

PRIMARY CARE & HEALTH SERVICES SECTION

Original Research Article

Timeliness of Care Planning upon Initiation of Chronic Opioid Therapy for Chronic Pain

Michael Von Korff, ScD,* Judith A. Turner, PhD,^{†,‡,§}
Susan M. Shortreed, PhD,^{*,¶}
Kathleen Saunders, JD,* Dori Rosenberg, PhD,
MPH,* Stephen Thielke, MD, MSPH, MA,^{†,||} and
Linda LeResche, ScD^{||}

*Group Health Research Institute, Seattle, Washington, USA; Departments of [†]Psychiatry and Behavioral Sciences, [‡]Rehabilitation Medicine, [§]Anesthesiology and Pain Medicine, [¶]Biostatistics, and ^{||}Oral Medicine, University of Washington, Seattle, Washington, USA; ^{||}Geriatric Research, Education, and Clinical Center, Puget Sound Veterans Affairs Medical Center, Seattle, Washington, USA

Correspondence to: Michael Von Korff, ScD, Group Health Research Institute, 1730 Minor Avenue, Suite 1600, Seattle, WA 98101, USA. Tel: 206-287-2874; Fax: 206-287-2871; E-mail: vonkorff.m@ghc.org.

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Abstract

Background. Chronic opioid therapy (COT) guidelines recommend developing a COT care plan at the initiation of COT.

Objective. Assess the timeliness of care planning upon initiation of COT.

Design. Observational cohort study in a setting incentivizing and tracking documentation of COT care plans in electronic health records (EHRs).

Participants. Study participants (N = 896) were aged 45 years or older, had initiated an episode of opioid use within the prior 6 months, and reported regular use of prescription analgesics when screened for a baseline interview about 3 months after an index opioid prescription

Measures. A timely care plan was defined by an EHR documented care plan prior to or within 4 months after the index opioid prescription.

Results. Among COT initiators, 30% had a timely COT care plan documented in the EHR within 4 months following index prescription, while 51% had a documented COT care plan within 12 months following index prescription. Among those interviewed at 1 year follow-up (N = 735), 252 (34.2%) reported opioid use on 7 or more days in the prior 2 weeks. Less than half (45.6%) of the 252 individuals who sustained regular opioid use at 1 year had predicted at baseline that it was somewhat, very, or extremely likely they would be using opioids regularly in 1 year.

Conclusions. Patients initiating COT were unlikely to have timely COT care plans. Many who sustained regular opioid use at 1 year had not anticipated using opioids long term.

Key Words. Opioids; Chronic Pain; Primary Care; Quality of Health Care

Introduction

Large increases in addiction and fatal overdoses involving prescription opioids have accompanied increased prescribing of opioids for chronic pain [1–6]. This has led to calls for greater caution in prescribing chronic opioid therapy (COT) [7]. A commonly recommended precaution is developing a COT care plan at the initiation of COT to guide patient monitoring and coordination of care [8]. Research in community practice settings has found that recommended precautions are infrequently implemented

[9–11]. Recommended precautions for COT implicitly assume that elements of a care plan (e.g., designating a clinician responsible for COT management, assessment of risks of substance abuse, defining a treatment regimen, setting a schedule for ongoing COT monitoring) have been completed at COT initiation, so that risks of potential adverse COT outcomes can be minimized at the outset or recognized early in the course of treatment before they become difficult to reverse. However, it may often be unclear when COT begins, as some patients who sustain opioid use long term initially expect opioid use to be short term [12]. For this reason, it is unclear whether it is possible to ensure that recommended universal precautions are performed upon the initiation of COT.

The objective of this study was to determine whether physicians in care settings with near-universal documentation of COT care plans [13] completed COT care plans on a timely basis among patients initiating COT. Timely completion was defined as care plan documentation within 4 months of initiating or re-initiating use of COT. There is no research assessing the extent to which COT care plans are developed and documented on a timely basis. This is important because care plans for COT can provide information needed to guide COT monitoring and coordination of care. While it is not known whether timely documentation of a COT care plan reduces opioid-related risks, developing a COT care plan at COT outset is consistent with universal precautions recommended by COT guidelines [8], such as evaluation of substance-abuse risk factors, discussing likely benefits and potential risks with patients, setting expectations for the frequency of COT monitoring including check-back visits and urine drug screening, and agreeing on therapeutic goals that can be used to assess whether patients are experiencing hoped-for benefits.

