Implementation of a Process for Initiating Naltrexone in Patients Hospitalized for Alcohol Detoxification or Withdrawal

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BACKGROUND: Naltrexone trials have demonstrated improved outcomes for patients with alcohol use disorders. Hospital initiation of naltrexone has had limited study.

OBJECTIVES: To describe the implementation and impact of a process for counseling hospitalized patients with alcohol withdrawal about naltrexone.

DESIGN: A pre-post study analysis.

SETTING: A tertiary academic center.

PATIENTS: Patients hospitalized for alcohol withdrawal.

INTERVENTIONS: (1) Provider education about the efficacy and contraindications of naltrexone and (2) algorithms for evaluating patients for naltrexone.

MEASUREMENTS: The percentages of patients counseled about and prescribed naltrexone before discharge and the percentages of pre- and postintervention patients with 30-day emergency department (ED) revisits and rehospitalizations.

RESULTS: We identified 128 patient encounters before and 114 after implementation. The percentage of

patients counseled about naltrexone rose from 1.6% preimplementation to 63.2% postimplementation (P<.001); the percentage of patients prescribed naltrexone rose from 1.6% to 28.1% (P<.001). Comparing preintervention versus postintervention groups, there were no unadjusted differences in 30-day ED revisits (25.8% vs 19.3%; P=.23) or rehospitalizations (10.2% vs)11.4%; P=.75). When adjusted for demographics and comorbidities, postintervention patients had lower odds of 30-day ED revisits (odds ratio [OR]=0.47; 95% confidence interval [CI], 0.24-0.94) but no significant difference in rehospitalizations (OR = 0.76; 95% CI, 0.30-1.92). In subgroup analysis, postintervention patients counseled versus those not counseled about naltrexone were less likely to have 30-day ED revisits (9.7% vs 35.7%; P = .001) and rehospitalizations (2.8% vs 26.2%; P<.001).

CONCLUSIONS: The implementation of a process for counseling patients hospitalized for alcohol withdrawal about using naltrexone for the maintenance of sobriety was associated with lower 30-day ED revisits but no statistically significant difference in rehospitalizations. *Journal of Hospital Medicine* 2018;13:221-228. © 2018 Society of Hospital Medicine

Icohol use disorders (AUDs) are common, with an estimated lifetime prevalence of 17.8% for alcohol dependence. Alcohol misuse is costly, accounting for \$24.6 billion in annual healthcare expenditures, including \$5.1 billion for alcohol-related hospitalizations. Anumber of trials have demonstrated that naltrexone can help patients with AUDs maintain abstinence or diminish heavy drinking. A recent meta-analysis of pharmacotherapy trials for patients with AUDs reported that for patients using 50 mg of naltrexone daily, the number needed to treat was 12 to pre-

vent a return to heavy drinking and 20 to prevent a return to any drinking. ¹¹ Despite good evidence for its effectiveness, naltrexone is not prescribed to the majority of patients with AUDs. In a study of veterans with AUDs cared for in the Veterans Affairs health system, only 1.9% of patients were prescribed naltrexone over the 6-month study period. ¹² A 2003 survey of 2 professional organizations for addiction treatment specialists reported that a mean of 13% of providers prescribed naltrexone to their patients. ¹³

When naltrexone is prescribed, it is most frequently in the outpatient setting. ³⁻¹⁰ Data for initiation of naltrexone in the inpatient setting are more limited. Wei et al. ¹⁴ reported on the implementation of a discharge protocol, including counseling about naltrexone, for hospitalized patients with AUDs at an urban academic medical center. They reported a significant increase in the prescription of naltrexone to eligible patients by the time of discharge that was associated with a significant decrease in 30-day readmissions. Initiation of naltrexone in the inpatient versus the outpatient setting has some potential advantages. First, patients hospitalized for alcohol withdrawal have AUDs, obviating the need for screen-

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TABLE 1. Patient Characteristics, Process and Outcome Measures Overall, and Pre- Versus Postintervention

