Evidence-based treatment for opioid use disorders: A national study of methadone dose levels, 2011-2017

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Abstract

The nation's methadone maintenance treatment (MMT) programs play a central role in addressing the current opioid epidemic. Considerable evidence documents the treatment effectiveness of MMT and, in turn, the importance of adequate dosing to MMT's effectiveness. Yet, as recently as 2011, 41% of patients received doses below the level of 80mg/day. Using survey data from a nationally representative sample of MMT programs in 2011 and 2017, we examine (1) the extent to which the nation's MMT programs are meeting evidence-based standards for methadone dose level and (2) characteristics of MMT programs that are associated with variation in performance. Our results show that forty-three percent of MMT patients receive less than 80mg/day in 2017, and 23% of methadone maintenance patients receive daily doses below 60mg. Results from multivariate regression analysis of the 2017 survey data show that private for-profit and public organizations significantly under-dosed patients compared to private nonprofit providers. Under-dosing also was more common in programs that serve high proportions of African-American patients. These results are concerning because MMT remains the medication of choice for vulnerable patients with the most severe opioid use disorders, and for-profit providers treat a growing proportion of MMT patients.

Keywords

Methadone; Opioid-Related Disorders; Substance Use Treatment

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1. Introduction

The nation's methadone maintenance treatment (MMT) programs play a central role in addressing the opioid epidemic. Indeed, the estimated number of patients receiving MMT increased by more than half between 2003 and 2015, from 227,000 to 356, 843 (Alderks, 2017). This paper provides current (2017), nationally-representative data on the extent to which the nation's MMT programs are meeting evidence-based standards for methadone dose levels during the opioid epidemic. We draw on methods and data from the National Drug Abuse Treatment System Survey (NDATSS); 2011 data from this survey showed that 41% of patients received dose levels too low for optimal effectiveness (D'Aunno, Pollack, Frimpong & Wuchiett, 2014).

Studies in many countries demonstrate the clinical effectiveness of methadone maintenance treatment (MMT) to promote individual recovery, to slow HIV transmission, and to reduce overdose death, drug injection, HIV risk behavior and HIV sero-conversion (Des Jarlais & Semaan, 2008; Faggiano, Vigna-Taglianti, Versino, & Lemma, 2003; Newman & Whitehill, 1979; Simpson, Joe, & Brown, 1997; Strain, Bigelow, Liebson, & Stitzer, 1999). A 2009 Cochrane review of randomized controlled trials found that methadone was significantly more effective than non-pharmacological approaches in retaining patients in treatment and in reducing heroin use (Mattick, Breen, Kimber, & Davoli, 2009). An updated Cochrane review (2014) also supported the effectiveness of MMT (Mattick, Breen, Kimber, & Davoli, 2014).

Prior research also shows that MMT effectiveness depends upon adequate dose levels (Faggiano et al., 2003). In particular, results from randomized controlled trials suggest that MMT programs that provide average doses in the range of 80–100 mg/day have superior rates of patient retention in treatment (Johnson et al., 2000; Kleber, 2008; Strain, 2006).

A potential confusion in methadone treatment arises from the need to individualize doses while ensuring therapeutic dose levels. On the one hand, methadone dosage should be determined for each patient given differences in individual metabolism, preferences, and circumstances. On the other hand, existing data suggest that patients who take at least 80mg/day of methadone, and who maintain an average plasma concentration of about 400ng/mL, display reduced illicit drug use and better retention in treatment (Strain, 2006). Although optimal dose varies across individuals, there is no evidence that these variations should prevent MMT programs from providing average doses in the range of 80–100 mg/day.

Given the need for effective MMT treatment during the nation's opioid epidemic, it is important to re-examine the extent to which MMT programs are meeting evidence-based standards for methadone dose level. Thus, this paper addresses two questions: First, to what extent are the nation's MMT programs currently meeting evidence-based standards for methadone dose level? Second, which characteristics of MMT programs are associated with variation in performance? To address this second question, we draw on prior research which indicates that variation in methadone dose levels is related to variables in three key categories: (1) patient characteristics; (2) program characteristics, including ownership, payment (i.e., managed care arrangements), accreditation and staff background; (3)

managerial attitudes and beliefs that may run counter to the use of evidence-based practices (D'Aunno et al., 2014; Pollack & D'Aunno, 2008).