Because the health plan in which this study was carried out set a code in its electronic health records (EHRs) when a standardized COT care plan was documented in the medical record, it was possible to assess the timeliness of COT care plan documentation. We also examined whether patients who were using opioids regularly at 1 year follow-up had expected they would sustain long-term opioid use, since COT care plans may be developed less often for patients who do not anticipate long-term opioid use.

Methods

Background and Setting

The Middle-Aged/Seniors Chronic Opioid Therapy (MASCOT) study was conducted at Group Health Cooperative, a large health plan in Washington state. MASCOT study procedures were approved by Group Health's Institutional Review Board.

Health Plan COT Guidelines

In September 2010, Group Health's integrated group practice implemented a multi-faceted COT risk reduction

initiative in accord with Washington state COT guidelines mandated by state legislation [14]. The Group Health initiative included a guideline establishing minimum standards for risk-stratified COT monitoring (including follow-up visits and urine drug testing), designation of a single physician as responsible for a patient's COT management, standardized care plans documented in the EHR, and prescription refill process modifications to prevent urgent refill requests [13]. Implementation was supported by practice tools (patient education materials, care plan template, an on-line calculator for estimating morphine-equivalent dose), performance measures, medical staff leader advocacy, an on-line clinician training program, clinician access to expert consultants in each primary care clinic, and financial incentives for completion of standardized COT care plans recorded in the health plan's EHR.

COT Care Plans

A COT care plan was a standardized electronic form (called a "smart set") that could be easily inserted into an EHR. When the form was completed, it specified the clinician responsible for managing the COT, the opioid regimen, and the patient's risk level (low, medium, high), which guided recommended frequency of follow-up. At a clinician's option, the care plan might also record goals for chronic pain care. An electronic COT care plan form could be completed quickly. Care plans were used to facilitate coordination of care and COT monitoring over time. The presence of a care plan in the EHR was indicated by a code, which allowed practitioners and Group Health to monitor progress toward developing care plans for all COT patients. Documenting care plans was incentivized at the clinic level as part of an initiative to improve the quality of care for chronic pain patients using opioids long-term.

Study Design

The analyses reported here were based on data for patients participating in the MASCOT study. They were identified from the enrollment files of Group Health integrated group practice clinics between September 2010 and March 2013. Study patients were aged 45 years or older and had been enrolled at Group Health for at least 1 year prior to being selected for the study. Patients were eligible for inclusion in the study if they had filled at least three prescriptions for opioids containing at least 60 days' supply of medication within 4 months of an index prescription, with a period of at least 90 days with no opioid prescriptions dispensed prior to the date that the index prescription was filled. Sixty days' supply was set as a threshold because preliminary studies had established that this was a threshold for increased likelihood of sustaining use of opioids 1 year later. Filling three prescriptions was required to ensure that potentially eligible patients were likely to still be using opioid analgesics, as most patients discontinue opioid use after receiving one or two prescriptions.

When contacted by telephone for a baseline interview approximately 3 months following index prescription, patients were eligible for inclusion in the study if they reported taking prescription analgesics on at least 7 days in the prior 2 weeks. Patients were excluded if they were incapable of doing a 25-minute telephone interview due to physical, mental, or hearing impairments; they were no longer enrolled at Group Health or planned to disenroll in the coming year; they did not speak English; or they were otherwise unable to participate in the telephone interview. Patients who had two or more cancer diagnoses in their EHR in the year prior to being selected for the study or who were receiving hospice or nursing home care were also excluded. Persons unwilling to permit use of their EHR information were not enrolled in the study.

Eligible and consenting COT patients completed a 25-minute baseline telephone interview approximately 3 months following their index opioid prescription. These patients were then re-interviewed 4 and 12 months after the baseline interview. The analyses reported in this paper are based primarily on data collected in the baseline interview, along with patients' EHR data.

