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Original Research Articles

An Evaluation of the Prescription of Opioids for Chronic Nonmalignant Pain by Australian General Practitioners

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Abstract

Objective. Our objective was to evaluate the quality of opioid analgesia prescribing in chronic nonmalignant pain (CNMP) by general practitioners (GPs, family physicians).

Design. An anonymous, cross-sectional questionnaire-based survey.

Setting. The setting was five Australian divisions of general practice (geographically based associations of GPs).

Methods. A questionnaire was mailed to all division members. Outcome measures were adherence to individual recommendations of locally derived CNMP practice guidelines.

Results. We received 404 responses (response rate 23.3%). In the previous fortnight, GPs prescribed long-term continuous opioids for CNMP for a median of 4 and a mean of 7.1 (\pm 8.7) patients with CNMP. Guideline concordance (GLC) was poor, with no GP always compliant with all guideline items, and only 31% GPs usually employing most items. GLC was highest for the avoidance of high dosages or fast-acting formulations. It was lowest for strategies minimizing individual and public health harms, such as the initiation of opioids on a time-limited trial basis, use of contracts, and the preclusion or management of aberrant behaviors. GLC was positively associated with relevant training or qualifications, registration with the Australian Prescription Drug Monitoring Programme, being an opioid substitution therapy prescriber, and female gender.

Conclusions. In this study, long-term opioids were frequently initiated for CNMP without a quality use-of-medicine approach. Potential sequelae are inadequate treatment of pain and escalating opioidrelated harms. These data suggest a need for improved resourcing and training in opioid management across pain and addictions.

Key Words. Pain Management; Primary Care; Opioids; Addiction; Quality of Health Care

Introduction

Historically, the nineteenth-century laissez faire opium trade in Imperial China resulted in such excess that early in the twentieth century, international, U.S., and Australian conventions swung toward restrictions and prohibition [1]. Lobbying and political activism from the hospice movement subsequently won a more liberal approach to pharmaceutical opioids (POs) for symptom control in the care of the dying [2], thus originated the specialty of pain medicine outside the context of perioperative anesthesia [3]. Opioid substitution therapy (OST), as a treatment for heroin dependency, was first reported half a century ago, offering methadone maintenance or detoxification [4]. OST with buprenorphine has been more recently used for PO dependency [5]. Despite these many utilities of POs, five billion people globally have little or no access to them [6]. This has led the World Health Organisation to lobby for improvements in the assessment and management of pain, and the classification of selected POs as essential medicines [6].

The improvements in terminal cancer pain control observed from chronic opioid therapy (COT) resulted in advocacy to extend this system of care to all "undertreated" chronic pain [1,3,6,7]. This included the indication of chronic nonmalignant pain (CNMP), a condition that is increasingly common and is of open-ended duration [1,3,7-9]. This change occurred despite many gaps in the evidence base for COT in CNMP, with many critical research questions unanswered [1,8,10,11]. Reviews indicate COT in CNMP results in only modest improvements in pain in highly selected patients over several months, without significant improvement in function [1,10,12]. Most trials have lacked standardized definitions or methods of measurement, were short-term and were conducted in specialist clinics, excluded populations with psychiatric or addiction histories, or were funded, or even terminated, by the pharmaceutical industry [1,8,10,13-16].

Over the last couple of decades, regardless of this limited evidence, the United States has experimented with a liberal approach to COT in CNCP [17]. Now, an estimated 95% of the POs prescribed in the United States are for the indication of CNMP [1], with as many as 90% of the patients in pain management settings receiving COT [18]. Over the decade from 1997, the U.S. milligram per capita use of POs increased from 74 mg to 369 mg, an increase of over 400% [18]. Despite comprising only 4.6% of the

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world's population, Americans have been consuming 80% total global PO supply [18].

The pharmaceutical industry seems to have strategically encouraged this new market by underwriting advocacy, prescription guidelines, patient literature, position statements, books, and medical education [8,13,16,19,20]. Legislative and regulatory changes have accelerated momentum for increased prescription [6]. Pain has become the "fifth vital sign," and failure to properly manage pain assessment scales may endanger a facility's reaccreditation, or result in emotional, financial, or professional penalties for health workers [2,21,22]. An uncritical protocolized emphasis on undermedication has ignored the risks of overmedication [21].