Study Variable	Overall (n=242)	Preintervention (n = 128)	Intervention (n = 114)	P Value
Age, years (SD)	45.9 (11.5)	45.2 (11.6)	46.7 (11.5)	.30
Female, %	28.5	28.1	29.0	.89
Race, %				
White	83.1	83.6	82.5	.81
Black	8.7	7.8	9.7	.61
Asian	1.2	0.8	1.8	.60
Other	7.0	7.8	6.1	.61
nsurance, %				
Private	23.3	20.3	28.1	.20
Medicare	11.4	11.7	11.0	.87
Medicaid	17.6	18.0	17.1	.87
Self-pay	47.6	50.0	43.9	.39
Length of stay, days (SD)	3.3 (2.6)	3.3 (3.0)	3.4 (2.1)	.89
Comorbidities, %				
Hypertension	25.2	18.0	33.3	.006
Anxiety/PTSD	15.7	7.8	24.6	<.001
Depression	12.4	6.3	19.3	.002
Cirrhosis	8.3	6.3	10.5	.23
Diabetes	5.0	2.3	7.9	.07
Congestive heart failure	2.1	2.3	1.8	1.00
Study outcomes, %				
Naltrexone counseling	30.6	1.6	63.2	<.001
Naltrexone prescribed	14.1	1.6	28.1	<.001
Naltrexone prescription filled	10.3	0.8	21.1	<.001
ED revisit within 30 days	22.7	25.8	19.3	.23
Rehospitalization within 30 days	10.7	10.2	11.4	.75

NOTE: Abbreviations: ED, emergency department; PTSD, posttraumatic stress disorder; SD, standard deviation. Statistically significant P values are in bold.

ing. Second, the outpatient trials of naltrexone typically required 3 days of sobriety before initiation, which is generally achieved during hospitalization for detoxification or withdrawal.

Previous work at our institution centered on standardizing the process of evaluating patients needing alcohol detoxification at the time of referral for admission.¹⁵ The use of a standardized protocol reduced the number of inpatient admissions for alcohol-related diagnoses but had no effect on the 30-day readmission rate (28%) for those patients who were hospitalized. Our hospitalist group had no standardized process for discharging hospitalized patients with AUDs, and the discharge process rarely included counseling on medications for maintenance of sobriety. In this manuscript, we describe the implementation and impact of a process for counseling patients hospitalized for alcohol detoxification or withdrawal about naltrexone for maintenance of sobriety by the time of hospital discharge.

METHODS

Study Setting

The University of North Carolina (UNC) Hospitals is an 803-bed

tertiary academic center. UNC Hospital Medicine is staffed by 29 physicians and 3 advanced practice providers (APPs). During the study period, there were 3 hospital medicine services at UNC Hospitals with a combined average daily census of approximately 40 patients, and each service was staffed by one attending physician every day of the week and one APP Monday through Friday.

Study Design

We used a pre-post study design, in which we implemented a new process for standardizing the discharge of hospitalized patients with AUDs, including a process for counseling about naltrexone by the time of discharge. We sought and received institutional review board (IRB) approval for this study (UNC IRB 15-1441).

Interventions

We formed an improvement team that included 3 physicians and an APP in hospital medicine, a general internist and a psychiatrist, both with expertise in the use of medications for

TABLE 2. Subgroup Analysis, Postintervention Patient Characteristics and Outcome Measures, Comparing Those Not Counseled Versus Counseled about Naltrexone before Discharge

Study Variable	Not Counseled (n = 42)	Counseled (n = 72)	P Value
Age, years (SD)	47.5 (12.0)	46.3 (11.3)	.57
Female, %	21.4	33.3	.18
Race, %			
White	76.2	86.1	.18
Black	11.9	8.3	.53
Asian	4.8	0.0	.06
Other	7.1	5.6	.73
Insurance, %			
Private	28.6	23.6	.58
Medicare	16.7	9.7	.28
Medicaid	16.7	15.3	.84
Self-pay	38.1	51.4	.17
Length of stay, days (SD)	3.4 (2.5)	3.3 (1.9)	.86
Comorbidities, %			
Hypertension	35.7	31.9	.68
Anxiety/PTSD	28.6	22.2	.45
Depression	28.6	13.9	.06
Cirrhosis	14.3	8.3	.32
Diabetes	9.5	6.9	.72
Congestive heart failure	2.4	1.4	1.00
Study outcomes, %			
ED revisit within 30 days	35.7	9.7	.001
Rehospitalization within 30 days	26.2	2.8	<.001

NOTE: Abbreviations: ED, emergency department; PTSD, posttraumatic stress disorder; SD, standard deviation. Statistically significant P values are in bold.

maintenance of sobriety, the director of UNC's Alcohol and Substance Abuse Program, and 2 case managers. The team developed a number of interventions, including group education, a process for patient identification, and algorithms for counseling about, prescribing, and documenting the discussion of naltrexone.