Timeliness of COT Care Plans

We refer to three reference points in our analyses: 1) the index opioid prescription; 2) the baseline interview; and 3) the 1-year follow-up interview. One criterion for the index prescription was that no opioid prescription had been dispensed in the prior 3 months. The index prescription was the first opioid fill in the 4 months prior to the date patients were identified for study eligibility.

Timely care plans were defined as COT care plans documented in the EHR within 4 months after the index opioid prescription or care plans documented before the index opioid prescription that may have been re-activated. We also report the percentage of patients with a COT care plan documented within 1 year of the index opioid prescription. The rationale for setting 4 months as a threshold for a timely care plan was that opioid use is often considered long term when it continues for at least 3 months. A 4-month threshold provides a 1-month grace period for the clinician to develop a care plan with patients initiating long-term opioid use. Patients can become physically or psychologically dependent on opioids within weeks or a few months of initiating opioid use, making discontinuation more difficult, suggesting the importance of timely patient evaluation and care planning when long-term opioid use is initiated. We considered documentation of a COT care plan to be a potential marker of actions recommended to occur at COT initiation [8] including evaluation of substance abuse risk factors, clarifying potential risks and likely benefits with the patient, setting expectations for ongoing COT monitoring and urine drug screening, and agreeing on

therapeutic goals that could be used to assess whether hoped-for benefits were being realized.

The study cohort was enrolled over a 2.5-year period that coincided with initiation of a health plan initiative to increase documentation of care plans [13]. For patients enrolled in the first 3 months of the study (out of a 30-month cohort enrollment period), the index prescription occurred prior to implementation of the initiative to increase documentation of care plans. The baseline interviews all occurred after the start of the health plan initiative. All of the 1-year follow-up interviews occurred at least 1 year after implementation of the health plan initiative.

As part of the initiative, the health plan asked primary care clinicians to initially focus on developing and documenting COT care plans for patients receiving high opioid doses (at least 120 mg morphine-equivalent dose). Since clinicians were initially focused on documenting care plans for high-dose COT patients, we assessed whether the timeliness of documented care plans differed for patients who joined the study during the first 9 months of the health plan initiative compared to patients who joined later on.

COT Initiators

The analyses reported in this paper focus on the timeliness of documentation of a COT care plan among the subset of MASCOT study participants who were identified as COT initiators. Because it is difficult to definitively identify patients initiating COT using only electronic pharmacy data, we used both interview and electronic pharmacy data to identify COT initiators. All study participants had a 3-month or greater gap between the index opioid prescription fill and prior opioid fills. However, many participants self-reported opioid use prior to the index opioid fill.

COT initiation was defined by not receiving an opioid prescription with a run-out date within 30 days of the index prescription. In addition, COT initiators reported in the baseline interview that either 1) the current episode of opioid use began less than 6 months before the baseline interview or 2) the current episode began at least 6 months prior to the baseline interview, but there was a period of 1 month or more when the patient was not using opioids and opioid use was re-initiated within the last 6 months.

Patient Characteristics

Age at the time of the baseline interview, sex, history of mental health diagnoses, history of substance use disorder diagnoses, and history of alcohol use disorder diagnoses in the 2 years prior to the index prescription were each determined from EHR data. Patient characteristics ascertained in the baseline interview included race-ethnicity; educational attainment; average pain intensity and pain-related interference with daily activities rated

on 0–10 numerical rating scales [15]; number of bothersome pain sites (including back pain, neck pain, headache, stomach pain, extremity pain, chest pain) using items adapted from the Patient Health Questionnaire (PHQ)-15 [16]; self-reported widespread pain; moderate to severe depression defined by a score of 10 or greater on the PHQ-8 depression scale [17]; and current tobacco use. In the baseline interview, participants were asked: “How likely do you think it is that, 1 year from now, you will be using opiate pain medicines at least two or three times a week?” Response options were as follows: “Extremely unlikely, Very unlikely, Somewhat unlikely, Uncertain, Somewhat likely, Very likely, Extremely likely.”