This swing in prescription practice has led to PO abuse, becoming the fastest growing drug problem in the United States, reaching the scale of an epidemic and requiring urgent intervention [19,23]. Reports indicate that 80% of Americans between the ages of 12 and 20 have misused a controlled drug at least once [24]. Deaths by poisoning, increasingly from POs, now exceed deaths from motor vehicle accidents [9,25]. While the per capita rate of treatment admissions for substance abuse has not changed from 1999 to 2009, admissions for heroin have dropped 5%, and admissions for PO misuse have increased 430% [24,26]. America's enduring trend of rising life expectancies has reversed and has decreased by 4 years since 1990 among the least educated non-Hispanic whites [27]. This is attributed to increasing PO overdoses [27], and correlates with non-Hispanic whites being overrepresented in the most chaotic subset of COT users [28]. Prescriber bias may account for why whites, as against blacks, are more likely to be prescribed POs and less likely to receive risk reduction strategies [29,30].

Indications that these harms are not offset by improved pain outcomes have come from clinical reflections [17], and both population and clinical studies [10,31,32]. In a population survey of CNCP in Denmark, COT use was associated with higher pain scores, lower physical activities, and lower quality of life [33]. In a large prospective trial of workers with compensable back injuries, only 27% and 16% of those on COT had significantly improved pain or function, respectively [34].

In Australia, as in the United States, most POs are prescribed by general practitioners (GPs), with nonmalignant pain the most common (96.5%) indication [1,35]. Frequently, GP consultations manage CNMP (18.3%) or involve prescribing POs (5.6%) [35,36]. For the first time since 2001, opioid overdose deaths have risen especially among older Australians [37]. This has been driven by increasing PO prescription, which parallels increasing demand for OST, particularly for oxycodone [1,35,37]. In Australia, as in the United States, POs are replacing heroin as the misuse opioid of choice [1,5].

Best practice in CNMP includes the avoidance of undertreatment as well as the minimization of risks. Best prac-

tice should be aided and informed by guidelines providing "actionable" recommendations from "pre-processed evidence" [38]. CNMP prescription guidelines vary widely and are continuously evolving [39]. Recently, the release of a COT prescription guideline was associated with a reduction in both high-dose prescription and overdose deaths [40]. North American GPs describe pain prescription guidelines as helpful [7,20,39], yet infrequently report guideline concordance (GLC) [1,7,14]. There is no equivalent data for Australian GPs. In order to identify areas for improvement [1,20], we undertook to assess selfreported GLC by Australian GPs in the opioid management of CNMP.

Methods

Questionnaire

There is a lack of "gold standard" or validated instrument to quantify the quality of GPs' use of COT [10]. Hence, we developed a questionnaire (Appendix) based on local guidelines developed by a multidisciplinary pain center and disseminated to local GPs to improve the community management of CNMP [1,41,42].

Demographic variables were collected, including the presence of postgraduate training or gualifications in pain, addiction, OST, or mental health (excluding brief industrysponsored education) [8,13,16,20,31]. In New South Wales, GPs can prescribe OST without specific training for up to five established patients [43]. We elicited whether respondents had registered for Australia's opt-in Prescription Drug Monitoring Programme (PDMP). The Prescription Shopping Information Service provides information by telephone about patients seeing multiple doctors or receiving multiple opioids [1]. Six questionnaire items allowed a response along a visual analog scale. The seventh and eighth were composite questions, and offered the categorical responses "never," "occasionally," and "often." The seventh elicited the frequency of regular monitoring of four pain management outcomes, and the eighth elicited the frequency of management responses to suspected aberrant behaviors during the previous 2 years. Ethics approval was granted by the Hunter New England Human Research Ethics Committee (Reference: 10/11/ 17/5.03).

Recruitment

Five urban and rural divisions of general practice (geographically based associations of GPs) agreed to participate. Divisions posted a study pack to all GP members in mid-2011, with a blanket repeat mail-out a month later. The study pack included an information statement, the survey, and for four divisions a letter of support from the chief executive officer. Responses were invited anonymously via prepaid envelopes. A monetary incentive of \$25 was offered for each returned survey and donated to the Medical Benevolent Society.

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Analysis

Respondents not reporting any patients on daily COT for over 3 months in the last fortnight were excluded from all GLC analyses. To understand associations of overall GLC, in addition to the descriptive data, we devised a priori two measures: a continuous total score and a dichotomous score. First, to assess GLC as a continuous outcome score, we scored each of the eight items from 0 to 100 points, giving a maximum score of 800 points. For the six visual analog score items, a score of 100 was given for reporting 100% frequency of GLC. For the two categorical items, a score of 100 reflected reporting "often" on every subitem, with 0 being scored for "never" reporting any subitem. Second, to assess GLC by a simple dichotomous outcome, we chose a cut point of scoring over 50 on over half of the items. In other words, GPs had to report GLC with most items most of the time, the latter proportion also chosen elsewhere [39], or averaging over "occasionally" for the two categorical questions. This cut point representing only modest guideline adherence was chosen by our multidisciplinary group to delineate "better" or "poorer" GLC. For the descriptive statistics, continuous data have been summarized using the mean and standard deviation (SD) (median, minimum, and maximum were used for nonparametric data). Categorical data have been summarized as counts and percentages of each category. To assess the consistency with which respondents adhered to guidelines, we estimated correlation between the items.