2. Material and Methods

2.1. Sampling frame and sample.

This paper uses methods and data from the National Drug Abuse Treatment Systems Survey (NDATSS), a nationally representative longitudinal survey of MMT programs conducted in 1988, 1990, 1995, 2000, 2005, and 2011 (D'Aunno, Pollack, Jiang, Metsch, & Friedmann, 2014). To provide current data on methadone dose levels, we focus on data from the 2017 NDATSS (n=236); we also show 2011 descriptive data as a benchmark (n=200). Consistent with earlier papers, we define an MMT program as a physical facility with resources dedicated to treating opiate use disorders primarily through methadone. In 2017, 84% of eligible programs completed both director and supervisor surveys; this rate was 90% in 2011.

A key strength of the NDATSS is its split panel design: each survey wave since 1988 included programs from prior waves (panel programs), and each wave also added representative samples of newer programs. The addition of new programs keeps the NDATSS representative of the changing population of US treatment programs. Replacing programs that exit the sample over time (e.g., due to closure) also ensures adequate sample size and attendant statistical power. Because the Substance Abuse and Mental Health Services administration (SAMHSA) licenses all MMTs, our sample frame includes the full US population of approved MMTs (Chen, D'Aunno, & Wilson, 2017).

2.2. Data collection, reliability and validity.

We collected data from both the director and supervisor of clinical services of each participating organization using a telephone survey. We used established methods to promote validity and reliability; these methods include cognitive pre-testing, intensive training for interviewers, and advanced notice to participants about key topics covered in the survey. This enables participants to consult administrative and financial records ahead of time (Groves, 1988).

2.2.1. Weights.—We formulated survey weights to ensure representativeness and account for possible nonresponse bias in the data. These weights were developed for the programs that had either the director or the clinical supervisor completing at least some of the main interviews. The weights were calculated across three stages of adjustments: stage 1 adjustments for refusers in a screener survey; stage 2 adjustments for nonresponse in the director or supervisor surveys; and stage 3 adjustments for correcting the differences between the sample and the target population using post-stratification. We developed adjustments for stages 1 and 2 using results of logit regression analyses comparing responding to nonresponding programs along several key variables (Chen et al., 2017).

2.3. Variables

Methadone treatment practices.—We calculated the percentage of patients in each program who received doses below 40, 60, or 80 mg/day from information provided by clinical supervisors. To ensure that we measure the dose level that programs dispense for patients whose dose levels have stabilized, we limit the data to patients who had been receiving the same methadone maintenance dose for at least 2 weeks.

Patient characteristics.—Prior work has identified patient race/ethnicity and patient employment status to be correlated with dosing levels (D'Aunno & Pollack, 2002; D'Aunno, Pollack, Frimpong, et al., 2014; Pollack & D'Aunno, 2008). We accounted for these characteristics using responses from the clinical supervisor survey, including variables reflecting the percentage of African American and Hispanic/Latino patients, and the percentage of patients who are currently unemployed. These measures are characteristics of the mix of patients at the program level of analysis; we do not have data from individual patients.

Program characteristics.—Prior research also indicates that certain organization-level traits are related to dose levels (D'Aunno & Pollack, 2002; Pollack & D'Aunno, 2008). These characteristics include: form of ownership (public, private not-for-profit, and private-for-profit); program age and size; accreditation status; staffing patterns; whether managed care contracts are included in financial arrangements; and managerial attitudes.

We used measures from the director survey on program ownership (with private nonprofit as the referent category), the number of years a program has been operating (program age), and a dummy variable indicating if program was accredited by either the JCAHO or the Commission on Accreditation of Rehabilitation Facilities (CARF) (1=yes; 0=no). Following Pollack and D'Aunno (2008), we also used data from clinical supervisors to measure the percentage of staff members who are in recovery.

To examine the relationship between managed care arrangements and dosing, we included two separate variables. First, we incorporated a measurement of managed care stringency. Following Lemak and Alexander (2001), we define managed care stringency as the proportion of patients whose coverage necessitates prior authorization in advance of receiving any services. Second, we measured the proportion of patient referrals originating from a managed care entity. Finally, using data from clinical supervisors, we included the number of patients receiving methadone treatment at a given clinic.

