Italy's Electronic Health Record System for Opioid Agonist Treatment

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Abstract

Electronic health record systems (EHRs) play an increasingly important role in opioid agonist treatment. In Italy, an EHR called the Multi Functional Platform (MFP) is in use in 150 opioid-agonist treatment facilities in 8 of Italy's 23 regions. This report describes MFP and presents 2010 data from 65 sites that treated 8,145 patients, of whom 72.3% were treated with methadone and 27.7% with buprenorphine. Patients treated with buprenorphine compared to methadone were more likely to be male ($p < 0.01$) and younger ($p < 0.001$). Methadone compared to buprenorphine patients had a higher percentage of opioid-positive urine tests ($p < 0.001$) and longer mean length of stay ($p = 0.004$). MFP has been implemented widely in Italy and has been able to track patient outcomes across treatment facilities. In the future, this EHR system can be used for performance improvement initiatives.

Keywords

Electronic health record; methadone treatment; buprenorphine treatment; Italian drug abuse treatment

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1. Introduction

Many nations have developed drug abuse treatment services to address the widespread prevalence of drug addiction and its associated morbidity and mortality, crime, incarceration and a variety of social problems. Some countries have developed systems to capture data describing their patient population and treatment outcomes. These systems have been used to obtain information on the types and prevalence of drugs used, identify emerging problems, determine the effectiveness of treatment services, plan for treatment services to meet the needs of the patients, and support evidence-based decision making (Donmall, 1999; Maffli et al., 2008). These systems can also supply data required by national governments or by international bodies, such as the European Union's (EU's) European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), which requires national reporting of a minimal data set of treatment demand indicators (EMCDDA, 2000).

There are several reports in the scientific literature on addiction treatment data systems from the US and Europe; however, most of these reports are from more than a decade ago. In the 1990s, the UK created a national data system that captured the intake characteristics of individuals presenting for drug abuse treatment at clinics and physicians' offices (Donmall, 1999). At that time, the reports were completed on carbon paper and sent to a regional center which entered and cleaned the data for transmission to a centralized national office. Through this system, 750 treatment agencies as well as general practitioners voluntarily reported treating 34,875 individuals over a 6-month period. At that time, the system did not include patient outcomes, although plans were being made to add the length of treatment service and the reason for discharge to the database.

Starting in 1995, German drug treatment centers reported patient data to the central government and by 1999, 530 drug treatment centers from all over Germany were reporting to the federal government (Simon, Hoch, & Holz, 1999). This system collected data on the number of patients treated, their background characteristics in terms of family and legal history, services delivered and treatment outcomes. Unlike the UK system, in Germany, as in many other countries, no data were collected on the provision of services to drug-dependent patients treated by general practitioners.

In the US, admission and discharge data has been collected since 1989 as part of the Treatment Episode Data Set (TEDS), a federally mandated minimal data set of demographic information and substance use information on admission to publicly-funded programs. The data are sent by treatment providers to each state substance abuse agency, which aggregates the data and forwards it to the federal government (Drug and Alcohol Services Information System, 2012). As these data are reported by providers in different formats, there were considerable delays in reporting TEDS data centrally (Carise, McLellan, Gifford, & Kleber, 1999). In order to improve the rapidity of reporting more detailed information, the Drug Evaluation Network System (DENS) was created by McLellan and colleagues (Carise et al., 1999) to report admission data from the Addiction Severity Index (McLellan et al., 1992), a structured interview that covers 6 domains, including drug and alcohol use, family, employment, legal, health, and psychiatric problems. In addition, basic discharge information was to be collected, including type of treatment, length of stay and reason for discharge, although compliance with this aspect of the system was reported as poor and the program funding was eventually discontinued. Unlike TEDS reporting, DENS was completely voluntary and so inducements to participate included providing the treatment program with a laptop computer, offering complete access to their program's data, as well as access to the national database from which trends and comparisons could be drawn.

A more recent paper described the Swiss system, which like the system in the UK, is one of voluntary reporting (Maffli et al., 2008). Planning started in 2000 to harmonize the disparate systems used to collect drug treatment data in Switzerland. After a period of stakeholder consultation and piloting, the system had been in operation by 2005 in three of five treatment sectors. It collected data on admission and discharge and included socio-demographic information, substance use and treatment history, and date of admission and treatment service type. Upon discharge, the socio-demographic and substance use items were collected along with discharge information including the date of discharge, type of treatment received, and reason for discharge. Data were collected via paper or electronic format and web-based data entry. Local research institutions aggregated the data and forwarded it to the federal government.