Multiple linear regression was used to assess the effect of demographic and clinical variables on the continuous guality score; multiple logistic regression was used for the dichotomized quality outcome. In both cases, univariate analyses were initially carried out; variables with Wald test P values <0.25 were included in a multivariate model. Interactions terms were then assessed. To derive the most parsimonious model, variables were removed if there was no reduction in effect size of the remaining terms, and the Akaike information criteria did not increase. Variables not reaching the univariate significance threshold were sequentially reincluded in the final model if there was a reduction in the Akaike information criteria. Multicollinearity was assessed by checking the variance inflation factors. For each regression, model assumptions were tested by inspecting residual diagnostic plots and performing appropriate tests. All analyses were programmed in R v2.13 and SAS v9.2 (SAS Institute Inc, Cary, NC. R Foundation for Statistical Computing, Vienna, Austria) [62].

Results

There were 404 responses from the 1,735 surveys distributed, a response rate of 23.3%. Respondents' mean age was 50.9, with 55% being male, with clinical experience of almost two decades, 72% were located in major cities, 30% had postgraduate training, 70% were registered with the PDMP, and 16% were OST prescribers (see Table 1 for participant demographics). Only 52% OST prescribers reported postgraduate training.

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 Table 1
 Characteristics of sample demographics

Characteristic	Statistic/Class	Total (N = 404: Unless Specified)
Gender	Male	223 (55%)
	Female	180 (45%)
Age (N = 400)	Mean (Std)	50.91 (10.66)
	Median (min, max)	51.50 (25.00, 80.00)
Years as GP in Australia (n = 399)	Mean (Std)	19.74 (11.77)
, , , , , , , , , , , , , , , , , , ,	Median (min, max)	20.00 (0.00, 51.00)
Country of graduation	Australia	290 (72%)
, ,	India	25 (6.2%)
	South Africa	13 (3.2%)
	Other	75 (19%)
Billing	Private	55 (14%)
5	Bulk billing (i.e., no patient fee)	143 (36%)
	Mixed	203 (51%)
Workplace role	Sole practitioner	65 (16%)
	Partner or associate	191 (48%)
	Employed permanent	112 (28%)
	GP registrar	19 (4.7%)
	Locum	14 (3.5%)
Sessions (i.e., half days) per week (N = 400)	Mean (Std)	7.60 (3.03)
	Median (min, max)	8.00 (2.00, 40.00)
Number of GPs (N = 391)	Mean (Std)	5.88 (3.98)
	Median (min, max)	5.00 (0.00, 24.00)
Fulltime equivalent (N = 283)	Mean (Std)	4.60 (3.38)
	Median (min, max)	4.00 (0.00, 40.00)
Patients seen last fortnight (N = 395)	Mean (Std)	214.08 (118.83)
5 ()	Median (min, max)	200.00 (0.00, 1000.0)
CNMP patients prescribed opioids last fortnight ($N = 396$)	Mean (Std)	9.75 (12.01)
	Median (min, max)	5.50 (0.00, 100.00)
CNMP patients in last fortnight prescribed opioids	Mean (Std)	7.10 (8.71)
continuously over 3 months ($N = 384$)	Median (min, max)	4.00 (0.00, 50.00)
Training or qualifications	Absent	281 (70%)
	Present	122 (30%)
OST prescriber	Yes	61 (16%)
·	No	331 (84%)
OST prescriber: Number of OST patients (N = 59)	Mean (Std)	12.81 (19.55)
· · · · · · /	Median (min, max)	3.00 (0.00, 80.00)
Prescription Drug Monitoring Programme registered	Yes	273 (70%)
	No	116 (30%)

CNMP = chronic nonmalignant pain; GP = general practitioner; OST = opioid substitution therapy.

In the previous fortnight, median total patient number was 200. Respondents prescribed POs to a median of 5.50 patients for CNMP. Of these, a median of 4.00 were on POs continuously for over 3 months.

GLC was reported most frequently for the items pertaining to the use of injectable or high doses (mean 13.0%, SD 21) and the use of long-acting formulations (mean 77.5%, SD 28.2) (Table 2). GLC was reported least frequently for having a documented opioid agreement (mean 12.7%, SD 25.8). For the question on regular monitoring, less than half "often" checked for aberrant behaviors. For the management of suspected aberrant behavior, respondents had a low GLC overall. Only one option, referral to pain specialists, was reported more than "occasionally."

