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Characteristics of methadone-related overdose deaths and comparisons between those dying on and off opioid agonist treatment (OAT): A national cohort study.

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Summary

Background: Opioid users, particularly those with a history of injecting and dependence, have a high risk of fatal poly-substance and methadone-related overdose. **Aim:** To describe characteristics of methadone-related overdose deaths and assess if differences exist between those dying on and off opioid agonist treatment (OAT). **Methods:** A descriptive study of all persons dying of drug overdose involving methadone on the Irish National Drug Related Deaths Index (NDRDI) in 2012 and 2013. **Results:** A total of 182 methadone-implicated deaths were recorded. 78% (n=142) were male; with a mean age of 36 years. Of the cohort, 61% (n=111) were not in receipt of opiate agonist treatment (OAT) at the time of death, 15.9% (n=29) had a previous history of non-fatal overdose and 24.7% (n=45) a history of alcohol dependence. Analysis and interpretations are limited by incomplete data on other characteristics but where available show that 89% (n=73) were injecting drug users, with 57.8% (n=26) injecting drugs at the time of death. History of mental illness was recorded in 96.3% (n=77) of cases, with 94.7% (n=107) having history of substance dependency treatment. Polysubstances were implicated in 86.8% (n=158) of deaths. The majority died in a private dwelling (74.7% n= 127) and were not alone 67.4% (n=114). **Conclusions:** Methadone-related fatal overdose is a significant cause of death in young Irish, who share many characteristics with other drug-related deaths. Improved monitoring, risk assessment and OAT retention strategies is warranted to inform national drug overdose plans and overdose prevention.

Key Words: Overdose; methadone; opioid agonist treatment (OAT)

1. Introduction

Opioid users, especially those with a serious opiate addiction and those who inject drugs, are at risk of overdose deaths [4, 11, 18, 22, 25]. Efforts to compare accidental drug overdoses across countries are problematic but there is evidence of increasing deaths from prescription opioids and decreasing deaths from illicit drug use [17]. Enhanced and robust surveillance and monitoring systems are necessary to reduce drug-related deaths among drug users on Opioid Agonist Treatment (OAT). With the prevalence of methadone-related overdose deaths increasing globally, concerns arise regarding the diversion of OAT drugs, in particular black market methadone [4, 16]. Recent data in the UK underscored that half of drug-related deaths were among people who used opiates and had no recent contact with drug services [21]. Public Health England commented on various contributors to this increased trend in 2016, which included variations in the purity and availability of street opiates, patterns of poly-substance use, use of new psychoactive substances, and the increasing age and poor physical health of drug users [24].

Whilst OAT, particularly methadone pharmacotherapy, is shown to reduce mortality among individuals with problem opioid use [3, 7, 10, 23, 25, 26], accidental overdose deaths often occur after a

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reduction in opioid tolerance following a period of abstinence, for example when exiting OAT, recently detoxified or prison discharge [6,10, 20, 26]. Cousins et al. [4] observed that primary care methadone treatment patients were almost four times more likely to die during periods *'off treatment'*, in those initial high risk few weeks after leaving treatment. Definitions of *'off treatment'* generally mean *'not receiving a methadone prescription for three days since the end of the previous prescription'* [4]. Mortality risks for methadone patients include having a history of alcohol misuse [13], consuming a methadone dose below 60mg [15], Human Immunodeficiency Virus (HIV) infection [14], medical co-morbidity [19] and history of psychiatric illness with co-prescription of benzodiazepines [13,19]. Factors reducing overdose risks centre on living with a partner, having a younger age, not abusing benzodiazepines and remaining in treatment [2, 13, 23].

In Ireland (study location), the Irish National Drug-Related Deaths Index (NDRDI) report for the period 2004-2013 on deaths from poisoning and deaths among drug users. The most recent report showed that alcohol was implicated in 1 out of 3 poisoning deaths in 2013, poly-substance poisoning in 60% of deaths, and an increase in heroin-related deaths [12]. Patterns of benzodiazepine consumption and use of other drugs whilst on methadone treatment are of increasing concern in Ireland [4, 9]. Irish patients on methadone identified as having significant risk of fatal overdose are those patients with medical issues such as HIV and Hepatitis C Virus (HCV) infection, a history of imprisonment and homelessness. Another Irish study identified a history of imprisonment as being an increased risk of death while on methadone treatment [26].