1.1. The Italian System

During the last two decades in Italy, there have been attempts to build a national information system to harmonize data collection across the country's treatment system. Early data collection efforts (Decreto Ministero della Sanità, 1997) did not permit data analysis that met the emerging European Union standards for reporting epidemiological data on patients entering drug abuse treatment. In June 2010, following the EU's push to harmonize such epidemiological data (called Treatment Demand Information or TDI) across countries, the Italian Ministry of Health and National Department for Antidrug Policies implemented a new national data system for outpatient substance abuse treatment programs of its National Health Service (NHS). This system, known as SIND (Sistema Informativo Nazionale sulle Dipendenze – National Information System on Addiction), is based on anonymous individual patient records and allows the collection of more detailed information for epidemiological purposes than possible with earlier Italian data systems. Importantly, the Italian Department for Antidrug Policies, which is the agency responsible for national and European standardized data management of the drug abuse treatment services of the Italian NHS, is also implementing an electronic medical record for its outpatient services. These EHR data are automatically de-identified and select items are sent to populate the SIND database, which then undergo quality control at the Department prior to being forwarded to the EMCDDA.

The EHR system permits patient outcome analysis based on patient characteristics and types of treatments received. The predominant type of outpatient drug abuse treatment in Italy is opioid agonist treatment (OAT) delivered in specialized programs offering methadone and buprenorphine. Methadone, a full opioid agonist, is used throughout the world, and has been shown in clinical trials over the past 40 years conducted on several continents to reduce opioid use (Mattick, Breen, Kimber, & Davoli, 2009). It has also been shown in longitudinal effectiveness studies to reduce HIV risk behavior (Lott, Strain, Brooner, Bigelow, & Johnson, 2006), HIV sero-conversion (Metzger et al., 1993), and criminal behavior (Hubbard et al., 1989). Methadone has been available in Italy since 1974. Buprenorphine, a partial μ-opioid agonist, has also been shown to be effective in reducing heroin use (Mattick, Kimber, Breen, & Davoli, 2008). A recent Cochrane review concluded that while both methadone and buprenorphine are effective in reducing opioid use, buprenorphine is not quite as effective as methadone, especially in adequate doses (between 60 and 120 mg) (Mattick et al., 2009). Buprenorphine has been available in Italy since 1999. The buprenorphine/naloxone combination, a formulation designed to reduce the likelihood of injecting buprenorphine, has been available in Italy since 2007. Expansion of opioid agonist treatment, and in particular buprenorphine, in France (Auriacombe et al., 2004) and in Baltimore (Schwartz et al., in press) has been associated with decreased mortality from heroin overdose.

The purpose of the present paper is to report on the use of the EHR in Italy's opioid agonist programs. The paper will provide a brief context of Italy's national treatment services, describe its data system, and report on patient data and outcomes for over 8,000 patients receiving methadone and/or buprenorphine throughout Italy in 2010.

2. Materials and Methods

2.1. The Italian treatment system

The Italian public sector drug abuse treatment system is distributed throughout the nation and consists of approximately 1,650 centers, of which 550 are outpatient and the rest are residential (therapeutic communities) or day treatment programs. Hospital-based detoxification is also available, primarily for alcohol dependence. Treatment is provided free-of-charge to individuals seeking such treatment. The outpatient centers include opioid agonist treatment with methadone and buprenorphine, as well as psychosocial services. At some of the outpatient centers, medical care for HIV and hepatitis infection is provided on-site. The decision to use methadone or buprenorphine is made by treating physicians in consultation with their patients. Although physicians are permitted to prescribe opioid agonist treatment through their practices outside the confines of drug abuse programs, most such care is provided through the NHS's drug abuse treatment programs. In 2010, a total of 107,117 patients were treated with opioid agonists of whom 83.3% received methadone and 16.7% received buprenorphine.