There were 284 GPs with complete data for all demographic and clinical variables suitable for regression analyses (Table 3). No GP scored 100% on all eight items; one scored 100% on seven items, another on six items, and 18 GPs scored 100% on five items. For the GLC continuous outcome score out of 800, after adjusting for confounders, greater GLC was seen in GPs with postgraduate training, in OST prescribers, and in PDMPregistered GPs. For our assessment of GLC as a dichotomized outcome, there were 88 (31%) better

Table 2 Guideline concordance items: Descriptive data

Item	N (%)*	Mean (Std)	Median (Min, Max)	Categorical Item Proportions
Proportion-prescribed injectable opioids or doses over the equivalent of 120 mg oral morphine per day.**	339 (98.5)	13 (21)	3 (0, 100)	
Proportion with structured risk assessment for opioid-related problems prior to the first script?	331 (96.2)	47.3 (41.1)	50 (0, 100)	
Proportion with agreement to start the opioid strictly on a time-limited trial basis?	334 (97.1)	39.5 (36.2)	25 (0, 100)	
Proportion with a documented multidisciplinary pain management plan?	340 (98.8)	46.9 (35.4)	50 (0, 100)	
Proportion with a written agreement regarding therapeutic boundaries for their opioid medications?	338 (98.3)	12.7 (25.8)	0 (0, 100)	
Proportion on long-acting rather than short-acting opioids?	334 (97.1)	77.5 (28.2)	87 (0, 100)	
How often do you regularly (at least every 3 months) assess your current COT patients in each of the following areas?***				Not at all/ occasionally/often
Total	340 (98.8)	74.7 (23.1)	75 (0, 100)	
Analgesia	340 (98.8)	14.1 (6.7)	20 (0, 20)	11/38/51%
Activities of daily living	340 (98.8)	16.1 (5.5)	20 (0, 20)	3.9/32/64%
Adverse events	340 (98.8)	15.9 (5.8)	20 (0, 20)	5.2/31/64%
Aberrant opioid behaviors (taking medications in ways not authorized by the prescribing doctor)	340 (98.8)	13.6 (6.7)	10 (0, 20)	11/42/47%
How often in the last 2 years have you used the following strategies with COT patients where you were concerned about aberrant opioid behaviors?***				Not at all/ occasionally/often
Total	333 (96.8)	43.8 (19.6)	40 (0, 100)	
Contacted the PDMP	338 (98.3)	7.8 (7)	10 (0, 20)	37/47/16%
Referred to pain specialist for opinion or management	339 (98.5)	14 (5.7)	10 (0, 20)	4.7/50/45%
Referred to addiction medicine specialist or drug and alcohol service	338 (98.3)	7.2 (6.6)	10 (0, 20)	38/49/13%
Opioid rotation including OST	334 (97.1)	6 (6.2)	10 (0, 20)	47/46/7.9%
Terminated opioid medications	338 (98.3)	8.6 (5.6)	10 (0, 20)	23/66/11%
Total score all items	310 (90.1)	430 (116.7)	420.5 (162.5, 770)	

* N = Number of responses from sample reporting having patients on opioids over 3 months.

** For only this item, a low score was more guideline concordant.

*** For these items, "never" was scored as 0, "occasionally" as 10, and "often" as 20.

COT = chronic opioid therapy; PDMP = Prescription Drug Monitoring Programme.

prescribers. Statistically significant higher odds ratios for good GLC were obtained by respondents with female gender, postgraduate training, and PDMP registration.

It is worth noting the consistency of results across both the continuous and dichotomized score of GLC. Postgraduate training was significant in both multivariate models, increasing the GLC score by 44 points in the continuous model and increasing the odds of better GLC by 1.8-fold in the dichotomous model. PDMP registration was also significant in both multivariate models, increasing the GLC score by 36 points in the continuous model and increasing the odds of better GLC by twofold in the dichotomous model. Being an OST prescriber or being female was significant in one multivariate model each. OST prescribers had a higher continuous GLC score of 40 points, and in the dichotomous model, female gender increased the odds of better GLC 2.9-fold.