Group Education

We presented evidence about medications for the maintenance of sobriety at a regularly scheduled hospitalist meeting. An hour-long session on motivational interviewing techniques was also presented at a separate meeting. All created algorithms were circulated to the group electronically and posted at workstations in the hospitalist work area. As data were generated postimplementation, control charts of process measures were created, posted in the hospitalist work area, and presented at subsequent group meetings.

Identification of Patients

We focused our interventions on patients admitted for alcohol detoxification or withdrawal (including withdrawal seizures). We asked our group to preferentially admit these patients to

1 of our 3 hospitalists services, on which the service APP (K.S.) was also an improvement team member.

Creation of Algorithms and Scripts for Counseling

We created a simple algorithm for evaluating patients for naltrexone. We recommended that all patients admitted for alcohol detoxification or withdrawal be counseled about naltrexone for the maintenance of sobriety before discharge. The contraindications to naltrexone we included were (1) concurrent opioid use, (2) documented cirrhosis, and/or (3) liver function tests greater than 3 times the upper limit of normal by the time of hospital discharge.

We also created a suggested script for motivational interviewing (supplemental Appendix 1). This was presented at a group meeting and circulated via e-mail. The actual counseling technique and process was left up to individual providers. In practice, counseling took place in the course of daily rounds, generally the day before or day of hospital discharge.

Prescription of Medication

For interested patients without contraindications, we recommended a prescription of naltrexone at 50 mg daily for 3

TABLE 3. Subgroup Analysis, Postintervention Patient Characteristics and Outcome Measures, Comparing Those Not Prescribed Versus Prescribed Naltrexone before Discharge

Study Variable	Not Prescribed (n=82)	Prescribed (n = 32)	P Value
Age, years (SD)	47.1 (11.0)	45.9 (12.9)	.64
Female, %	28.0	31.3	.74
Race, %			
White	82.9	81.3	.83
Black	8.5	12.5	.52
Asian	2.4	0.0	.37
Other	6.1	6.3	.98
insurance, %			
Private	24.4	28.1	.68
Medicare	13.4	9.4	.56
Medicaid	18.3	9.4	.24
Self-pay	43.9	53.1	.38
Length of stay, days (SD)	3.4 (2.2)	3.3 (1.8)	.81
Comorbidities, %			
Hypertension	36.6	25.0	.24
Anxiety/PTSD	28.1	15.6	.23
Depression	22.0	12.5	.30
Cirrhosis	12.2	6.3	.51
Diabetes	8.5	6.3	1.00
Congestive heart failure	2.4	0.0	1.00
Study outcomes, %			
ED revisit within 30 days	22.0	12.5	.25
Rehospitalization within 30 days	13.4	6.3	.28

NOTE: Abbreviations: ED, emergency department; PTSD, posttraumatic stress disorder; SD, standard deviation.

months. For patients prescribed naltrexone without medical insurance (n = 17), we utilized our existing pharmacy assistance program, whereby discharging patients can obtain an initial 14-day supply after applying to the program and then can fill subsequent prescriptions if they meet program financial requirements.

Follow-up Appointments

For patients with established outpatient providers, we asked patients to schedule follow-up appointments within a month of discharge. Patients prescribed naltrexone without primary providers (n=16) were eligible for an existing program, the UNC Transitions Program, whereby patients identified as having moderate-to-high risk of hospital readmission can receive a follow-up appointment at UNC Internal Medicine or UNC Family Medicine within 2 weeks of discharge.

Creation of "Smart Phrases"

To aid in documentation, we created "smart phrases" (easily accessed, previously created phrases that can be adopted by all users) within the hospital electronic health record. We created one smart phrase for documentation of counseling

about naltrexone, which included dropdown menus for contraindications and the patient's preference and one for discharge instructions for patients started on naltrexone (supplemental Appendix 2).

Implementation

After the presentation of suggested interventions in July 2015 and the subsequent dissemination of educational materials, we implemented our new process on August 1, 2015.