Managerial attitudes.—Prior studies (Caplehorn, Lumley, & Irwig, 1998; Pollack & D'Aunno, 2008) indicate that many managers and staff members hold beliefs and values that are in-tension with the use of evidence-based practices, especially views about abstinence approaches to recovery and lack of support for harm reduction or other approaches to HIV prevention. Thus, using 5-point Likert scales, program directors reported the extent to which (1=no extent; 5=a very great extent) their programs distributed pamphlets on HIV prevention and needle cleaning and the extent to which their program includes staff working specifically on HIV prevention (1=no extent; 5=a very great extent). For the latter variable, we characterize MMT programs as having limited commitment to HIV prevention if

directors indicate "no extent" or "a limited extent" of staff dedicated to this task. Clinical supervisor's endorsement of 12-step recovery models has also been associated with lower methadone dose. Therefore, we included the percentage of patients referred to self-help groups.

Geography.—We included census division (Northeast, Midwest, South and West) as a control variable, with Northeast as the referent category.

2.4. Data analysis.

We performed multivariate censored regression analysis on data from the 2017 survey wave, accounting for the possibility of censored dependent variables at 0 and at 100%. Some independent variables (e.g. percent of patients requiring prior authorization) displayed missing observations in the 2017 NDATSS survey wave. When a given MMT displayed missing values for these variables, we imputed values by calculating predicted values using multiple regression analysis based on the observed values of these variables within the same MMT program in prior waves (Raghunathan, Lepkowski, Van Hoewyk, & Solenberger, 2001; Little & Rubin, 2014). This imputation had no substantive impact on our point estimates. Imputation was conducted using IVEware; all other analyses were performed using Stata Version 12.

3. Results

Table 1 provides descriptive statistics for dependent and independent variables stratified by year (2011, 2017), weighted by program sample weights, and further adjusted by program size (i.e., total number of methadone patients) to reflect typical client experience.

As Table 1 shows, we found relatively stable dosing patterns across time. Our results show that forty-three percent of MMT patients receive less than 80mg/day, and 23% of methadone maintenance patients receive daily doses below 60mg. We also find that about ten percent of patients experience maintenance doses below 40mg/day. Within both adjusted and unadjusted analyses of time trend, we find little evidence that the prevalence of under-dosing appreciably changed between 2011 and 2017.

Table 2 shows results from multivariate analyses for the 2017 wave.

We find several notable multivariate patterns. At all three dose thresholds, private for-profit and public organizations exhibited a significantly higher proportion of under-dosed patients than did private nonprofit providers.

Under-dosing was more common in programs serving high proportions of African-American patients. This observation also holds at all three dose thresholds.

Referral from managed care is uncommon (see Table 1), but was also associated with under-dosing. Last, programs in southern states appear significantly less likely to under-dose.

4. Discussion

Prior research indicates that methadone under-dosing markedly declined between 1988 and 2011 (D'Aunno et al., 2014). Our analysis suggests that progress subsequently stalled. Forty-three percent of MMT patients receive less than 80mg/day, and 23% receive daily doses below 60mg. These patterns are concerning because prior research shows that rates of relapse to opioid use are higher when methadone doses are too low (Strain, 2006; Faggiano et al., 2003). Similarly, results from several prior studies show that higher methadone dose is associated with longer tenure in treatment (see Kelly, O'Grady, Mitchell, Brown & Schwartz (2011) for a useful review of relevant literature and a careful multi-site study of factors related to retention in MMT). Moreover, MMT remains the medication of choice for many patients with the most severe opioid use disorders.

Some correlates of under-dosing are also concerning. For-profit programs are significantly more likely than others to provide low doses. They are also a growing MMT market segment. Between 2011 and 2017, the proportion of MMT patients treated by private for-profit programs increased from 41% to 46%.

It is not clear why programs located in Southern states are less likely to provide low dose levels of methadone. One possible explanation is that these programs are younger and began using evidence-based treatment practices at their inception. In other words, younger MMT programs may not have had to undergo organizational change to reach effective levels of methadone dosing.

4.1   Study limitations

Our findings must be evaluated in light of study limitations. The most important limitations reflect our lack of individual patient-level data, including data about individual-level factors associated with lower doses. There are several factors to consider. These include individuals' use of particular combinations of opioids and other substances that may warrant lower doses. For example, recommended dosing may be lower for patients who report concomitant alcohol or benzodiazepine use. Patient preferences for lower doses (for example among those who wish to transfer to buprenorphine) also may legitimately drive dosing decisions. Similarly, some patients may anticipate a shorter course of treatment, for example, due to financial constraints, that promote their preference for lower doses. Last, there may be individuals who are tapering effectively from higher methadone doses to lower doses. In sum, a limitation of the current study is that we did not measure these factors and we were not able to include them in the analysis.