2.2. The Italian Electronic Health Record System

Starting in 2001, in the Veneto Region, the city of Verona's NHS opioid agonist treatment programs began using an electronic health record system called the Multi Functional Platform (MFP). MFP's reach was expanded to all of the agonist programs in the Veneto Region in 2003. In 2006, a data extraction program was developed and integrated into MFP in order to automate structured measurement of patient outcomes. Subsequent to its successful use in Veneto, in order to encourage its use throughout the country, the National Anti-Drug Department demonstrated MFP to all Italian Regional treatment services and offered it for only a nominal annual fee for maintenance. While Regions were free to use whatever data management system they wished (as long as they reported the required minimal SIND data set centrally), as of 2011 MFP was chosen by 150 clinic sites in 8 of Italy's 21 regions including Veneto, Liguria, Lombardy, Friuli Venezia Giulia, Umbria, Marche, Basilicate, Molise, and Sicily. The Italian National Anti Drug Department launched a multi-site evaluation termed Project Outcome of its opioid agonist treatment program based on MFP data in 2009.

For SIND reporting and for evaluation purposes, select MFP data elements for each patient treatment with methadone or buprenorphine in participating programs are automatically extracted annually by the Department. All individual patient records are automatically de-identified using "RecordHasher" software which creates a code consisting of a string of 64 hexadecimal characters for each record using an SHA2 256-bit hashing protocol. The system is unidirectional and therefore it is impossible to reconstruct the original data from which the code was generated.

MFP was implemented to meet three needs. First, it fulfills Italy's obligation to provide the EMCDDA with treatment demand indicator data. These data are automatically extracted from MFP. Second, it serves as an EHR for the day-to-day patient management operations of the treatment centers. Its data elements include the type and number of services received, doses of opioid agonists administered, and drug and other laboratory test results. Third, it

provides the Department with the capability of evaluating treatment outcomes across patient types, treatment centers, regions, and the country as a whole.

2.3. Aim of the Present Analysis

This report uses data from the MFP to examine the characteristics and outcomes of patients in opioid agonist treatment in Italy in 2010, including a comparative analysis of patients receiving treatment with methadone and buprenorphine.

2.4. Treatment Programs Analyzed

For a treatment program's data to be included in the present analysis, it had to have: (1) used the MFP system for at least one year prior to 2010 and (2) to have treated at least 10 patients per year with methadone and/or buprenorphine. In 2010 and 2011, 31 treatment units (called Servizi Tossicodipendenze or SerT) with 65 clinical sites in regions of Liguria, Lombardia, Veneto, Umbria, Marche and Sicily met this inclusion criteria (out of a total of 150 sites in 8 regions in the total MFR user universe).

2.5. Outcome Measure

In an effort to create a common outcome metric that could be used across multiple programs, the Department decided to emphasize urine testing for drugs of abuse. The Department asked providers to collect a minimum of one urine sample per week per patient. The primary outcome for the present analysis was the imputed number of days of abstinence from opioids during pharmacotherapy calculated in the following manner: (a) The number of days between two successive positive opioid urine tests were imputed to be days of opioid use (positive days); (b) the number of days between two successive negative opioid urine tests were imputed to be days of opioid abstinence (negative days); and, (c) the number of days between a positive and a negative urine opioid test were imputed to be divided evenly between days of opioid use and days of abstinence.

Based on this approach, patients were classified into three categories: non-responders, low-responders, and responders, based on the percentage of days imputed to be free from the use of opioids (<30%, between 30% and 60%, and > 60%, respectively).

2.6. Data analysis

Data were analyzed using SPSS version 17. Student t tests were used to analyze continuous variables and χ^2 tests of independence were used to analyze categorical variables.

3. Results

3.1. Participants

There were 31 treatment units (SerT) with 65 sites that met the above-mentioned study inclusion criteria. Of the total of 9,244 patient records available, 22 patients were excluded from these analyses because they came from sites that had data from fewer than 5 patients, 690 patients were excluded because they received treatment for less than 30 days (which could have been for detoxification only or for drop-out during the dose induction phase of maintenance treatment), and 387 patients were excluded because there was a technical problem in transferring urine test result data from the lab at one site. Thus, included in the sample for analysis were 8,145 patients who received opioid agonist treatment in the Italian public treatment system in 2010. Patients in the sample were treated in the following regions of the country: Veneto (33.7%), Lombardy (20.6%), Liguria (18.5%), Sicily (13.9%), Umbria (9.9%), and Marche (3.5%).

As shown in Table 1, the opioid agonist sample of 8,145 patients consisted of 5,888 methadone patients (72.3%) and 2,257 (27.7%) buprenorphine patients. The majority of the opioid agonist sample was male (6,857; 84.2%) and of Italian nationality (7,915; 97.2%). Buprenorphine patients were significantly more likely to be male and to be of Italian nationality than methadone patients (both $ps<0.01$). Among the 228 non-Italian patients, the largest group were citizens of African nations (27.0%), followed by Asian (23.6%), and Eastern European nations (23.6%).