Data Collection

Patients were identified for inclusion in the study analysis by querying UNC Hospitals' billing database for the inpatient diagnosis codes (diagnosis-related groupings) 896 and 897, "alcohol/drug abuse or dependence without rehabilitation therapy," with and without major comorbidity or complication, respectively, and with hospital medicine as the discharging service. All encounters were then manually reviewed by 2 investigators (J.S. and C.M.). Encounters were included if the history and physical indicated that the primary reason for admission was alcohol detoxification or withdrawal. Encounters with other primary reasons for admission (eg, pancreatitis, gastro-

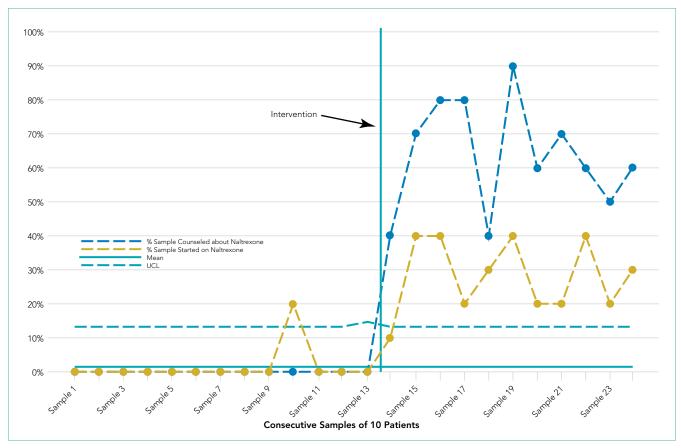


FIG. Percentages of consecutive samples of 10 patients hospitalized for alcohol withdrawal or detoxification counseled about and started on naltrexone for maintenance of sobriety by the time of discharge. The mean values were calculated by averaging the results of the preintervention samples. The UCL was calculated according to standard rules for control charts, utilizing the mean and n value for each sample. Lower control limits were also calculated, but were less than 0 for all samples and are not displayed. Values above the UCL meet criteria for special cause variation, meaning they are unlikely to have occurred because of normal variation or chance alone. NOTE: Abbreviation: UCL, upper control limit.

intestinal bleeding) were excluded. For patients with multiple encounters, only the first eligible encounter in the pre- and/ or postimplementation period was included. Comorbidities for identified patients were assessed via the search of study encounters for the *International Classification of Diseases*, 9th Revision-Clinical Modification codes for hypertension, anxiety, depression, cirrhosis, diabetes, and congestive heart failure.

Process, Outcomes, and Balancing Measures

The study process measures included the percentage of patients hospitalized for alcohol detoxification or withdrawal with documentation of counseling about naltrexone by the time of discharge, before and after process intervention. Documentation was defined as the description of counseling about naltrexone in the discharge summary or progress notes of identified encounters. We also measured the percentage of patients started on naltrexone before and after intervention. Lastly, we measured the percentage of patients prescribed naltrexone who filled at least 1 prescription for the medication, assessed by calls to the pharmacy where the medication was prescribed. Prescriptions that could not be confirmed (ie, paper rather than electronic prescriptions) were counted as not filled.

For outcome measures, we recorded the percentages of

study patients who returned to the emergency department (ED) and were readmitted to UNC Hospitals (inpatient or observation) for any reason within 30 days of discharge. These outcomes were determined by manual chart review.

In order to ensure the new process was not associated with delays in patient discharge, we measured the mean length of stay in days for study patient encounters before and after intervention as a balancing measure.

Statistical Analysis

Demographic and clinical characteristics for included patients were compared for the 16 months preimplementation (April 1, 2014 through July 31, 2015) and the 19 months postimplementation (August 1, 2015 through February 28, 2017). Descriptive statistics were calculated by using the Student t test for continuous variables and the χ^2 test for dichotomous variables. We used multivariate logistic regression to evaluate the associations between the intervention arms (pre- vs postintervention) and study outcomes, adjusting for age, gender, race, insurance type, and medical comorbidities. We chose these variables for inclusion based on their association with study outcomes at the $P \le .20$ level in bivariate analyses. P < .05 was considered statistically significant. All analyses were performed by using

Stata version 13.1 (StataCorp LLC, College Station, Texas).

For 2 process measures, the percentages of patients counseled about and started on naltrexone, we plotted consecutive samples of 10 patients before and after intervention on a control chart, using preintervention data to calculate means and control limits.

Subgroup Analysis

We used multivariate logistic regression to evaluate the associations between counseling versus no counseling and prescription of naltrexone versus no prescription for study outcomes in the postintervention subgroup, adjusting for age, gender, race, insurance type, and medical comorbidities.

