



European Monitoring Centre
for Drugs and Drug Addiction

What are the outcomes for assessing drug treatment?

A review of long-term observational studies on the treatment of opioid dependence

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Background

- Drug use and addiction, notably to opioids, are important public health problems with high costs to individual and society
- Continuing discussion about treatment effectiveness, chronicity complicates
- Lack of clear overview of studies and outcomes, although specific outcomes have been reviewed (e.g. abstinence, injecting, HIV) and specific interventions (methadone, buprenorphine, heroin..)
- To our knowledge no review to date has provided an overview of the outcomes being assessed in the major treatment outcome studies of opioid dependence (regardless of the intervention offered)
- We aimed to assess what outcomes are being used in the largest prospective treatment studies to understand gaps, needs and areas for further research

Objectives

- General background questions underlying our study and for future analysis:
 - Are treatment outcomes consistent with the objectives of treatment?
 - Are treatment outcomes comparable?
 - Are data available to replicate those evaluations?
- Specific objective of this presentation:
 - Discuss the outcomes reported in the literature of observational prospective studies on the treatment of opioid users

Methods – search strategy

- We searched Pubmed and Cochrane databases for “substance-related disorders” AND “observational study”
- No publication date or language limitations
- Prospective cohort studies

In addition:

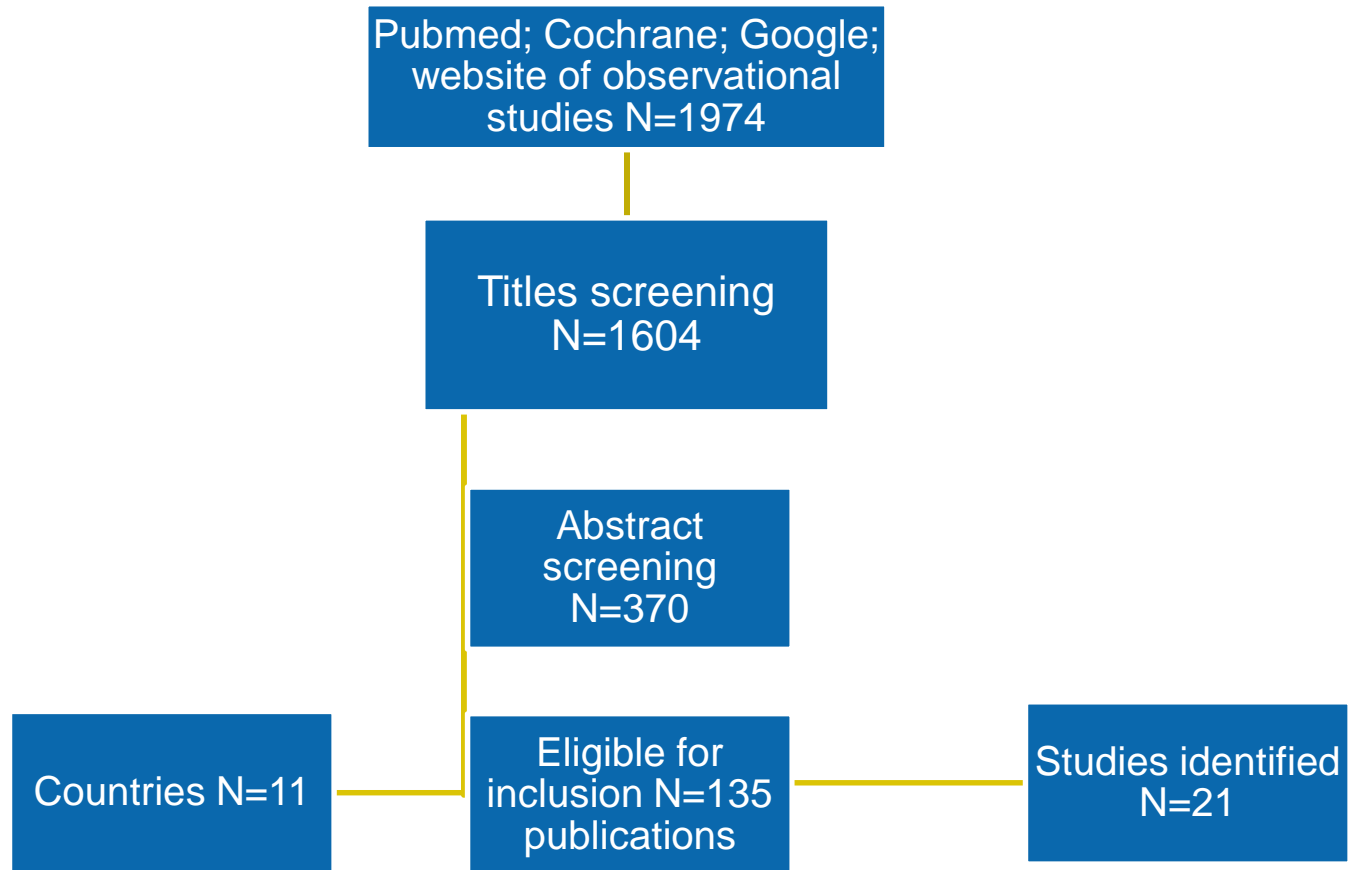
- Searched “related citations” to 12 known large studies
- Free text search for the known study acronyms
- Checked websites of the known studies
- Registered protocol in Prospero database (Ferri et al. 2014)