The mean age of the sample was 37.0 (8.9) years old. Patients treated with buprenorphine compared to methadone were significantly younger ($p<0.001$); had significantly higher levels of education ($p<0.001$); and, were more likely to be employed ($p<0.001$). Less than 20% of the total sample reported living with a spouse or significant other, although in this regard there were no significant differences between the buprenorphine and methadone treatment samples.

The average age of onset of opioid use for the total sample was 21.6 (6.2) years old, with buprenorphine patients starting opioid use at a significantly younger age than methadone patients ($p=0.001$). Methadone patients were significantly more likely to report using cocaine or crack compared to buprenorphine patients ($p<0.001$). Methadone patients were significantly more likely to have injected drugs than buprenorphine patients ($p<0.001$). However, 52% of the data are missing for this variable and hence this result must be viewed with considerable caution.

Data collected for treatment provided in 2010 are shown in Table 2. The average medication dose (SD) during treatment was 8.3 (6.8) mg of buprenorphine and 51.6 (37.9) mg of methadone. The mean number of urine samples analyzed per patient was 23.1 (18.4). Urine drug testing results for the entire sample and for the methadone and buprenorphine sub-samples are also shown in Table 2. Overall, 20.7% of the urine tests were positive for opioids (i.e., morphine). Methadone patients had a significantly higher percentage of both opioid, cocaine and cannabis urine-positive tests compared to buprenorphine patients (all $ps<0.001$). Following the classification for imputed "opioid-free days" described above in Methods, overall, the entire sample had 78.4% opioid-free days during the year with the buprenorphine sample having a significantly higher percentage of opioid-free days than the methadone sample ($p<0.001$).

The majority (75.3%) of patients treated with opioid agonist medications were classified as treatment responders, meaning they were estimated to be abstinent from opioids for at least 60% of days in treatment. A significantly higher proportion of the buprenorphine compared to the methadone sample was classified as treatment responders ($p < 0.001$). Among the responders, the buprenorphine patients had a higher percentage of imputed "opioid-free days" compared to the methadone patients ($p< 0.001$).

There were 952 (11.7%) patients classified as "partial responders". The percentage of "opiate-free days" for this group was 46.5% with no significant differences between buprenorphine and methadone patients ($p = 0.169$).Non-responders constituted 13% of the entire sample. The percentage of "opioid-free days" for the non-responders in the entire sample was 10.6%. Significantly more methadone patients were classified as non-responders compared to buprenorphine patients $(p<0.001)$. During periods of abstinence from opioids of abuse, the rates of positive urine tests for other non-opioid drugs were 21.3% for cannabis and 11.7% for cocaine.

The mean (SD) length of stay in treatment during the year was 246.2 (110.1) days (out of a possible 365 days). Methadone patients had a significantly longer length of stay compared to

buprenorphine patients, 248.4 (109.4) *v.* 240.5 (111.7) days *(p*=0.004), although the difference of 7.9 days between the groups would not appear to be clinically significant.

With respect to adherence to medication administration/dispensing, the entire sample received 74.6% of their expected doses of medication. Methadone patients were significantly more likely to adhere to their medication schedule than buprenorphine patients (*p*<0.001).

4. Discussion

In an effort to improve system-wide reporting of addiction treatment and patient outcome data, The Italian National Anti-drug Department made the Multi Functional Platform (MFP) electronic health record (EHR) system available to its National Health Care system's opioid agonist treatment programs. In contrast to some earlier reports from other countries in years past which have reported on older technological approaches (Donmall, 1999; Simon et al., 1999), advances in computer technology have permitted the adoption of a uniform web-based data system in Italy. The MFP system is being used as an epidemiologic data gathering tool for patients in treatment to meet national and international reporting requirements, as an EHR for patient management at the clinic level and as a national tool for patient outcome monitoring.