Discussion

We found that no COT prescriber was always compliant with every guideline item, and that less than one third were usually compliant with most items. If the low response rate

Univariate Multivariate Univariate Univa				Continuous			Dichotomous		
Variable Name Class N (%) Coefficient (95% CI) P Value (95% CI) OR (95% CI) Gender Male 166 (58.45) Referent (95% CI) OR (95% CI)				Univariate		Multivariate	Univariate		Multivariate
Gender Male 166 (58.45) Referent 1.76 (1.06, -1.06) 0.0292 1.76 (1.06, -1.06) 0.098 (0.96, -1.03 (-2.14, 0.08) 0.098 (0.96, -0.98 (0.96, -1.03 (-2.14, 0.08) 0.0688 0.098 (0.96, -0.98 (0.96, -1.03 (-2.14, 0.08) 0.0688 0.098 (0.96, -0.98 (0.96, -0.98 (0.96, -1.03 (-2.14, 0.08) 0.0688 0.098 (0.96, -0.98 (0.96, -1.03 (-2.14, 0.08) 0.0688 0.098 (0.96, -0.98 (0.96, -0.98 (0.96, -0.98 (0.96, -1.03 (-2.14)) Referent Referent Workplace role Partner or associate 12 (25) 12 (-92 (-17.05, 42.89) 0.398 (1.98, -0.94 (0.64, -0.82)) 0.0404 1.16 (0.64, -0.82) Workplace role Partner or associate 16 (514.1) Referent 1.41 (0.8, 2, -0.04) 0.338 (0.04, -0.93) 0.0404 Referent 71 (25) 12 (-92 (-17.05, 42.89) 0.398 (0.96, -0.33) 0.14 (0.64, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0.66, -0.33) 0.04, -0.66, -0.33 (0.04, -0.66, -0	Variable Name	Class	N (%)	Coefficient (95% CI)	P Value	Coefficient (95% CI)	OR (95% CI)	P Value	OR (95% CI)
Age -1.18 (-2.43, 0.06) 0.0625 0.38 (0.96, 0.98 (0.96, Years as GP in Australia Veats as GP in Australia -1.03 (-2.14, 0.08) 0.0688 0.98 (0.96, 0.98 (0.96, Country of graduation Australia 213 (75) Referent 1.41 (0.8, 2 Workplace role International 71 (25) 12.92 (-17.05, 42.89) 0.3881 1.41 (0.8, 2 Workplace role Partner or associate 146 (51.41) Referent 1.41 (0.8, 2 Workplace role Employed permanent 71 (25) 12.92 (-17.05, 42.89) 0.3981 1.41 (0.8, 2 Workplace role Employed permanent 73 (25) 12.92 (-17.05, 42.89) 0.3981 1.41 (0.8, 2 Korkplace role Employed permanent 73 (25) 12.92 (-17.05, 42.89) 0.3981 0.64 Korkplace role Employed permanent 78 (27.46) 10.46 (-19.75, 40.67) 0.4976 0.16 (0.64, 0.68, 0.06) Corv Employed permanent 78 (27.46) 10.46 (-19.75, 40.67) 0.438 (0.08, 0.06) 0.038 (0.04, 0.06) 0.040 (0.64, 0.02) 0.400 (0.64, 0.02) 0.41 (0.05, 0.06) 0.040	Gender	Male Female	166 (58.45) 118 (41.55)	Referent 29.09 (2.95, 55.24)	0.0292		Referent 1.76 (1.06, 2.93)	0.0288	2.88 (1.53, 5.72)
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Workplace role International 71 (25) 12.92 (-17.05, 42.89) 0.3981 1.41 (0.8, 2 Workplace role Partner or associate 146 (51.41) Referent Referent Employed permanent 78 (27.46) 10.46 (-19.75, 40.67) 0.4976 1.41 (0.8, 2 Employed permanent 78 (27.46) 10.46 (-19.75, 40.67) 0.4976 1.16 (0.64, 1.16 (0.64, 1.16 (0.64, 1.16 (0.64, 1.16 (0.62, 14.35)) GP registrar 14 (4.93) -45.96 (-106.23, 14.3) 0.135 0.039 (0.08, 0.03, 1.16 (0.72, 1.16 (0.72, 1.18 (-5.65, 2.7)) 0.38 (0.04, 0.35, 0.04, 0.35) 0.044 1.51 (0.72, 0.34 (0.85, 0.34 (0.85, 0.34, 0.85)) 0.34 (0.85, 0.34, 0.36) 0.34 (0.85, 0.34, 0.36) 0.34 (0.85, 0.34, 0.36) 0.34 (0.85, 0.34, 0.36) 0.34 (0.85, 0.34, 0.36) 0.34 (0.85, 0.36	Country of graduation	Australia	213 (75)	Referent			Referent		
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	OST prescriber	No	242 (85.21)	Referent			Referent		
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PDMP-registered No 84 (29.58) Referent Referent	PDMP-registered	No	84 (29.58)	Referent			Referent		
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	Programme.								