COT Management

Descriptors of patients’ COT management were assessed using EHR data including the following: 1) the number of quarters in the 2 years prior to the index prescription date that the patient received 45 or more days’ supply of opioids; 2) whether patients had any contact (in person or otherwise) with the prescribing physician or their primary care physician in the 4 months following index opioid prescription; 3) whether patients had an in-person visit with the prescribing physician or their primary care physician in the 4 months following their index opioid prescription; 4) the average daily opioid morphine-equivalent dose [12] for the 90-day period starting

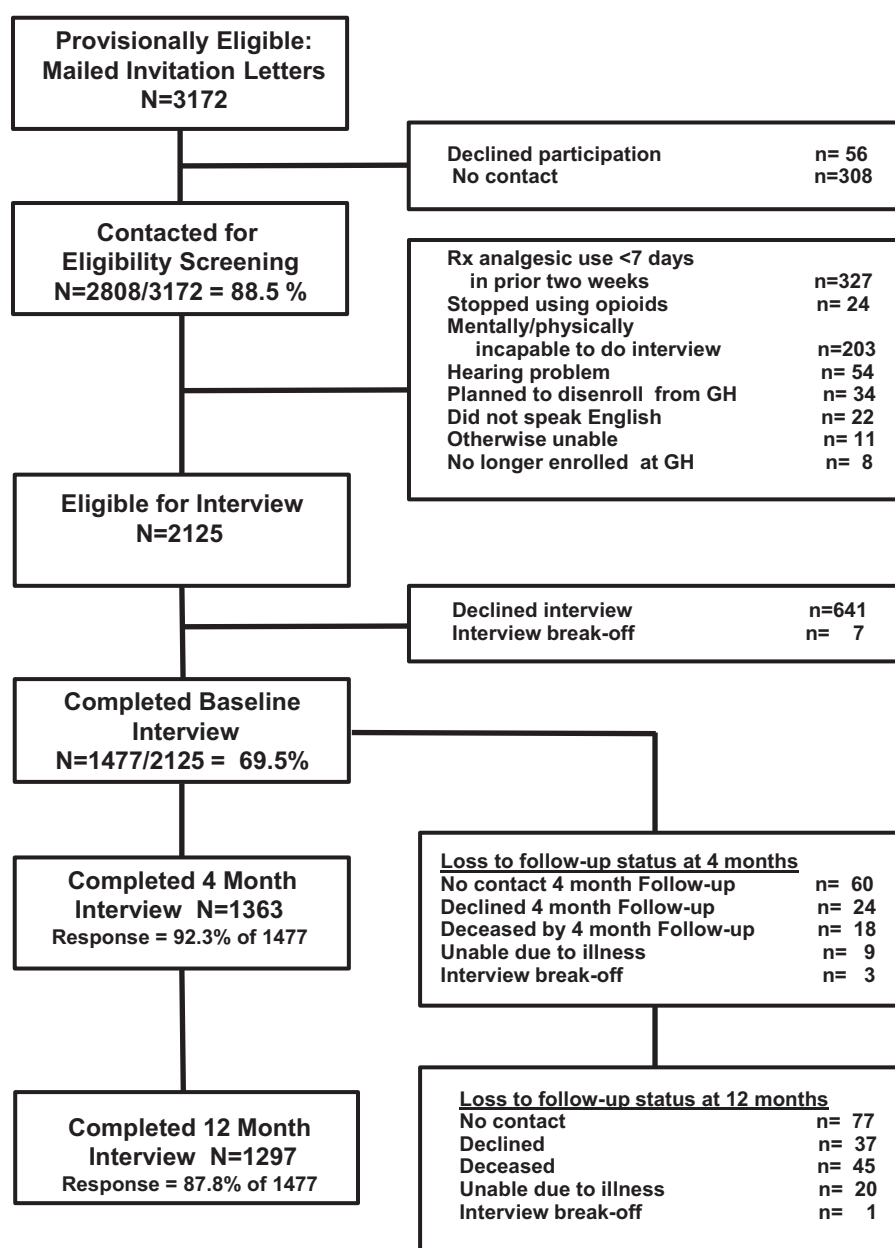


Figure 1 MASCOT study cohort enrollment and participation.