In the US, where less than half of health care providers have an EHR system (Tai & incentives for physician offices and health care systems to adopt EHR systems (Estabrooks et al., 2012). Indeed, all health care providers in the US are expected to adopt an EHR by 2015 (Blumenthal, 2009). The advances in data technology that have made the MFP system possible in Italy, will also make it possible in the US to segment access to sensitive substance use data stored in an EHR such that specific parts of the record can be made available to those with particular permission to view such sensitive data (Tai & McLellan, 2012). This capacity makes it possible to comply with existing US federal law regarding the confidentiality of substance abuse treatment records (Code of Federal Regulations[42 CFR Part 2]), which are more stringent than those of general health records. It is hoped that increased use of EHR systems in the US will lead to improvements in patient outcomes (Ghitza et al., 2012), patient safety, increased treatment efficiency, and slow the escalating costs of health care (Tai & McLellan, 2012). Finally, data captured in the new US EHR systems are expected to be used for epidemiological purposes, much like the SIND system in Italy.

There are always implementation challenges to the adoption of EHR systems. In Italy, the Department has disseminated its EHR system through a voluntary process of attraction by making a modern web-based data system available for free to Regions and to providers. While this has resulted in its widespread use, it is not being used universally in the Italian NHS. It is hoped in the future that its use will be expanded through continued provider education, although at the present time there are no plans to mandate its implementation.

Another challenge to the use of EHR systems is the ability of providers to acquire and enter the data. Provider adherence to data entry requirements has been adequate but not perfect. For example, while there are few missing data elements for critical variables such as medication dose, missing data ranged from 5.3% for employment status, 8.7% for educational status, 11.9% for martial status, and 52.0% for route of ingestion. There are at least three potential mechanisms that could explain the reasons for missing data, including: the questions were not asked of patients, the questions were asked but the responses were not recorded (on paper prior to entering in the data system), or the responses were recorded but the data were not entered in the electronic record. It is not clear what the reasons for

missing data are in the MFP system for the above-mentioned variables; however, efforts are underway to examine reasons for missing data and to correct these oversights.

Analyzing patient opioid use outcomes based on the imputed number of days of drug use and abstinence has its strengths and weaknesses, as do all methods of imputing missing data. If weekly urine tests are collected for analysis for all patients during the year, given the window of a positive opioid drug test of about 2 days, our approach seems like a reasonable and clinically meaningful way to extrapolate a series of point-prevalence data points to estimate patient drug use during their sojourn in treatment. The advantage of imputing days of use and abstinence is that it is a more meaningful concept for the lay public and policymakers than the percentage of positive drug tests. Of course, either for administrative, financial or clinical reasons, it is not always indicated, appropriate, or possible to collect urine tests with such frequency. Urine tests may be collected more frequently for individuals doing poorly in treatment or conversely patients doing poorly may be more likely to refuse urine collection efforts. These are challenges that should be explored in clinical practice as EHRs become more widely used.

The comparative data on methadone and buprenorphine treatment in Italy presented in this report showcase examples of the types of analyses and insights that can be gleaned from a widely-implemented EHR system. We chose to compare methadone and buprenorphine treatment because these are the two most common forms of medication treatment for opioid dependence in Italy, and indeed throughout the world. Other applications of the EHR system could include a comparative analysis of patient outcomes and provider performance for each region, or by clinic site.

Both methadone and buprenorphine patients in programs using MFP in Italy appeared to be achieving good treatment outcomes. The average length of stay of the total sample was 246.2 days, with statistically significant but clinically minor differences between the methadone and buprenorphine samples. As would be expected, the group classified as responders were retained in treatment longer (mean of 251.3 days) than the partial responder group (mean of 234.9 days), which in turn was retained longer than the non responder group (mean of 226.8 days). Surprisingly, there was little difference between the responder groups in terms of their adherence to medication administration.

It would appear from patients' baseline characteristics that providers and their patients are opting for buprenorphine rather than methadone for individuals with less severe problems as indicated by higher rates of employment, lower rates of cocaine use, and lower rates of drug injecting among patients treated with buprenorphine.