In 1998, the Methadone Treatment Protocol (MTP) was introduced in Ireland [8] which resulted in a change to how methadone could be prescribed and dispensed. These new national regulations required that all patients being prescribed methadone are registered on a central treatment list (CTL). When patients are no longer in receipt of methadone through either completion of a treatment episode or defaulting from treatment, the patient's name is removed from the register after one month. It is therefore possible to identify which methadone-implicated deaths relate to people registered on the CTL and those not registered. Our study aimed to describe the characteristics of methadone-related overdose deaths in Ireland over a 24-month period and assess if differences existed between those dying when registered and not registered for OAT. We also considered that there may have been identifiable differences between those who died and were not on treatment at the time of death and those who died and were in receipt of treatment at the time of death.

2. Methods

The National Drug Related Deaths Index (NDRDI) in Ireland is an epidemiological database which records all deaths by drug and/or alcohol poisoning, deaths among drug users and deaths among those who are alcohol dependent. To ensure comprehensiveness, data for the NDRDI are collected from four sources, the Coroner Service, the Hospital In-Patients Enquiry Scheme (HIPE), the Central Treatment List (CTL) and the General Mortality Register (GMR) through the Central Statistics Office. The Coroner Service establishes the cause of death in cases of sudden or unexpected death and will, following an inquest, determine the cause of violent or unnatural deaths including those caused by drug and alcohol poisoning. Data from 48 coroners districts nationally are included in the NDRDI. HIPE is a computer-based patient information system which collects medical data on discharges and deaths in acute general hospitals in Ireland. Sixty hospitals, accounting for 95% of all hospitals nationally, enter data on this register and where appropriate this data is automatically entered onto the NDRDI. The CTL is a statutory register of all patients receiving methadone treatment in Ireland. This register provides data for those on methadone treatment at the time of death which is sent electronically to the NDRDI by CTL staff. The GMR formally records, categorises and codes all notified deaths in Ireland with only one underlying cause and one external cause recorded for each death. This data are sent electronically to the NDRDI. Cases from the different data sources are cross-matched to avoid duplication and a comprehensive set of variables is collected on each unique drug-related death.

The NDRDI categorises drug-related deaths into poisonings and non-poisonings. Poisonings or fatal overdoses are defined as deaths in individuals due to the toxic effects of the consumption of drug(s) and/or other substance(s) and do not include adverse reactions to prescribed medications. For this study, all methadone-related poisoning deaths were extracted from the NDRDI for 2012 and 2013. Anonymised data on the following characteristics was collected on the full study cohort (n = 182); age, gender, place of residence, registered for methadone treatment, drug

Table 1: Demographics

	n	%
Year		
2012	89	49.9
2013	93	51.1
Sex		
Male	142	78.0
Female	40	22.0
Age Group		
<25	24	13.2
25-34	74	40.6
35-44	47	39.1
45+	37	20.3
Place of residence		
Dublin city/county	128	70.3
Other city area	12	6.6
Other areas	42	23.1
Location of death		
Private dwelling	127	74.7
Homeless accommodation	23	12.6
Public place	9	4.9
Public building	5	2.7
Other	6	3.3
Present at time of death		
Alone	55	32.5
Partner/children	27	16.0
Family	37	21.9
Friends	24	14.2
Other	26	15.4
Known to be registered on OAT at time of death	71	39.0

and alcohol dependence, history of overdose, history of blood borne viruses, ante- and post-mortem toxicology. Incomplete data was available on the following characteristics, location at time of death (n=170), presence of others at fatal overdose (n=169), history of mental illness (n=80), history of injecting (n=82), ever treated for substance dependency (n=113), injecting at time of death (n=45) and treated for drug problems at the time of death. (n=97). Descriptive statistics (frequencies, percentages) were used to summarise the characteristics of those dying of methadone-related poisonings. Statistical tests using SPSS included chi-squared tests, t-tests and p-values were used to assess differences in categorical data, with a significance level of 0.05. Multi-nominal logistic regression analysis was used to determine predictors for being on and off methadone treatment at the time of death.