Table 3 Regression analyses

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created a sample bias toward those interested in opioid comorbidities, these figures would have actually overestimated GLC. Poorer GLC would increase the environmental availability of POs driving misuse and potentially hasty regulatory responses [2,8,44,45].

There may be a range of reasons for such poor GLC in this study. Fee-for-service GPs practicing streamlined medicine may be unable or unwilling to target GLC [8,17,44-47]. Pain presentations are often associated with other multiple comorbidities lacking simple solutions [35]. GPs may feel GLC is ineffective and so unnecessary [48]. They may prioritize the doctor-patient relationship, and fear losing a patient angry or frustrated due to a structured policy on refill scripts [11,22,44-46]. There may be a perceived loss of control over the prescription process [49], or a clinical inertia to continue COT prescribed by colleagues over decades [11,19,46,49]. Pharmaceutical industry-funded education may encourage a permissive approach to POs [8,11,13,16,19], or leave GPs unaware of prescription guidelines [38,44]. Structural reasons may account for low GLC, such as underfunding causing long waiting lists for multidisciplinary pain services or addiction services [1,9,42,49].

The most frequently implemented GLC strategies, on long-acting formulations and high dosages, are debatable as indicators of best practice [29,50]. The preference of long-acting formulations has been promoted by pharmaceutical companies to seemingly avoid addiction [11,19]. However, when tampered with for parenteral misuse, they act as if short-acting [47]. Lower dosages, likewise, may not guarantee safety. No safe ceiling dose has been established [12], with one U.S. study finding that most overdoses occur with lower COT doses [32]. Most GPs reported "often" monitoring three of the four assessments. This would imply the provision of time, two-way communication, and patient involvement [29,44]. These four assessments were not found so frequently elsewhere in document reviews [34,39] or from self-report [7].

The least frequently implemented GLC strategies concerned preliminary contracting about boundaries, and the preclusion and management of aberrant behaviors, areas of difficulty in similar U.S. groups [48,51]. Foregoing these strategies compromises unwary GPs and patients for the often challenging negotiations involved in opioid maintenance [16,22]. Quality COT, as with guality palliative care, involves preparation for an ending [3]. Most COT was not initiated on a time-limited trial basis, contributing to its infrequent termination. Where COT had been gradually ceased during a multidisciplinary pain rehabilitation program, those previously on COT had improved pain outcomes, even more so than those who were not [52]. Elsewhere, CNMP patients have reported similar levels of satisfaction with treatment whether or not they are on COT [33]. With aberrant behaviors being regarded as a proxy for addiction [31], even when patients were developing addiction, only 11% of our respondents "often" stopped COT.

Female GPs had higher rates of GLC, presumably related to their significantly lower rates of PO prescription [35]. The prevalence of COT in Australia is unclear. Similar to the median 6–10 patients on COT reported by Canadian GPs [20], the current study found COT prescribed to a median of four (mean of seven) patients per fortnight. It is unknown how frequently these patients are reviewed, but in one U.S. study, only half of the patients on COT had regular office visits every 6 months [30]. With about 27,000 GPs in Australia [53], the prescription volume figures of this study add support to extrapolations from Tasmanian data that approximately 88,000 Australians initiate long-term COT per annum (F. Shand, personal communication, March 22, 2012).

The U.S. government has responded to escalating harms by proposals, including mandatory COT prescriber and consumer education, and improvements in PDMPs [23].

The principles of opioid maintenance for the treatment of pain are said to be similar to those for the treatment of addiction [31]. Uneducated or disinterested GPs, such as GP registrars, locums, or those unregistered with the PDMP, had the lowest GLC, and those with training or OST experience had the highest. While addiction skills are said to be central to pain management [8], to the authors' knowledge, this is the first time that they have been associated with a higher quality of analgesia prescription. Patients frequently present with comorbidities spanning along a continuum of pain and addiction [5,8,45,54]. Encouragement from authorities for training and experience in addiction management should, thus, improve both the management of pain and the management of opioid dependency no matter the provenance [1,8].

Consumers require information about their responsibilities, the structuring involved in COT, and its limitations and toxicities [51]. The problematic pharmacokinetics of methadone may be familiar in OST programs. However, in the United States, where methadone is now mainly prescribed as an inexpensive analgesic [18], it is overrepresented in overdoses [25]. Consumers require education to avoid this risk so that they do not use additional doses for breakthrough pain [25].