1 month following index prescription; 5) whether the patient received predominately short-acting or long-acting opioids in the same 90-day interval; 6) whether the patient received 45 or more days' supply of sedative-hypnotic medications in the same 90-day interval; 7) whether the index prescription was received before June 2011, from June 2011 to May 2012, or after May 2012, which was used to determine whether the percentage of COT patients with timely care plans increased in later phases of implementation of the risk reduction initiative.

From baseline interview data we assessed the number of days each patient reported using opioids in the prior 2 weeks. We also assessed psychosocial problems attributed by the patient to use of prescription opioids and opioid control concerns with the Prescription Opioids Difficulties Scale (PODS) [18–19]. Typical PODS items were as follows: "Opiate medicines have caused me to lose interest in my usual activities" and "In the last 3 months, I have felt that I could not control how much or how often I used opiate medicine." To assess sustained opioid use at the 1-year follow-up, we determined the percentage receiving 60 or more days' supply of opioids in the 4 months prior to the 1-year follow-up interview (from EHR data) who also reported use of opioids on 7 or more days in the 2 weeks prior to the 12-month interview.

Analyses

We compared characteristics and opioid regimens of study patients who had recently initiated COT to patients who were continuing COT users. We then examined variables associated with the timeliness of documentation of COT care plans among COT initiators. Whether differences may be explained by random variation was assessed by chi-square tests for categorical variables and by t-tests for continuous variables. We also report the percentage of COT initiators who sustained regular opioid use at the 12-month follow-up interview by baseline patient ratings of the likelihood they would sustain opioid use 1 year later. We were interested in this relationship because one possible reason for a COT care plan not being developed at the outset of long-term opioid use is that it was unclear to the patient and to the clinician that opioid use was likely to be sustained long term.

Results

Study Enrollment and Interviews

Among 3,172 persons initially eligible, 2,808 (88.5%) completed telephone screening (Figure 1). Of those screened, 2,125 were eligible for the study. The

Table 1 Baseline patient characteristics for COT initiators and continuing users in MASCOT study

Variable	COT initiators	Continuing opioid users	P value based on χ^2 or t-test comparing confirmed COT initiators vs continuing opioid users
Number (%) of patients	896 (60.7%)	581 (39.3%)	
Age (at Index Rx date)			
Mean (SD)	63.7 (11.2)	65.3 (11.1)	0.007
Female	60.3%	67.6%	0.004
Education			
High school graduate	97.4%	93.5%	0.0002
Race-ethnicity			
Non-white or Hispanic	14.1%	15.5%	0.47
Average pain intensity (0-10)			
Mean (SD)	5.9 (1.9)	6.0 (1.9)	0.96
Pain interference (0-10)			
Mean (SD)	6.2 (2.2)	5.8 (2.5)	0.003
Pain days in past 6 months			
Mean (SD)	137.4 (54.8)	153.1 (50.8)	< 0.0001
Number of pain sites	3.2 (1.4)	3.7 (1.4)	< 0.0001
(bothered a little or a lot) mean (SD)			
Widespread pain	47.0%	61.3%	< 0.0001
PHQ-8 depression 10+	30.7%	29.7%	0.66
Drug use disorder diagnosis, prior 2 years	5.0%	7.9%	0.02
Alcohol use disorder diagnosis prior 2 years from EHR	7.5%	5.5%	0.14
Current tobacco use (self-report)	15.5%	10.3%	0.004
Mental disorder diagnoses in prior 2 years	42.1%	49.4%	0.006

baseline interview was completed by 1,477 persons. The 648 persons not interviewed at baseline included those who did not give permission for use of their EHR data. Follow-up interviews at 12 months were completed by 1,297 patients (87.8% of those interviewed at baseline).

COT Initiators

Sixty-one percent of the study patients were confirmed COT initiators (Table 1). The COT initiators were somewhat younger, more often male, and slightly more likely to have graduated from high school than continuing opioid users (Table 1). As shown in Table 2, the COT initiators had substantially fewer quarters in which they received 45+ days' supply of opioids in the prior 2 years compared to continuing opioid users (13.8% versus 57.5%) and were somewhat less likely to receive a

mean daily opioid dose of 40+mg morphine equivalents (12.6% versus 17.4%). At baseline, less than half (46%) of the COT initiators said it was somewhat, very, or extremely likely they would be using opioids regularly in 1 year, whereas the large majority of continuing opioid users (71%) said it was likely they would be using opioids regularly 1 year later (Table 2).