RESULTS

Patients

We identified 188 preimplementation encounters and excluded 12 patients (6.4%) for primary admission reasons other than alcohol withdrawal or detoxification and 48 (25.5%) repeat hospitalizations, leaving 128 unique patient encounters. We identified 166 postimplementation encounters and excluded 25 (15.1%) hospitalizations for admission reason and 27 repeat hospitalizations (16.3%), leaving 114 unique patient encounters (flow diagram in supplemental Appendix 3). The most common admission reason for the exclusion of encounters was withdrawal from a substance other than alcohol (supplemental Appendix 4). The percentages of encounters excluded in preimplementation and postimplementation periods were similar at 31.9% and 31.4%, respectively.

The majority of patients were male and white, and almost half were uninsured (Table 1). There were no demographic differences between patients in the pre- versus postimplementation groups. For studied comorbidities, postintervention patients were more likely to have hypertension, anxiety, and depression.

Process Measures

The percentage of patients counseled about naltrexone rose from 1.6% preimplementation to 63.2% postimplementation (P<.001; Table 1). The percentage of patients prescribed naltrexone at discharge rose from 1.6% to 28.1% (P<.001). When consecutive samples of 10 patients were plotted on a control chart, the fraction of almost every postintervention sample was above the upper control limit for those same process measures, meeting control chart rules for special cause variation (Figure 1).16

Among those counseled about naltrexone before discharge, 34 of 74 patients (45.9%) had no contraindications to naltrexone and were interested in taking the medication. Among the 40 patients who were counseled about but not prescribed naltrexone, 19 (47.5%) declined, 9 (22.5%) had liver function tests elevated more than 3 times the upper limit of the reference range, 9 (22.5%) had concurrent opiate use, and 3 (7.5%) had multiple contraindications.

Among the 34 patients who were prescribed naltrexone, 25 (73.5%) filled at least 1 prescription as confirmed by phone call to the relevant pharmacy.

Outcome Measures

Comparing preintervention to postintervention patients, there were no differences in ED revisits or rehospitalizations within 30 days in the unadjusted analysis (Table 1). In the adjusted analysis, the postintervention odds ratio (OR) for ED revisits was lower (OR = 0.47; 95% confidence interval [CI], 0.24-0.94); the OR for rehospitalization (OR = 0.76; 95% CI, 0.30-1.92) was not significant.

Subgroup Analysis

Postintervention patients who were documented to have counseling about naltrexone before discharge had significantly lower unadjusted rates of ED revisit (9.7% vs 35.7%; P=.001) and rehospitalization within 30 days (2.8% vs 26.2%; P<.001; Table 2). In adjusted analysis, the ORs for 30-day ED revisit (OR=0.21; 95% CI, 0.07-0.60) and rehospitalization (OR=0.07; 95% CI, 0.01-0.35) were significantly lower in those counseled.

There were no significant differences in 30-day ED visits or rehospitalizations for those prescribed versus not prescribed naltrexone in the postintervention group (Table 3). In the adjusted analysis, the ORs for those prescribed naltrexone for ED revisit (OR = 0.53; 95% CI, 0.16-1.79) and rehospitalization (OR = 0.43; 95% CI, 0.09-2.10) were not statistically significant.

Balancing Measure

The mean length of stay for all patient encounters was 3.3 days. There were no differences in length of stay comparing pre- with postintervention patient encounters (Table 1) or those postintervention patients counseled versus not counseled (Table 2).

DISCUSSION

Our study demonstrates that counseling about medications for the maintenance of sobriety can be implemented as part of the routine care of hospitalized patients with AUDs. In our experience, about half of the patients counseled had no contraindications to naltrexone and were willing to take it at discharge. Almost three-fourths of those who were prescribed naltrexone filled the prescription at least once. The counseling process was not associated with increased length of stay. In the adjusted analysis, postintervention patients had significantly lower odds of 30-day ED returns. Additionally, in subgroup analysis, postintervention patients counseled about naltrexone had significantly lower rates of subsequent healthcare utilization compared with those not counseled, with absolute differences of 26% for ED revisits and 22% for rehospitalizations within 30 days.