Methods – inclusion / exclusion criteria

Inclusion criteria:

- Population = sample of opioid users
- Intervention = any drug treatment
- Outcomes = any outcome at follow-up (base-line data or covariates of outcomes excluded)
- Study design = non-experimental observational prospective cohort studies (efficacy studies / RCTs excluded)
- Data reporting quality e.g. loss to follow-up (LTFU)

Search strategy – results



Methods – data extraction

- Study acronym
- Author
- Publ year
- Treatment objective: end of Tx / mainten. / both
- Study method
- Data coll. period
- Setting / sample
- Eligibility criteria
- Sampling
- **Main outcomes**
- **Secondary outcomes**
- Measures used
- Main outcome re abstinence
- Measures abstinence
- N baseline
- Follow-up interval (months)
- **N at end of FU**
- **LTFU %**
- Factors LTFU
- Abstinence rates (n, %)
- Covariates of abstinence
- Epidemiological phase heroin use available
- Time since initiation available
- Results regarding retention available
- Reference

Results

- Preliminary analysis here presented includes data from 9 of the 12 'known' studies: ALIVE, ATOS, DATOS, DORIS, DTORS, NDTMS, NTORS, ROSIE, VEDETTE
- Five countries: Australia, Ireland, Italy, UK (4x, of which 1 from Scotland), USA (2x), one national sample each (not Au)
- Data collection 1988 – 2007 (publication date 2001-)
- Median FU 25.5 months (range 5-144, IQR 12-36)
- N = 16,801 at end of FU
- % LTFU median 32.7 (range 31-56, IQR 32-44)

Results – main outcome domains

Drug use (8/9 studies)

Abstinence (6/9)

Crime (6..)

Harm (4)

Health (3)

Mortality (3)

Treatment / study
aspects (3)

Social functioning (3)

Cost-effectiveness /
economic issues (2)

Recovery (1)

Needs of treatment
providers & seekers (1)

Results – Drug use (8/9 studies)

- Heroin use in last 3 months / last year (DATOS, DORIS)
- Days heroin use in the four weeks preceding interview / zero days of use in last 28 days (ATOS, NDTMS)
- Drug type, Frequency, Quantity (ROSIE)
- Classes of injection patterns /transitions (ALIVE)
- Regular (weekly or +) use for all six illicit drugs, Daily use of opiates, Injecting behaviour, Alcohol (NTORS)
- Being currently drug free, being currently drug free excluding cannabis, severity of dependence (DORIS)
- Abstinence (DTORS)
- (VEDETTE)? (cocaine use as covariate of retention)

Results – Abstinence (6/9 studies)

- Not using any illicit drug / Not using any illicit drug excluding cannabis (ROSIE)
- Stopped using the drugs that they reported using at baseline, Stopped the regular use of all drugs, Levels of drug consumption (mean value of all drugs used in the seven days prior to interview) (DTORS)
- Ceased injection over 12 year FU period (stopped injecting and reported no injection at subsequent visits) (ALIVE)
- Treatment retention / abstinence therapy had lowest retention (VEDETTE)
- Been totally drug free (excluding possible alcohol and tobacco use) for a 90-day period in advance of being interviewed (self-reported drug use and service usage), also excluding cannabis (DORIS)
- Abstinence from heroin use, crack use or both; Reduction in days used at group level; "Reliable improvement" (12 days or more reduction in last 28 days) (NDTMS)