PDMPs assist the identification of both misusers and misprescribers [23]. In one U.S. commercially insured population, the heaviest 5% COT users accounted for 70% total opioid use [55]. Elsewhere, the heaviest COT consumers accessed more prescribers than the average patient (3.3 vs 1.9, respectively) [56]. To promote routine checking of PDMPs, U.S. proposals support funding for the additional care burden required [23]. This burden may be one reason why the majority of our respondents did not "often" actually contact the PDMP during the evaluation of aberrant behaviors. Increased mandatory demands, if unremunerated, may cause some GPs to totally withdraw from the rightful prescription of POs [47,50], or simply to exclude these patients ("patient dumping") [22]. Most of those at increased risk of overdose due to COT misuse may not be identified by PDMPs, and this will require more nuanced clinical monitoring [1,9,28,45]. PDMPs can identify prescribers generating high volumes of POs [23], with one Californian study finding that 3% of physicians prescribed 62% of all morphine equivalents [56]. Such physicians have been characterized as "dated, dishonest or duped" [57].

Any swing from a *laissez faire* to a more restrictive prescription culture may become a perceived threat to the rightful prescription of POs for acute or terminal pain [8,16,19]. It is likely that the pharmaceutical industry will vigorously defend a liberal prescription culture and support any backlash from consumers [57]. Industry will certainly support the proposed changes to the fifth edition of Diagnostic and Statistical Manual of Mental Disorders which will see fewer patients on COT reaching the criteria for addiction, and thus "being made to suffer by receiving inadequate (treatment)" [58]. Those high prescribers being subjected to sanctions have protested such intrusions as a "witch-hunt" based on "hysteria" about addictions [57,59].

Improving prescription practices requires a cultural shift from a binary view of pain and addictions [17]. Such divisions oscillate depending on changes in the diagnostic criteria for dependency or the effectiveness of PDMPs [47,58]. Pain outcomes have been shown to improve with systematic adherence to guidelines and the principles of universal precautions [40,60]. However, for an already overburdened GP to prioritize the time and diligence involved in more responsible prescription, specific reimbursement will be required [51].

Future research should focus on the development of a time-efficient pilot CNMP model of care and treatment outcome measures for GPs that are suitable for audit, feedback, and research [1,8,11]. Epidemiological studies and policy development could be based on the extraction of data from GPs' routine electronic health records and the linkage of this to outcome measures [11]. Finally, the exclusion of all cancer patients from chronic pain research should not be regarded as a limitation *per se* [20,30], as what were once rapidly fatal illnesses have become common, chronic, and incurable illnesses with the same safety issues as CNMP [3,19,54].

Strengths and Weaknesses

This is the largest GP sample surveyed specifically on COT in Australia. A strength of the current study is the surveying of five complete rural and urban divisions of GPs, and the inclusion of more transient GPs, such as registrars and locums.

A limitation of these results is the 23.3% response rate, despite our utilization of numerous strategies to optimize it. It may have reflected discomfort with this area [7]. It is a common problem, with similar GP surveys reporting response rates of 4–29% [7,14,48–50,61]. Despite this, the demographics composition of the

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sample resembled that of the largest Australian GP surveys [61].

A significant limitation of this work, and of any work on COT, is the absence of a validated instrument of evaluation [10]. Our survey instrument had good construct validity being based on and aligned with respected Australian guidelines designed for GP use [1,42]. The fact that the various statistical analyses were consistent, whether outcomes were treated as continuous or dichotomous, gives strength to these data.

The use of self-report data may cause a social desirability response bias with an overestimation of guideline compliance compared with the use of actor patients, videotaping, or medical record reviews [39]. Potential sampling bias was evidenced by the overrepresentation of OST prescribers, with our estimates indicating less than 5% of Australian GPs are authorized OST prescribers [43,53]. However, this would bias away from the null, indicating that any non-GLC demonstrated would be even poorer if the sample was representative.

Conclusions

In this study, GPs are frequently initiating and maintaining patients on COT in a nonevidence-based fashion, with no respondents being fully guideline-compliant and less than a third usually complying with most strategies. The improvement of prescription quality requires COT education delivered without corporate sponsorship spanning across pain and addictions, along with increased investment in clinical support. Doing so may preempt overrestrictive regulatory responses to an iatrogenic epidemic, and achieve a reduction in the burden of pain and opioidrelated suffering.