5. Conclusion

Through measures such as the ACA Medicaid expansion and the bipartisan CURES Act, policymakers are seeking to address arguably the greatest public health crisis in America since the emergence of HIV and AIDS. As policymakers seek to expand access to medication-assisted treatment, attention must be paid to minimum dosing standards and to other evidence-based practices.

In particular, programs that predominantly serve African-Americans remain more likely to dispense low methadone doses. Although much recent public attention focuses on rural non-Hispanic whites, African-Americans continue to experience high and rising rates of opioid use disorders and accompanying overdose deaths in the United States (IDPH, 2017). Efforts to reduce racial disparities in care processes are thus a critical concern in the treatment of opioid use disorders.

Policy-makers and managers responsible for MMT programs might be able to intervene to improve methadone dosage levels and to decrease the racial disparities we observe. One possibility is that SAMHSA's Center for Substance Abuse Treatment could work with State Opioid Treatment Authorities (SOTAs), who have regulatory oversight of MMT programs in their states, to launch a campaign that includes distributing and re-emphasizing treatment guidelines on effective dose levels. Accrediting bodies could work in conjunction with this campaign to cite programs whose patients have both stabilized methadone doses under 60 mg/day and urine drug screens that indicate illicit opioid use. At the same time, a campaign such as this could include training for managers and staff members in MMT programs to recognize potential racial bias in clinical decision-making.

Acknowledgments

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Highlights

- Prior research shows that methadone under-dosing declined between 1988 and 2011

- Our analysis shows stable dosing patterns between 2011–2017

- 45% of methadone maintenance treatment (MMT) patients receive less than 80mg/day

- 23% of MMT patients receive daily doses below 60mg

- Many MMT patients receive below-recommended doses of methadone

Table 1.

Descriptive Statistics

	Sample-weighted data		Data weighted by program size	
	2011 Mean (SD)	**2017** Mean (SD)	**2011** Mean (SD)	**2017** Mean (SD)
Percentage of patients receiving methadone doses:				
Below 40 mg/day	10.96 (8.21)	11.31 (11.28)	10.27 (7.26)	9.93 (8.57)
Below 60 mg/day	24.70 (13.14)	24.92 (17.42)	22.81 (12.71)	22.70 (12.68)
Below 80 mg/day	43.72 (19.45)	44.60 (23.35)	40.68 (19.05)	42.93 (18.87)
Patient characteristics				
% Black	18.18 (22.65)	15.99 (20.47)	17.37 (21.14)	16.32 (21.29)
% Hispanic	16.73 (21.99)	16.20 (19.84)	18.25 (22.62)	13.12 (19.24)
% of patients who are unemployed	49.65 (22.44)	49.25 (27.43)	53.35 (20.61)	44.58 (22.95)
Program characteristics				
Ownership status				
Private not-for-profit	43.97 (49.81)	44.92 (49.89)	49.23 (50.17)	43.93 (49.78)
Private For-profit	43.26 (49.72)	45.72 (50.00)	40.60 (49.28)	46.14 (50.00)
Public	12.77 (33.49)	9.36 (29.22)	10.17 (30.34)	9.93 (30.00)
Joint Commission accreditation	30.99 (46.41)	31.81 (46.74)	24.42 (43.11)	30.52 (46.21)
% of staff who are in recovery	14.86 (15.71)	19.32 (18.38)	13.87 (13.66)	17.76 (15.39)
% of patients required pre-authorization of services	19.49 (34.15)	29.38 (35.17)	21.97 (36.27)	21.62 (32.14)
% of patients referred from managed care organizations	3.73 (14.69)	2.72 (7.60)	3.85 (14.37)	2.52 (7.18)
Number of methadone patients served in the last fiscal year	454.92 (435.56)	349.60 (379.38)	869.00 (834.48)	758.87 (553.82)
Program age	23.00 (12.97)	22.75 (13.81)	24.78 (13.01)	22.26 (13.94)
Harm reduction/HIV prevention				
Provide HIV prevention pamphlet	93.66 (24.45)	89.88 (30.25)	93.72 (24.34)	90.24 (29.77)
Provide needle cleaning pamphlet	39.57 (49.08)	38.10 (48.71)	36.15 (48.22)	31.23 (46.49)
Limited staff dedicated to HIV prevention	43.66 (49.77)	62.83 (49.47)	38.42 (48.81)	79.45 (45.77)
% of patients refered to self-help groups	60.38 (36.87)	56.63 (39.69)	63.54 (36.86)	60.36 (39.75)
Region				
Northeast	27.46 (44.79)	26.16 (44.08)	29.83 (45.92)	31.97 (46.77)
Midwest	21.83 (41.46)	19.10 (39.43)	21.35 (41.12)	17.41 (38.03)