Given these apparent baseline differences between patients receiving buprenorphine and methadone, outcome data must be interpreted with caution. A recent Cochrane review comparing buprenorphine to methadone treatment outcomes in clinical trials indicated that methadone at adequate doses was more effective in suppressing heroin use than buprenorphine treatment (Mattick et al., 2009). The buprenorphine patients in the Italian MFP system appear to have better outcomes in a number of measures compared to methadone patients, including lower percentage of urine drug tests positive for opioids, cocaine, and cannabis; more opioid-free days; higher percentage classified as treatment responders. In contrast, methadone patients show greater adherence to their dosing regimen and are retained in treatment longer. Of course, these findings must be considered in light of the evaluation design of this convenience sample whose treatment was determined by clinical judgment and not by random assignment, and whose samples have baseline differences in age, education, employment status, rates of injection, and co-occurring use of cocaine that indicate a greater level of dysfunction at treatment entry among the patients

treatment with methadone compared to buprenorphine. Nevertheless, these are interesting and potentially important findings that increase understanding of the Italian treatment system and may warrant further investigation. Such insights would not have been possible without a widely-used, uniform EHR system in place. EHR systems can play an important role in providing timely data on treatment processes and outcomes to more accurately characterize treatment systems and to inform service planning and policymaking.

There are two types of limitations to this paper. The first type is related to the lack of patient outcome data prior to the implementation of the EHR system. Such pre-EHR system data are lacking precisely because there was no nationwide system that could aggregate patient data across the disparate electronic and paper records of the many treatment programs. Therefore, it was not possible to conduct a pre-post analysis of the impact of implementing the EHR system on patient outcomes. Notwithstanding this limitation, it is precisely because of the lack of pre-implementation data that fielding a nationwide EHR system is a prerequisite to having a large patient registry and the ability to conduct large-scale, prospective outcomes analyses at relatively low cost, and to conduct wide-scale, data-driven performance improvement projects.

The second type of limitation is related to the comparison of outcomes of patients treated with methadone or buprenorphine in programs using the MFP. The extent to which these findings generalize to those patients treated in Italian programs that do not utilize the MFP is not known. In addition, the measure of days of abstinence is only an estimate based on the results of consecutive urine drug tests, and cannot be considered a precise measure. The days of abstinence metric was developed by the Italian treatment authorities because it can be more readily conveyed to lay audiences and the public than alternative ways of describing treatment outcomes. Finally, patients were not randomly assigned to medication, and hence patient preferences and selection bias may have had an impact on outcomes. More broadly, this analysis should not be viewed as a rigorous comparative evaluation of the efficacy of methadone vs. buprenorphine medication (Mattick et al., 2008). Rather, it is more appropriate to view this analysis as an example of how data from a widely-implemented EMR system can reveal unique and meaningful insights about patient populations and treatment outcomes. There are limitations to any large data system that incorporates information from multiple organizations, which undoubtedly vary in their specific data collection practices. Over time, systems like the MFP can be used to encourage streamlining of data collection practices and for cross-site performance improvement. Even considering its limitations, the MFP data is able to characterize the Italian treatment system in a degree of detail that would not be possible if programs maintained their data systems in isolation. The use of such systems has the potential to contribute to more informed, evidence-driven decision making by agencies charged with supporting national drug abuse treatment systems.

Moving forward, the Italian treatment system will be focusing on improving data entry adherence, further disseminating the MFP system, and using results to enhance quality improvement activities to improve patient outcomes. It is hoped that other treatment systems report on successes and challenges of their EHRs as they are more widely implemented.

Acknowledgments

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Table 1

Baseline Characteristics of Patients in Italian Opioid Treatment Programs Participating in Project Outcome in 2010. ($N = 8,145$)

Variable	Total Sample	Buprenorphine ($n = 2,257$)	Methadone ($n = 5,888$)	p
Age, mean (*SD*)	37.0 (8.9)	35.8 (8.8)	37.4 (8.9)	<.001
Male, n (%)	6,857 (84.2%)	1,969 (87.2%)	4,888 (83.0%)	<.001
Nationality, n (%)				
Italian	7,915 (97.2%)	2,216 (98.2%)	5,699 (96.8%)	.001
Other	228 (2.8%)	41 (1.8%)	187 (3.2%)	.001
Married [a]$_n$ (%)	1,275 (17.8%)	378 (18.8%)	897 (17.4%)	.143
Employed [1b]$_n$ (%)	4,912 (63.7%)	1,503 (70.1%)	3,409 (61.2%)	<.001
Educational level[2,c]$_n$ (%)	1,738 (23.4%)	558 (26.8%)	1,180 (22.0%)	<.001
Age of first opiate use, mean (*SD*)	21.6 (6.2)	22.0 (6.1)	21.4 (6.2)	.001
Injected drugs [3,d]$_n$ (%)	2,903 (74.3%)	625 (64.1%)	2,278 (77.6%)	<.001
Secondary Cocaine or Crack Use, n (%)	2,382 (29.2%)	595 (26.4%)	1,787 (30.3%)	<.001

[1] Employed either permanently or temporarily

[2] Completed at least upper middle school

[3] Including heroin, methadone or other opioids

[a] Missing data as follows: 11.1%; 12.2%; and, 11.9% for buprenorphine, methadone and total samples.