3. Results

There were 182 poisoning deaths where methadone was implicated as a cause of death on the NDRDI over the two-year period 2012-2013. Of the 182 individuals included, over three quarters (78%, n=142) were male; the mean age was 36 years with the lower and upper quartiles being 28.75 and 41 years, and 70.3% of the deceased were resident in Dublin city or county. The place of death was recorded for 170 of the cases with the majority (74.7%, n= 127) dying in a private residence, 12.6% (n=23) in a homeless hostel, and 7.6% (n=14) dying in either a public place or building. Where recorded (n=169), in over two thirds (67.5%) of fatal overdoses there was a third-party present (Table 1).

The majority of the deceased were not registered for OAT at the time of death, 61% (n=111). One quarter 24.7% (n=45) of the individuals who died were known to have alcohol dependency and 15.9% (n=29) had a history of overdose in the past. Where recorded, the most common blood borne virus (BBV) infection in this cohort was HCV (23.6%), followed by HIV (6.6%) and Hepatitis B Virus (HBV)(1.6%). However history of BBV was not always available in the sources used by the NDRDI. For several characteristics, data was not available to the NDDRI from the available sources. For clarity, the denominators for these characteristics are included in brackets. Where data was available, 96.3% (77/80) had a known history of mental illness, 89% (73/82) of individuals were re-

Table 2: Dependencies and Treatment History

	n	%
A. Mental Illness		
A1. Alcohol dependency mentioned	45(/182)	24.7
A2. History of mental illness	77 (/80)	96.3
A3. Ever treated for substance dependency	107 (/113)	94.7
B. Drug Use		
B1. Recorded history of overdose	29 (/182)	15.9
B2. History of injecting drugs	73 (/82)	89.0
B3. Injecting at time of death	26 (/45)	57.8
B4. Treated for drug problem at time of death	89 (/97)	91.8
C. Virology recorded		
C1. Hepatitis B	4 (/182)	2.2
C2. Hepatitis C	43 (/182)	23.6
C3. Hepatitis Unspecified	3 (/182)	1.6
C4. HIV	12 (/182)	6.6

Table 3 Comparison between those on OAT and not on OAT

	Not registered on OAT at the time of death (n=111)	Registered on OAT at the time of death (n=71)	p-value
Mean age	34.22 (SD: 11.0)	38.99 (SD: 8.4)	*0.003
Sex			
Male	74.6 (89/111)	80.2 (53/71)	0.463
Female	25.4 (22/111)	19.8 (18/71)	
Place of residence			
Dublin city/county	63.1 (70/111)	81.6 (58/71)	*0.024
Other city area	6.3 (7/111)	7.0 (5/71)	
Other areas	30.6 (34/111)	11.4 (8/71)	
Alcohol dependency mentioned	27.0 (30/111)	21.1	0.386
Ever Treated for drug dependency	73.1 (19/26)	98.6	*<0.01
Ever Injected	79.5 (31/39)	97.7	*0.012
Injecting at time of death	55.0 (11/20)	60.0	0.220
History of mental illness	97.7 (43/44)	94.4	0.585
Ever treated for substance dependency	85.7 (36/42)	100	*0.002
Hepatitis C	16.2 (18/111)	35.2	*0.004
HIV	4.5 (5/111)	9.9	0.220
Polydrug poisoning	91.9 102/111)	87.3	0.322
Coroner's verdict (n=171)			0.148
Accident	1.0 (1/104)	0 (0/67)	
Misadventure	77.9 (81/104)	89.6 (60/67)	
Suicide	4.8 (5/104)	1.5 (1/67)	
No verdict/Not recorded	16.3 (17/104)	8.9 (6/67)	

Continuous variables assessed by independent T-test; Categorical variables assessed by Chi-square. *Variables deemed statistically significant, p<0.05

corded as having a history of injecting drugs, with 57.8% (26/45) documented as injecting drugs at the time of their death. The majority, 94.7% (107/113), had been treated for substance dependency at some stage, with 91.8% (89/97) being treated for problem drug use at the time of death (Table 2).

Table 3 compares those registered for OAT at the time of death to those who were registered for OAT. When comparing the available data for those who were registered for OAT at their time of death, statistically significant differences were found in: mean age (p=0.003), place of residency (p=0.024), ever treated for drug dependency (p=0.000) and Hepatitis C (p=0.003); however, none of these remained significant on the multivariate logistic regression, except those who had been recorded as ever treated for drug dependency.