Timely COT Care Plans

Overall, 95.6% of the COT care plans documented for study patients who were COT initiators were developed by primary care clinicians. By June 2011, 75% of all COT patients had COT care plans documented in their EHR, while by April 2013 this percentage had increased to 84% of all COT patients. Among the COT initiators, only 30% had a care plan documented in their EHR within 4 months of their index prescription date,

Table 2 Chronic opioid therapy (COT) management characteristics for COT initiators and continuing opioid users in MASCOT study

Variables	COT initiators	Continuing opioid users	P value based on χ^2 or t-test comparing confirmed COT initiators vs continuing opioid users
Number of quarters with 45+ days' supply of opioid use in 2 years before Index Rx			< 0.0001
None	79.2%	33.9%	
1	6.9%	8.6%	
2+	13.8%	57.5%	
Any contact with prescribing physician or PCP in 4 months after index Rx	65.4%	64.9%	0.84
Any face-to-face contact with prescribing physician or PCP in 4 months after index Rx	49.8%	45.6%	0.12
Opioid dose			
Mean (SD) in 3 months*	21.2 (23.0)	23.9 (32.9)	0.063
< 20 mg MED	65.2%	69.0%	< 0.0001
20 to < 40 mg MED	22.2%	13.6%	
40+ mg MED	12.6%	17.4%	
Predominant use of . . . *			
Short-acting opioids	88.0%	84.5%	0.051
Long-acting opioids	12.0%	15.5%	
Days used opioids in prior 2 weeks at baseline			0.16
Mean (SD)	12.8 (2.7)	12.5 (2.8)	
Sedative use 45+ days in 3 months*	19.0%	22.0%	0.15
Expects to use opioids regularly in 1 year			
Somewhat, very, extremely unlikely	53.7%	16.0%	< .0001
Uncertain	14.7%	13.1%	
Somewhat likely	11.6%	14.1%	
Very-extremely likely	20.0%	56.7%	
Index Rx month before			
June 2011	40.7%	40.3%	0.98
June 2011-May 2012	41.6%	42.0%	
June 2012 or later	17.6%	17.7%	

*Medicine use variables from EHR data are estimated for a 3-month (90-day) period starting 1 month (30 days) following index opioid prescription. MED = morphine-equivalent dose.

including pre-existing COT care plans (Table 3). The percentage of COT care plans documented prior to the date of the index prescription was 12.6% among COT initiators. Among COT initiators, 51% had a COT care plan documented within 12 months of their index prescription. In contrast, 57% of continuing opioid users had a documented care plan by 4 months and 72% by 12 months.

Among COT initiators, those with a recent history of a drug use disorder diagnosis (60% versus 29% of those without this diagnosis), a recent history of a mental disorder diagnosis (38% versus 25%), and current

tobacco users (43% versus 28%) were more likely to have timely COT care plans (Table 3). COT initiators who reported that it was somewhat, very, or extremely likely that they would sustain use of opioids on a regular basis had a timely COT care plan much more frequently than patients who were uncertain or thought it unlikely that they would sustain use of opioids. For example, 22% of those who thought continued opioid use was somewhat, very, or extremely unlikely were found to have a timely COT care plan, compared to 46% of those who thought that continued opioid use was somewhat, very, or extremely likely (Table 3).

