)	6703 (35.7)	6317 (33.7)	1080 (5.8)	**18761**
Missing	1 (14.3)	0(0.0)	1 (14.3)	5 (71.4)	**7**
Age in year; median, mean (SD)§	48, 46.8 (15.5)	62, 59.5 (16.6)	50, 49.5 (19.4)	53, 52.3 (20.0)	**54, 52.1 (18.6)**
Length of hospitalization in days; median, mean (SD)†€	4, 6.3 (14.8)	3, 5.8 (10.3)	3, 5.4 (9.6)	3, 7.2 (29.3)	**3, 5.8 (12.5)**
Race, n (%)‡					
Black	2300 (20.5)	2685 (23.9)	5593 (49.8)	662 (5.9)	**11240**
White	3658 (20.5)	5953 (33.4)	7249 (40.7)	964 (5.4)	**17824**
Other	159 (12.6)	244 (19.3)	783 (61.8)	80 (6.3)	**1266**
Missing*	2281 (19.4)	3592 (30.6)	5261 (44.8)	597 (5.1)	**11731**
Insurance, n (%)‡					
Medicare	1701 (14.4)	4604 (39.0)	4914 (41.6)	592 (5.0)	**11811**
Medicaid	1319 (28.0)	967 (20.5)	2215 (46.9)	218 (4.6)	**4719**
Commercial	1209 (15.3)	2040 (25.8)	4292 (54.3)	360 (4.6)	**7901**
Uninsured	1174 (36.2)	634 (19.5)	1081 (33.3)	357 (11)	**3246**
Missing*	2995 (20.8)	4229 (29.4)	6384 (44.4)	776 (5.4)	**14384**

* About 1/3rd cases are missing information on race and insurance status because data linkage was not completed at the time of writing the paper. However, we do not believe that the smoking status rates as presented in the table above will very much between the obtained partial sample and the full sample. Our plan is to add in the missing data when available.

† duration of hospitalization was missing for 2007 patients

‡ Chi square test of independence $p < .0001$

§ Chi square test of median equality $p < .0001$

SD: standard deviation

Table 3. Patient characteristics assessed during the bedside consult

	N = 1,535
Have you used cigarettes in the past 30 days?	
No	9 (1%)
Yes	1451 (94%)
Missing	75 (5%)
Before coming to the hospital did you use cigarettes…*	
Daily	1333 (92%)
Non-daily	88 (6%)
Missing	30 (2%)
How many years did you use cigarettes?*	
Median (Range)	23.5 (80)
Mean (Standard Deviation)	24.8 (13.9)
Missing (n)	75
On the days that you used cigarettes how many did you use?*	
Median (Range)	10 (80)
Mean (Standard Deviation)	15 (11.1)
Missing (n)	116
How soon after you wake up do you use cigarettes?*	
< 5 minutes	1147 (79%)
6-30 minutes	126 (9%)
31-60 minutes	29 (2%)
> 60 minutes	15 (1%)
Missing	134 (9%)
How many quit attempts of at least 24 hours have you made in the past year?*	
0	1295 (89%)
1	112 (8%)
2 or more	44 (3%)
How long did your quit attempt last? (in days)*†	
0	58 (37%)
1	13 (8%)
2-30	51 (33%)
> 30	34 (22%)
On a scale of 1-5 with 5 being the strongest, how much do you intend to quit tobacco once you are discharged from the hospital?*	
1	116 (8%)
2	192 (13%)
3	550 (38%)
4	160 (11%)

5	413 (29%)
Missing	20 (1%)
On a scale of 1-5 with 5 being the strongest, how confident are you to remain quit once you are discharged from the hospital? [*]	
1	259 (18%)
2	485 (33%)
3	560 (39%)
4	46 (3%)
5	79 (5%)
Missing	22 (2%)
Methods used to quit during most recent quit attempt [*†]	
Unassisted quitting	94 (60%)
Class	2 (1%)
Quit line	1 (1%)
Prescription medication	11 (7%)
Over the counter medication	13 (8%)
E-cigarette	28 (18%)
Have you experienced strong cravings to smoking since admission? [*]	
No	806 (56%)
Yes	626 (44%)
Missing	19 (1%)
Would patient be interested in getting some nicotine medication while in hospital? [*‡]	
No	83 (13%)
Yes	506 (81%)
Missing	37 (6%)
Cessation aid recommended [*]	
Patch	762 (53%)
Gum	70 (5%)
Lozenge	557 (38%)
Zyban/Wellbutrin	18 (1%)
Chantix/Varenicline	47 (3%)

[*] among those who have used cigarettes in the past 30 days
[†] among those who had at least 1 quit attempt
[‡] among those who had cravings to smoking

Table 4. Outcomes for patients who received bedside counseling and IVR versus IVR follow-up only

	Bedside + IVR	**IVR Only**	**RR (95% CI)**
Ineligible to receive calls (wrong or inactive numbers, blocked numbers etc.…)	195/1475 = 13%	601/3925 = 15%	N/A
Reached within 1-Month Post-Discharge (of those eligible to receive calls)	703/1280 = 55%	1613/3324 = 49%	1.13 (1.07-1.20)
Used medications within 1-Month Post-Discharge (of those who were reached by phone)[*]	144/703 = 21%	92/1121 = 8%	2.5 (1.96-3.20)
Abstinent from smoking within 1-Month Post-Discharge (of those reached by phone)[*†]	359/703 = 51%	304/1121 = 27%	1.9 (1.67-2.12)
Abstinence within 1-Month Applying Intent-To-Treat (of those activated for follow-up)[*†]	359/1475 = 24%	304/3443 = 9%	2.8 (2.39-3.16)

CI: confidence interval

[*] Excluding 492 false positives identified during IVR calls among the IVR only group

[†] Last known smoking status