Results – Crime / Legal (6/9 studies)

- Crime: selling/supplying drugs, handling stolen goods. Legal problems: being arrested, other (eight legal problem categories) (ROSIE)
- Offending (levels of acquisitive offending [burglary of a business or dwelling, theft of vehicle, bag snatching or robbery], high-cost offending, committing an acquisitive crime in the past four weeks) (DTORS)
- Ever arrested, arrested over the last 17 months, having committed any crime and any acquisitive crime over the last 17 months (DORIS)
- Crime / Criminality / Illegal activity / Arrests (ATOS, DATOS, NTORS)

Results – Harm (4/9) / Health (3/9) / Death (3/9)

- Injecting risks (DATOS, DTORS, ROSIE)
- Overdose (DTORS, ROSIE, VEDETTE)
- Mental health (ATOS, NTORS, ROSIE)
- Suicidal ideation (NTORS)
- Physical health (poor appetite, tiredness etc.) (ROSIE)
- Injection related health problems (ATOS)
- Mortality (ATOS, NTORS, VEDETTE)

Results – Treatment / Study aspects (3/9 studies)

- Retention (NDTMS, ROSIE, VEDETTE)
- Discussing a care plan and being happy with it (DTORS)
- Intake completion (for detox and abstinence modalities – as indicator for improved outcomes) (ROSIE)

Results – Social functioning (3/9 studies)

- Employment (DATOS, ROSIE)
- Accommodation (DTORS, ROSIE)
- (Family) relations (DTORS, ROSIE)
- Recovery self-perceptions include “Able to socialise and relate” etc. (DATOS)

Results – cost-effectiveness / economic (2/9)

- Cost-effectiveness of services: “net saving of £6,500 per person for drug treatment, compared to no treatment”, “net gain in health as measured by QALYs”, “drug treatment ~ 80% chance of being cost-effective for the individual”(DTORS)
- Economic issues: “social costs incurred by the cohort included crime costs, health and welfare service use, the use of drug misuse services” and “criminal justice costs” (NTORS)

Results – Other outcomes (1 study each)

- Recovery: “...evidence of any opioid or cocaine use, any daily alcohol use, and illegal activity before treatment” (urine, hair test, interview), nine “recovery perception areas” at follow-up (DATOS)
- Needs of treatment providers & seekers (DTORS)

Limitations

- These are preliminary findings, not yet validated
- Not all studies identified have yet been included (9 out of 21)
- This is a global explorative analysis, not permitting full detail on the different outcomes, a meta-analysis on specific outcomes might improve understanding of definitions and comparability
- To some extent results may be dependent on the specificity of the wording used in the publications e.g. “economic issues” and “cost-effectiveness” can be similar or actually indicate very different outcomes (but we show some detail on definitions), some studies mention “social functioning” others “recovery perceptions” that include a social variable
- Outcomes may have been missed in data extraction (still to validate)
- Outcomes may have been measured but not (yet) reported (publication bias), although then perhaps not relevant

Limitations – cont.

- Search for ‘observational studies’ is unreliable (not indexed as for RCTs)
- Protocols (with originally planned outcomes) are not systematically registered as for the RCTs
- Additional publications on the same study may have been missed (no unique study number as for RCTs)
- Although all studies included reported outcomes for a separate sample of opioid users, not all outcomes were always reported separately for opioid users
- Some outcomes mentioned here were reported in a qualitative format, complicating potential meta-analysis
- Some studies included reported additional variables as co-variates of the outcome investigated (they were then not included as outcome)

Conclusions

- In preliminary analysis, the range of outcomes in nine large observational prospective studies of opioid users suggests variation in measures of treatment success (treatment objectives?)
- Where the same outcome domains are covered, measures of treatment success seem to vary
- There appears to be a need for developing further consensus on what are the main outcomes to assess the successful treatment of opioid users

Discussion and way forward

- Can studies based on registries (National Drug Treatment Monitoring System (NDTMS)) and prospective cohort studies be analysed jointly?
 - outcomes collected from registries records
 - outcomes collected through special study forms (protocols)
- Look at (consistency and comparability of) instruments used to measure outcomes.
- Separate by treatment modality (maintenance vs. abstinence)
- Be more restrictive i.e. only include quantitative outcomes reported separately for opioid users? (meta-analysis)

Publications assessed in preliminary analysis

ALIVE: Galai N, Safaeian M, Vlahov D, Bolotin A, Celentano DD; ALIVE Study. Longitudinal patterns of drug injection behavior in the ALIVE Study cohort, 1988-2000: description and determinants. *Am J Epidemiol.* 2003 Oct 1;158(7):695-704.