Table 3 Percentage of chronic opioid therapy (COT) initiators with timely COT care plan by patient characteristics

Variables		Percent (N = 896)	χ^2 and <i>P</i> values
Timely care plan		30.2%	
Age at Index Rx	45-54	29.6%	4.40
	55-64	29.4%	<i>P</i> = 0.22
	65-74	35.5%	
	75 +	26.0%	
Male		27.8%	1.66
Female		31.9%	<i>P</i> = 0.20
Education			
Less than high school		34.8%	
High school		34.0%	4.29
Some college/vocational training		26.7%	<i>P</i> = 0.23
College graduate		32.0%	
Caucasian, non-Hispanic		31.0%	1.08
Non-white or Hispanic		26.4%	0.30
PHQ-8 depression			
0-5		30.6%	1.86
6-9		26.9%	<i>P</i> = 0.40
10+		32.5%	
Drug use disorder diagnosis	No	28.7%	19.9
	Yes	60.0%	<i>P</i> < 0.0001
Alcohol use disorder diagnosis	No	29.7%	1.71
	Yes	37.3%	<i>P</i> = 0.19
Current tobacco use (self-report)	No	27.9%	13.0
	Yes	43.2%	<i>P</i> = 0.0003
Mental disorder diagnosis	No	24.9%	17.0
	Yes	37.7%	<i>P</i> < 0.0001
PODS Psychosocial Problems	0-3	32.5%	
	4-7	28.3%	2.71
	8+	26.8%	<i>P</i> = 0.26
PODS Control Concerns	0-3	33.2%	
	4-7	27.4%	3.1
	8+	28.6%	<i>P</i> = 0.22
Expects to use opioids in one year	Somewhat, very, extremely unlikely	22.0%	47.0
	Uncertain	28.2%	<i>P</i> < 0.0001
	Somewhat likely	44.7%	
	Very, extremely likely	46.1%	

Table 4 Percentage of chronic opioid therapy (COT) initiators with timely COT care plans by opioid management variables

Variables	Percent (n = 896)	X ² and p-values
Any contact with prescribing physician or PCP in 4 months following index prescription		
No	27.7%	1.41
Yes	31.6%	<i>P</i> = 0.24
Any face-to-face contact with prescribing physician or PCP in 4 months following index prescription		
No	28.2%	1.75
Yes	32.3%	<i>P</i> = 0.19
Opioid dose in 3 months*		
< 20 mg MED	30.1%	
20 to < 40 mg MED	30.8%	0.04
40 + mg MED	30.1%	<i>P</i> = 0.98
Predominate use of extended-release opioids*		
No	29.8%	0.65
Yes	33.6%	<i>P</i> = 0.42
Days used opioids in prior 2 weeks at baseline		
< daily use	28.6%	0.33
14 days	30.7%	<i>P</i> = 0.56
Sedative use 45 + days in 3 months*		
No	28.9%	3.2
Yes	35.9%	<i>P</i> = 0.08
Index prescription month		
Before June 2011	23.6%	
June 2011–May 2012	35.4%	13.2
June 2012 or later	33.5%	<i>P</i> = 0.001

*Medicine use variables from automated data are estimated for a 3-month (90-day) period starting 1 month (30 days) following index opioid prescription. Sedatives include anxiolytics, sleep medicines, and muscle relaxants.

Among COT initiators, the percentage with a timely COT care plan was low whether or not the patient had contact with the prescribing physician within 4 months of the index prescription (32% versus 28%, Table 4). Thus, failure to develop a care plan on a timely basis was not solely due to the clinician's not seeing the patient. The percentage with a timely COT care plan did not differ by opioid dose, use of extended release opioids, or frequent use of sedatives. A timely COT care plan was slightly more likely to be present for patients whose index prescription occurred in the second half of 2011 or later (Table 4). Clinicians were initially asked to focus on developing COT care plans for patients on high opioid doses, so less attention may have been paid initially to developing COT care plans for new COT patients. However, even after the initiative had been in place for 3 years, less than 35% of COT initiators had a care plan documented in their medical record within 4 months of initiating opioid use.

Among the 735 COT initiators interviewed at the 1-year follow-up, 252 (34.3%) had received at least 60 days' supply of opioids in the prior 4 months and reported

that they had used opioids on 7 or more days in the prior 2 weeks. Among the COT initiators who sustained regular opioid use at 1 year, only 45.6% (115 of 252) predicted in the baseline interview that it was somewhat, very, or extremely likely that they would be using opioids at least two to three times a week 1 year later.