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Appendix

Opioids: Prescribed & Illicit, Understanding & Management (OPIUM) GP Survey

Information about you and your practice (Please complete by ticking boxes or writing in the spaces provided)

- 1. What is your sex? \Box Male \Box Female
- 2. What is your age? _____ years
- 3. For how many years have you worked as a General Practitioner (GP) in Australia?
- In what country did you graduate from your primary medical degree?
 □ Australia Other (please specify):
- 5. How would you best describe your current position within the practice?
 - □ Sole Practitioner
 - □ Partner or Associate
 - □ Employed Permanent Doctor
 - □ GP registrar
- 6. How many sessions per week do you work as a GP? _
- 7. Including yourself, how many GPs work at your main practice location?
- Number: _____ & Full Time Equivalents: ___
- 8. How does your practice bill? (Tick one box only.)
 - □ Predominantly private billing
 - Predominantly bulk billing
 - $\hfill\square$ Mixed private and bulk billing
 - \Box Other (please specify) _
- 9. Postcode of your main practice address:
- 10. Please list any post graduate qualifications or additional training you have in the areas of Drug & Alcohol, counselling, psychiatry, Opioid Substitution Therapy (OST), pain management or similar:

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- 11. Are you registered with the Prescription Shopping Information Service? □ Yes □ No
- 12. How many patients do you estimate you have seen in the last fortnight? _
- 13. To how many of these patients (from Q12 above) did you prescribe opioid analgesics for Chronic Non Malignant Pain (CNMP)?
- 14. How many of these patients (from Q13 above) have been prescribed opioid analgesics for 3 continuous months or more?

In the remaining questions, the abbreviation COT stands for Chronic Opioid Treatment and refers to patients being prescribed opioids for 3 continuous months or more for CNMP. The following questions therefore relate to the patients you identified in Q 14. If your answer to Q14 was "none", please go to Question 23 on page 4. Otherwise, please continue by marking your preference on the line below.

15. What proportion of your COT patients are prescribed injectable opioids *or* doses over the equivalent of 120 mg oral Morphine per day (ie 80 mg Oxycodone, 400 mg oral Tramadol, 40 mg Methadone, 25 μg/hr Fentanyl patches, or 40 μg/hr Buprenorphine patches)? (*Please mark the line with an X*)

1	1	1	1	1
0%	25%	50%	75%	100%

16. What proportion of your COT patients did you do a structured risk assessment for opioid related problems <u>prior</u> to starting the first opioid prescription? (*This includes asking about previous problems with medications, mental health, drug or alcohol problems*)

1	1	1	1	1
0%	25%	50%	75%	100%

17. What proportion of your COT patients did you agree to start the opioid strictly on a time-limited trial basis?

1	11	11	1	1
0%	25%	50%	75%	100%

18. What proportion of your COT patients has a documented multidisciplinary pain management plan? (*This includes for example physical therapies (exercise, physiotherapy, acupuncture), counseling or lifestyle issues, referral to relevant specialists*)



19. What proportion of your COT patients has a written agreement regarding therapeutic boundaries for their opioid medications? (For example, no early prescriptions; no replacement of lost prescriptions or medications; single prescriber; single pharmacy)



20. What proportion of your COT patients for CNMP are on long acting rather than short acting opioids?



21. How often do you regularly (at least every three months) assess your current COT patients in each of the following areas? (please tick one box for each row)

		Not at all	Occasionally	Often
a.	Analgesia (assessment of pain using pain scores (0–10), Brief Pain Inventory, pain diary, or other scales)			
b.	Activities of daily living (eg. physical functioning, mood, sleep, relationships)			
c.	Adverse events associated with opioids (e.g. constipation, falls)			
d.	Aberrant opioid behaviors (taking medications in ways not authorized by the prescribing doctor)			

22. How often in the last 2 years have you used the following strategies with COT patients where you were concerned about aberrant opioid behaviors? (please tick one box for each row)

_		Not at all	Occasionally	Often
a.	Contacted the Australian Prescription Shopping Information Service			
b.	Referred to pain specialist for opinion or management			
c.	Referred to addiction medicine specialist or drug and alcohol service for opinion or management			
d.	Opioid rotation including OST			
e.	Terminated opioid medications			

23. Do you prescribe OST for the treatment of opioid dependence? $\hfill\square$ Yes $\hfill\square$ No

24. If yes, how many patients do you prescribe OST for? _

25. Which of the following would deter you from prescribing OST (or deter you from increasing your numbers if already a prescriber)? (please tick the appropriate box on each row)

	No	Yes
a. Negative experiences with opioid dependent patients		
b. Fear of the effect of opioid dependent patients on other patients		
c. Fear of violence		
d. Part time work		
e. Lack of opioid dependent patients in my practice		
f. Heavy workload		
g. Inadequate financial reward		
h. Colleague objections		
i. Lack of confidence		
j. Lack of specialist support		
k. Cost to patients		

26. What would encourage you to prescribe OST for your opioid dependent patients? (please tick the appropriate box on each row)

	No	Yes	
Better financial rewards			
More accessible training			
More accessible specialist support			
Help with practice staff training and organization			
Better evidence of safety and efficacy Other (please specify):			

Thank you for your time and patience in completing the questionnaire.

Please place your completed questionnaire in the reply paid envelope and return it by post.