ATOS: Darke S, Mills KL, Ross J, Teesson M. Rates and correlates of mortality amongst heroin users: Findings from the Australian Treatment Outcome Study (ATOS), 2001-2009. *Drug Alcohol Depend.* 2010 Dec 2.

DATOS: Flynn PM, Joe GW, Broome KM, Simpson DD, Brown BS. Recovery from opioid addiction in DATOS. *J Subst Abuse Treat.* 2003 Oct;25(3):177-86.

DATOS: Hubbard, R. L., Craddock, S. G., & Anderson, J. (2003). Overview of 5-year follow-up outcomes in the Drug Abuse Treatment Outcome Studies (DATOS). *Journal of Substance Abuse Treatment*, 25(3), 125-134. (abstract only)

DATOS: Murphy DA, Brecht ML, Herbeck D, Evans E, Huang D, Hser YI. Longitudinal HIV risk behavior among the Drug Abuse Treatment Outcome Studies (DATOS) adult sample. *Eval Rev.* 2008 Feb;32(1):83-112. (abstract only)

DATOS: Rao SR, Broome KM, Simpson DD. Depression and hostility as predictors of long-term outcomes among opiate users. *Addiction.* 2004 May;99(5):579-89. (abstract only)

DORIS: McKeganey N, Bloor M, McIntosh J (2008). Drug Outcome Research in Scotland (DORIS) Scotland 2001 - 2003 Key findings from the Drug Outcome Research in Scotland (DORIS) study. University of Glasgow Centre for Drug Misuse Research http://www.gla.ac.uk/media/media_101969_en.pdf (link not working)

DORIS: McKeganey, N. P., Bloor, M., Robertson, M. and Neale, J. (2006) Abstinence and drug abuse treatment: Results from the Drug Outcome Research in Scotland study. *Drugs: Education, Prevention & Policy*, 13(6), pp. 537-550.

DTORS: Donmall M, Jones A, Davies L, Barnard M. Summary of key findings from the Drug Treatment Outcomes Research Study (DTORS). Research Report 23 (summary). [UK] Home Office, 2009.

NDTMS: Marsden J, Eastwood B, Bradbury C, Dale-Perera A, Farrell M, Hammond P, Knight J, Randhawa K, Wright C; National Drug Treatment Monitoring System Outcomes Study Group. Effectiveness of community treatments for heroin and crack cocaine addiction in England: a prospective, in-treatment cohort study. *Lancet.* 2009 Oct 10;374(9697):1262-70. doi: 10.1016/S0140-6736(09)61420-3. Epub 2009 Oct 1. PMID: 19800681 [PubMed - indexed for MEDLINE]

NTORS: Gossop M, Marsden J, Stewart D. NTORS After Five Years. The National Treatment Outcome Research Study Changes in substance use, health and criminal behaviour during the five years after intake. National Addiction Centre, London, 2001. http://www.addictiontoday.org/addictiontoday/files/ntors_5.pdf

ROSIE: Comiskey CM, Kelly P, Leckey Y, McCulloch L, O'Duill B, Stapleton RD, White E. The ROSIE Study Drug Treatment Outcomes in Ireland - A Report for the National Advisory Committee on Drugs 2009. Dublin, 2009.

VEDETTE: Davoli M, Bargagli AM, Perucci CA, Schifano P, Belleudi V, Hickman M, Salamina G, Diecidue R, Vigna-Taglianti F, Faggiano F; VEdeTTE Study Group. Risk of fatal overdose during and after specialist drug treatment: the VEdeTTE study, a national multi-site prospective cohort study. *Addiction.* 2007 Dec;102(12):1954-9. (abstract only)

VEDETTE: Salamina G, Diecidue R, Vigna-Taglianti F, Jarre P, Schifano P, Bargagli AM, Davoli M, Amato L, Perucci CA, Faggiano F; VEdeTTE Study Group. Effectiveness of therapies for heroin addiction in retaining patients in treatment: results from the VEdeTTE study. *Subst Use Misuse.* 2010 Oct;45(12):2076-92. doi: 10.3109/10826081003791932.