Discussion

In a health plan in which over 80% of all COT patients had a COT care plan documented in their EHR, only 30% of patients initiating COT had a care plan documented within 4 months of their index opioid prescription. This is important because COT care planning and risk stratification are key features of opioid prescribing guidelines intended to protect patient safety [8]. The basic information in the care plan (treatment regimen, risk level, physician responsible for prescribing opioids) is essential for ongoing monitoring and coordination of COT care. Documentation of a care plan may be a marker for other actions that are supposed to occur at the initiation of chronic opioid therapy, including evaluation of substance-abuse risk factors, informing patients of likely

benefits and potential risks, setting expectations for ongoing monitoring of COT including check-back visits and urine drug screening, and setting therapeutic goals used to assess whether patients are achieving hoped-for benefits. Within 4 months, patients using opioids on a daily basis can become physically or psychologically dependent on opioids, making discontinuation more difficult. This suggests that it may be important to ensure that recommended precautions are taken at the initiation of COT. Our results suggest that recommended universal precautions may often not be implemented at the initiation of COT, consistent with prior research on compliance with COT guidelines [9–11].

Less than half (45.6%) of the COT initiators using opioids regularly at the 1-year follow-up had predicted in the baseline interview that they were likely to sustain regular opioid use in 1 year. Failure to develop COT care plans on a timely basis may in part be due to the fact that patients and clinicians do not expect opioid use to be sustained in the long term. This difficulty might be addressed by amending COT guidelines to recommend a clear demarcation between time-limited opioid prescribing for acute pain and initiation of long-term opioid prescribing for chronic pain. A clear transition from short-term to long-term opioid use might help ensure that patients are evaluated for substance-abuse risk factors, that patient and clinician have considered risks relative to likely benefits, that plans for ongoing monitoring of COT have been set, and that plans for managing COT are documented in the EHR.

This study was conducted in a health plan that emphasized and incentivized the development of COT care plans. Among all COT patients, over 80% had a documented COT care plan. Since documentation of COT care plans is likely to be less complete in typical community practice settings not emphasizing or incentivizing documentation of COT care plans, our results suggest that guidelines recommending COT care plans, prospective risk assessment, risk stratification, and risk-based monitoring may be based on a premise difficult to implement in community practice settings. In the absence of evidence that prospective risk assessment is routinely implemented and able to reduce risks of prescription opioid misuse and addiction [20], primary reliance on these risk reduction strategies in COT guidelines is of uncertain effectiveness for protecting patient safety.

Regarding study limitations, this research was conducted in a health plan that had recently implemented a major initiative to increase adherence to recommended COT guidelines, including incentivizing and documenting COT care plans. COT care plans were likely documented more often in this setting than in other care settings. The results reported here are consistent with studies in other settings, which have consistently reported low rates of compliance with COT guidelines in community practice settings [9–11]. The study cohort was limited to COT patients aged 45 years or older. The

timeliness of COT care planning may differ among younger COT patients.

This research is also limited by the lack of studies on whether COT care plans and other actions recommended by COT guidelines to be performed at the initiation of COT are effective in improving patient outcomes or in reducing COT risks [20]. A potential direction for future research would be to assess whether patient outcomes differ and whether risks of opioid misuse or addiction differ depending on whether or not a COT care plan was developed and documented in the EHR at the initiation of long-term opioid use. However, we found that COT care plans were more often developed on a timely basis for patients with a prior history of substance abuse or with mental health diagnoses, so observational analyses of patient outcomes may be biased by physicians' taking greater precautions with higher risk patients.

Conclusions

We conclude that even in a health plan that achieved high rates of documentation of COT care plans in the EHRs of patients receiving COT, only a minority (30%) of COT initiators had a COT care plan documented in their EHR within 4 months of their index opioid prescription. Among COT initiators, timely care plans were more often present for patients at higher risk of opioid misuse (e.g., with a recent history of drug abuse or mental health diagnoses). However, COT initiators receiving higher-risk drug regimens (e.g., higher dose, chronic use of sedatives) were not more likely to have a timely COT care plan. These results call into question the assumption that timely COT care planning and risk stratification are practical "universal precautions" [21] that can be expected to protect patient safety among persons initiating long-term use of opioid analgesics for chronic pain.

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