	Sample-weighted data		Data weighted by program size	
	2011 Mean (SD)	2017 Mean (SD)	2011 Mean (SD)	2017 Mean (SD)
South	27.46 (44.79)	32.47 (46.97)	24.72 (43.29)	35.42 (47.97)
West	23.24 (42.39)	22.27 (41.73)	24.10 (42.92)	15.20 (36.01)

Table 2.

Results from Multivariate Interval Regression Analysis, 2017 Data

	% of Patients below 40mg/day Coef. (95% CI)	% of Patients below 60mg/day Coef. (95% CI)	% of Patients below 80mg/day Coef. (95% CI)
Patient characteristics			
% Black	0.13 (0.04, 0.21)^**	0.16 (0.04, 0.28)^**	0.24 (0.08, 0.39)^**
% Hispanic	0.02 (−0.07, 0.11)	−0.01 (−0.14, 0.12)	0.02 (−0.15, 0.19)
% of patients who are unemployed	−0.06 (−0.15, 0.04)	−0.05 (−0.18, 0.08)	−0.01 (−0.19, 0.17)
Program characteristics			
Ownership status (ref. Private not-for-profit)			
Private For-profit	4.60 (−0.52, 9.73)^	7.00 (−0.04, 14.05)^	6.26 (−3.27, 15.80)
Public	6.29 (1.18, 11.41)*	12.23 (5.01, 19.46)^**	9.26 (−0.36, 18.89)^
Joint Commission accreditation	1.12 (−3.22, 5.45)	1.33 (−4.75, 7.41)	3.68 (−4.01, 11.37)
% of staff who are in recovery	0.05 (−0.12, 0.22)	0.00 (−0.19, 0.21)	0.04 (−0.20, 0.27)
% of patients required pre-authorization of services	0.02 (−0.03, 0.07)	0.06 (−0.01, 0.14)	0.05 (−0.06, 0.15)
% of patients referred from managed care organizations	0.18 (0.04, 0.32)*	0.17 (−0.03, 0.38)^	0.18 (−0.09, 0.45)
Number of methadone patients served in the last fiscal year[#]	−0.00 (−1.80, 1.79)	−0.50 (−2.98, 1.98)	−1.33 (−4.60, 1.95)
Program age	−0.06 (−0.21, 0.08)	−0.10 (−0.31, 0.11)	−0.16 (−0.44, 0.11)
Harm reduction/HIV prevention			
Provide HIV prevention pamphlet	4.50 (−2.18, 11.19)	−1.22 (−10.42, 7.97)	−9.55 (−21.59, 2.48)
Provide needle cleaning pamphlet	−2.34 (−6.35, 1.68)	−2.94 (−8.46, 2.58)	−7.51 (−14.87, −0.15)*
Limited staff dedicated to HIV prevention	−0.69 (−4.82, 3.45)	−2.63 (−8.42, 3.16)	−3.29 (−11.02, 4.44)
% of patients referred to self-help groups	−0.02 (−0.07, 0.03)	−0.04 (−0.11, 0.03)	−0.00 (−0.09, 0.09)
Region (ref. Northeast)			
Midwest	−4.93 (−9.26, 0.83)	−6.46 (−13.56, 0.64)^	−9.11 (−18.56, 0.35)^
South	−7.36 (−12.47, −2.26)^**	−6.38 (−13.52, 0.76)^	−10.12 (−19.64, −0.61)*
West	−2.74 (−8.12, 2.64)	−4.61 (−12.23, 3.00)	0.11 (−10.21, 10.42)

^
$p<0.1$,

*
$p<0.05$,

**
$p<001$,

#Log transformed