Ante- and/or post-mortem toxicology results were available for 171 of cases, with the majority, 86.8% (n=158), of the deaths being poly-substance related (including opiates, such as heroin and methadone). Methadone alone was found in 9% (n=16) of cases and 3.5% (n=6) were found to have opiates alone. A wide range of drugs were found in the toxicology results. Significant differences were noted regarding those registered and non-registered CTL individuals in terms of their use of prescribed medication. Individuals not registered on the CTL were statistically more likely to be using non-prescribed methadone (p<0.01), diazepam (p=0.02) and mirtazapine (p=0.02) at the time of death. (Table 4).

4. Discussion

This study reports on a particular cohort of drug-related deaths in Ireland where methadone has been implicated in the death, and builds on earlier studies conducted using NDRDI data [12]. There is growing concern about drug-related deaths in many jurisdictions [1, 6, 17]. The role that prescribed and diverted methadone plays in these deaths has been documented [4, 16] but there is a paucity of research on this unique cohort [13]. The study examined in greater detail the characteristics of those who died where methadone was implicated in the cause of death and to examine if there were differences in the characteristics of patients who were registered for OAT and those who were not.

Table 4 – Toxicology Results

Substance	N	% On OAT	% Not on OAT	% OAT not prescribed	% Non OAT not prescribed	p-value
Methadone	171	40.9	59.1	34.3	91.1	*<0.01
Heroin	60	46.7	53.3	100.0	100.0	-
Hypnotics (Non BZO)	84	44.0	56.0	78.4	87.2	0.378
Diazepam	131	39.7	60.3	71.2	87.3	*0.025
Alcohol	61	34.4	65.6	100.0	100.0	-
Flurazepam	52	55.8	44.2	69.0	91.3	0.086
Alprazolam	31	48.4	51.6	93.3	100.0	0.484
Amitryptlline	16	81.3	18.8	61.5	100.0	0.509
Cocaine	21	33.3	66.7	100.0	100.0	-
Mirtazapine	54	46.3	53.7	64.0	89.7	*0.046
Olanzapine	23	60.9	39.1	57.1	55.6	1.00
Tramadol	15	33.3	66.7	80.0	70.0	1.00
Citalopram	14	35.7	64.3	100.0	66.7	0.258

Continuous variables assessed by independent T-test; Categorical variables assessed by Chi-square. *Variables deemed statistically significant, p<0.05.

This study shows that methadone-related deaths account for a significant number of deaths in young men in Ireland. Over a two-year period, 142 men with a mean age of 36 years died in Ireland from what is a preventable cause of death. Despite the numbers, these deaths do not get the same attention, for example as road traffic deaths or deaths by suicide. Of note is the number of very young people (< 25 years) (n= 24) in this cohort. With an aging opiate using population, this finding was unexpected. Comparative analysis between those on and off treatment showed those dying off treatment were younger than those on treatment. Being on OAT may account for this finding, but consideration should also be given to the possibility that this group contains a younger cohort of less experienced drug users who had not yet come in contact with OAT. Further analysis of this younger cohort is necessary to determine their unique characteristics and inform specific overdose prevention to target this group.

This study showed that more people died off treatment (not registered for OAT) than in treatment (registered for OAT). Another Irish study which found that patients treated with methadone were nearly four times more likely to die in periods off treatment [4]. Of note is the numbers of those ever treated for substance dependence (94.7%). Accessing treatment offers an opportunity to target overdose strategies to this at-risk group. Consideration should be given to expanding opioid overdose strategies to services providing treatment for all drug types. This strategy is further supported by the study's finding that the majority of fatal methadone-related overdoses were poly-substance in nature, as evidenced in the literature [4, 9, 12,13, 24]. Some of those who died where methadone was implicated may not be opioid dependant and the use of diverted methadone may be experimental or used for the purpose of self-medicating for example withdrawal symptoms from other drugs. While significant numbers of those who died had previous contact with drug treatment services, the data available did not indicate if these were OAT providers.