[b] Missing data as follows: 5.1%; 5.3%; and,, 5.3% for buprenorphine, methadone, and total samples.

[c] Missing data as follows: 7.9%; 9.0%; and, 8.7% for buprenorphine, methadone, and total samples.

[d] Missing data as follows: 56.8%; 50.2%; and, 52.0% for buprenorphine, methadone, and total samples.

Table 2

Patient Treatment Data from in Italian Opioid Treatment Programs Participating in Project Outcome in 2010. (*N* = 8,145)

Variable[*]	Total Sample	Buprenorphine (*n* = 2,257)	Methadone (*n* = 5,888)	*p*
Dose, mean (*SD*)	—	8.3 (6.8)	51.6 (37.9)	—
Drug test results				
Opioid positive [1]*n* (%)	39,076 (20.7%)	6,288 (12.6%)	32,788 (23.7%)	<.001
Cannabis (THC) positive [a]*n* (%)	18,950 (21.3%)	5,444 (19.8%)	13,506 (22.0%)	<.001
Cocaine positive [b]*n* (%)	19,006 (11.7%)	4,161 (9.2%)	14,845 (12.7%)	<.001
Amphetamine positive [c]*n* (%)	345 (0.7%)	95 (0.6%)	250 (0.7%)	.061
"Opioid-free days"				
Total sample (%)	1,571,044 (78.4%)	473,734 (87.3%)	1,097,311 (75.0%)	<.001
Non responders (%)	25,509 (10.6%)	3,614 (11.7%)	21,895 (10.5%)	.000
Partial responders (%)	104,092 (46.5%)	17,157 (46.2%)	86,936 (46.6%)	.169
Responders (%)	1,441,443 (93.5%)	452,963 (95.4%)	988,480 (92.7%)	<.001
Response category				
Non responder[d]*n* (%)	1,060 (13.0%)	157 (7.0%)	903 (15.3%)	<.001
Partial responder[e]*n* (%)	952 (11.7%)	171 (7.6%)	781 (13.3%)	<.001
Responder[f]*n* (%)	6,133 (75.3%)	1,929 (85.5%)	4,204 (71.4%)	<.001
Treatment Adherence [g]				
Total, mean (*SD*)	74.6 (29.4)	69.0 (30.6)	76.6 (28.6)	<.001
Non responder, mean (*SD*)	71.8 (29.3)	63.2 (31.7)	73.3 (28.6)	<.001
Partial responder, mean (*SD*)	72.8 (27.9)	63.8 (28.6)	74.8 (27.4)	<.001
Responder, mean (SD)	75.3(29.7)	69.9 (31.0)	77.7 (28.7)	<.001
Number of days in treatment				
Total sample, mean (*SD*)	246.2 (110.1)	240.5 (111.7)	248.4 (109.4)	.004
Non responder, mean (*SD*)	226.8 (114.8)	196.0 (121.4)	232.2 (112.8)	.001
Partial responder, mean (*SD*)	234.9 (109.9)	217.1 (111.2)	238.9 (109.2)	.019
Responder, mean (*SD*)	251.3 (108.8)	246.2 (109.9)	253.6 (108.2)	.013

[1] Mean (SD) number of opioid urine tests analyzed per patient: 22.2 (18.4); 23.5 (18.3); and, 23.1 (18.4) forbuprenorphine, methadone, and total samples.

[a] No cannabis drug test for: 25.1%; 24.8%; and, 24.9% for buprenorphine, methadone, and total samples.

[b] No cocaine drug test for: 1.5%; 0.8%; and, 1.0% for buprenorphine, methadone, and total samples.

[c] No amphetamine drug test for: 52.5%; 48.0%; and, 49.3% for buprenorphine, methadone, and total samples

[d] Non responder: < 30% "drug-free days" (i.e., total number of days between two negative urine drug tests plus half the number of days between one positive and one negative drug test.

[e] Partial responder: 30% - 60% of "drug-free days."

[f] Responder: > 60% "drug-free days."

[g]Treatment adherence is calculated as the percentage of methadone or buprenorphine doses administered ordispensed divided by the doses prescribed.