The failure to demonstrate a difference in adjusted rehospitalization rates in the postintervention versus the preintervention group has several possible explanations. First, we had incomplete fidelity to our interventions, documenting counseling about naltrexone before discharge in over 60% of postintervention patients, raising the possibility that better fidelity may have resulted in improved outcomes. Related to this, only 28% of postintervention patients were prescribed naltrexone, which may be an inadequate sample size to demonstrate positive effects from the medication. Another possible explanation

is that the postintervention group had higher rates of some of the comorbidities we assessed, namely, anxiety, depression, and hypertension, which could have negatively impacted the effectiveness of the interventions to prevent rehospitalization; however, after adjusting for comorbidities, the odds of rehospitalization were still not significantly different. It is interesting that the odds of postintervention ED revisits (but not rehospitalizations) were lower in the adjusted analysis. It may be that patients who revisit the ED and are not rehospitalized are different in important ways from those who are readmitted. Alternately, the larger number of ED revisits overall (about twice the rate of rehospitalization) may have made it easier to identify positive effects from the intervention for this outcome than rehospitalization (ie, the study may have been underpowered to detect a relatively small reduction in rehospitalization). It is also possible, however, that the interventions were simply insufficient to prevent rehospitalization.

The subgroup analysis, however, did find significant differences in both outcome measures for postintervention patients counseled versus not counseled about naltrexone before discharge. There are several possible explanations for these results. First, there may have been unmeasured differences in those counseled versus not counseled that explain the reductions observed in subsequent healthcare utilization. For example, the counseled patients could have been more motivated to change and, thus, more readily approached by providers for counseling. The lack of any demographic differences between the 2 groups and the relative simplicity of the counseling part of the intervention occurring as part of daily rounds argue against this hypothesis, but there are many potential unmeasured confounders (eg, homelessness, ability to afford medications), and this possibility remains. A second possible explanation is that patients counseled about naltrexone could have been more likely than those not counseled to seek subsequent care at other institutions. A third possibility is that that the counseling about (and prescribing when appropriate) naltrexone itself led to the observed decreases in subsequent ED visits and hospitalizations. This hypothesis would have been more supported had we been able to demonstrate a statistically significant reduction in healthcare utilization in those prescribed versus not prescribed naltrexone. But there were nonsignificant trends in the reduction of ED revisits and rehospitalizations among those prescribed the medication, suggesting we may have been able to demonstrate statistically significant reductions with a larger sample size.

Comparing our results with existing literature is challenging. The majority of randomized trials of naltrexone for AUDs were conducted in the outpatient setting.³⁻¹⁰ Most of these trials utilized some type of psychosocial intervention in addition to naltrexone.^{3-5,8-10} The 1 prior naltrexone study we identified conducted in the inpatient setting by Wei et al.¹⁴ is the most similar to our study. The authors reported the effects of a new process for assessing hospitalized patients with AUDs, including the use of a discharge planning tool for all patients admitted with alcohol dependence. The discharge tool included prompts for naltrexone in appropriate patients. The mea-

sured outcomes included the percentage of eligible patients prescribed naltrexone at discharge and the percentages of ED revisits and rehospitalizations within 30 days. Postintervention, 64% of eligible patients were prescribed naltrexone compared with 0% before, very similar to our results. There were significant decreases among all discharged patients with alcohol dependence for 30-day ED revisits (18.8% pre- vs 6.1% postimplementation) and rehospitalizations (23.4% vs 8.2%). The study differed from ours in a number of important respects, including a location in a large urban setting and implementation on a teaching service rather than an attending-only hospitalist service. Additionally, the authors studied 1 month of process implementation and compared it to another month 1 year before the new process, with an overall smaller sample size of 64 patients before and 49 patients after implementation. Potential reasons why Wei et al.14 were able to document lower rehospitalization rates postintervention when we did not include the differences in patient population (eg, high homeless rate, lower percentage of female patients in Wei study) and secular trends unrelated to interventions in either study.

Limitations of our study include the nonrandomized and uncontrolled design, which introduces the possibility of unmeasured confounding factors leading to the decrease we observed in healthcare utilization. Additionally, the single-center design precludes our ability to assess for healthcare utilization outcomes in other nearby facilities. We had incomplete implementation of our new process, counseling just over 60% of patients. As our primary outcomes relied on documentation in the medical record, both undersampling (not documenting some interventions) and reporting bias (being more likely to record positive sessions from intervention) are possible. Lastly, despite a moderate total sample size of almost 250 patients, the relatively small numbers of patients who were actually prescribed naltrexone in our study lessens our ability to show direct impact.

In conclusion, our study demonstrates a practical process for counseling about and prescribing naltrexone to patients hospitalized for alcohol detoxification or withdrawal. We demonstrate that many of these patients will be interested in starting naltrexone at discharge and will reliably fill the prescriptions if written. Counseling was associated with a significant reduction in subsequent healthcare utilization. These results have a wide potential impact given the ubiquitous nature of AUDs among hospitalized patients in community and academic settings.

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