Retaining patients in OAT is an essential component of any national overdose prevention strategy [1, 6, 23]. This includes easy access, in a timely fashion, to OAT which should include the option of buprenorphine. OAT in Ireland [8] has expanded hugely over the past two decades with numbers in treatment expanding to over ten thousand. This accounts for approximately 50% of identified opioid users. Despite this high coverage there are still significant waiting times for OAT in some parts of the country with very limited access to buprenorphine as an alternative option to methadone. There is also concern that the OAT delivery models are preventing some opioid dependant patients, in particular those with over the counter (OTC) and prescribed opioid dependence accessing appropriate services [27]. Cousins et al. [4] reported that whilst numbers on methadone treatment are on the increase in Ireland, with a third treated in primary care, no corresponding decrease in deaths from opioid overdose has been recorded. This may, in part, be due to the above identified issues but also methadone diversion may be a contributing factor. The benefits and

protection afforded by OAT may be eroded by methadone diversion [4,16]. Further research is needed to establish the extent to which diversion contributes to methadone-related deaths in Ireland. Supervision of methadone, known to reduce overdose, is intrinsic to OAT in Ireland [8]. National OAT guidelines recommend full supervision in the first three months during the induction and stabilisation phases and thereafter reduced with increasing stability. The guidelines also recommend at least one methadone dose to be supervised weekly with doses of 80mls or more supervised at least twice weekly. Despite these guidelines, most methadone-related deaths in Ireland appear to be due to diverted methadone.

A third of methadone-related deaths are in patients accessing OAT. These patients are in contact with services, which provides a unique opportunity to risk assess and engage them in overdose prevention interventions such as overdose recognition, Cardio Pulmonary Resuscitation (CPR) and naloxone administration training. This study found that the majority of patients were not alone and were in a private dwelling at the time of the fatal overdose which supports the involvement of peers and family in overdose prevention programs. Of note was the low numbers of fatal overdoses occurring in homeless centres. Given that homelessness significantly increases mortality among opioid users and the high level of homelessness experienced by drug users in Ireland, this finding was contrary to what might be expected. It may be explained in part by the fact that OAT homeless accommodation in Ireland are staffed by experienced and well trained staff knowledgeable on the signs and treatment of overdose and the multi-occupancy of the sleeping accommodation where overdoses might be witnessed by third parties.

This national study is unique in an Irish context and is one of only a few studies that looks specifically at methadone-related deaths, and includes all patients dying over a two-year period in Ireland. Given the use of four different data sources by the NDRDI is it very unlikely that methadone-related deaths were missed or that duplications occurred. The missing data was due to it not being present in the original data sources used to populate the NDRDI. The number of different variables included in the data set are ambitious and if all data was available would provide a unique insight into this cohort. Consideration should be given to expanding data sources for the register, including the use of a standardised template that could be completed by the treatment provider at the time of death or last treatment provider known.

A number of limitations were identified in this study. Data was incomplete for many of the characteristics because it was not always available in the data sources that the NDRDI have access to. This makes analysis and interpretations difficult. The researchers, where possible, have identified the real denominator in the tables to clarify findings. The research is also limited by not being able to differentiate the different groups represented by those not registered for OAT. This includes: those never treated, just completed treatment, on waiting lists for OAT or in receipt of buprenorphine. There are also limitations in the interpretation of the "on CTL" group. These may include patients who have ceased OAT in the past 28 days but have not yet been exited from the register as patients remain on the treatment register for one month post treatment completion or default from treatment. This group is considered a high-risk group for overdose [4, 6,10, 20, 26] and has the potential to underestimate the numbers dying off treatment.

5. Conclusions

Methadone-related fatal overdose is a significant cause of death in young men in Ireland. This unique population share many of the same characteristics as other drug-related deaths [4, 11, 13, 18, 19, 22, 24, 25]. These are male gender, age (mid to late thirties), previous history of contact with treatment services, history of injecting drugs, high levels of mental illness, polysubstance toxicology on post-mortem and not in receipt of OAT. The majority dying from methadone-related overdose were not alone at the time of death and died in a private dwelling. The majority of patients were not on OAT at the time of the overdose but had previous contact with drug treatment services. These factors combined with other identified patient characteristics along with improved risk assessment and OAT retention strategies should inform any Irish national drug overdose plan. Improving access to more data sources for the NDRDI would provide more comprehensive data and further assist with targeting overdose prevention strategies.

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Contributors

All authors were involved in the study design, had full access to the survey data and analyses, and interpreted the data, critically reviewed the manuscript and had full control, including final responsibility for the decision to submit the paper for publication.

Conflict of interest

All authors declare no conflict of interest.

Ethics

Authors confirm that the submitted study was conducted according to the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.

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