International Models of Community Pharmacy-Based Dispensing of Methadone

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Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws; Virtual Workshop March 4, 2020

Disclosures

Funding:

JS – Employed by the University of Auckland, New Zealand

SN – Australian Government National Health and Medical Research Council (NHMRC) Career Development Fellowship (L2-Population Health) #1163961

Disclosures

SN – named investigator on research grants from Seqirus and Indivior (unrelated to this work)

JS – holds managed investment portfolios which may include pharmaceutical industry.

Features of community pharmacy methadone dispensing

Patient

- New vs existing
- Stable vs not yet stable
- Decision on dosing site made by patient or physician or both

Prescriber

- GP/primary care physician only
- OTS only
- GP/physician with OTS

Community pharmacy

- Type of pharmacy – independent or chain
- Private area available?
- Dosing - supervised and/or take home
- Patient payment
  - Dispensing fee only
  - Full cost of medication
  - No payment
- Training and accreditation
  - Pharmacy accreditation required
  - Pharmacist training required
  - Training recommended

GP – general practitioner
OTS – opioid treatment service

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Advantages, incentives, barriers and concerns

	Advantages / incentives	Barriers / concerns
Patient/client	Accessibility, anonymity, flexibility, support, discreet	Privacy, confidentiality, stigma, family and friends may also use pharmacy
Pharmacist	Job satisfaction Opportunity for specialization?	Concerns about staff safety, patient antisocial behaviors, community resistance. Need for training.
Pharmacy	High numbers of clients may be financially beneficial, depending on funding model In large chains, standardized training easier to implement across pharmacies.	Time, staff, resourcing In large chains, company decision not to offer service may affect many pharmacies

See references at end of presentation for research evidence

Features of pharmacy methadone dispensing (Australia)

- **Most patients** (e.g., 67-99%) **supervised dosing in pharmacies** (80% national average),
- **High community pharmacy participation** (≈half provide methadone/buprenorphine)
- **Most prescribing from primary care (2/3) and specialist clinics (1/3)** (some clinic induction)
- **Medication supply to pharmacies for free** by federal government
- Patients pay pharmacies a **daily dispensing fee** (offset by reduced travel costs[19])

State level clinical supports (vary a little by state):

- Drug and Alcohol Clinical Advisory Service (DACAS) **24 hour support line** for health professionals
- Project ECHO, local **pharmacotherapy networks** support
- **Consumer support orgs**

Project ECHO

Victorian Pharmacotherapy Area-Based Networks

Harm Reduction Victoria

Regulation of pharmacy methadone supply: Australia

1. Federal Scheduling (Schedule 8 – Controlled Drug)
2. State Acts/Regulations determine legal rules around prescribing/ administering
3. Policies from jurisdictional health departments determine how Opioid Agonist Treatments are provided (clinical guidelines)

Other regulations

- Methadone prescribers are accredited, pharmacy accreditation varies by state, individual pharmacists not usually accredited
- State health department approval before commencing treatment (i.e. a patient-prescriber specific ‘permit’ - limits patient to one prescriber)

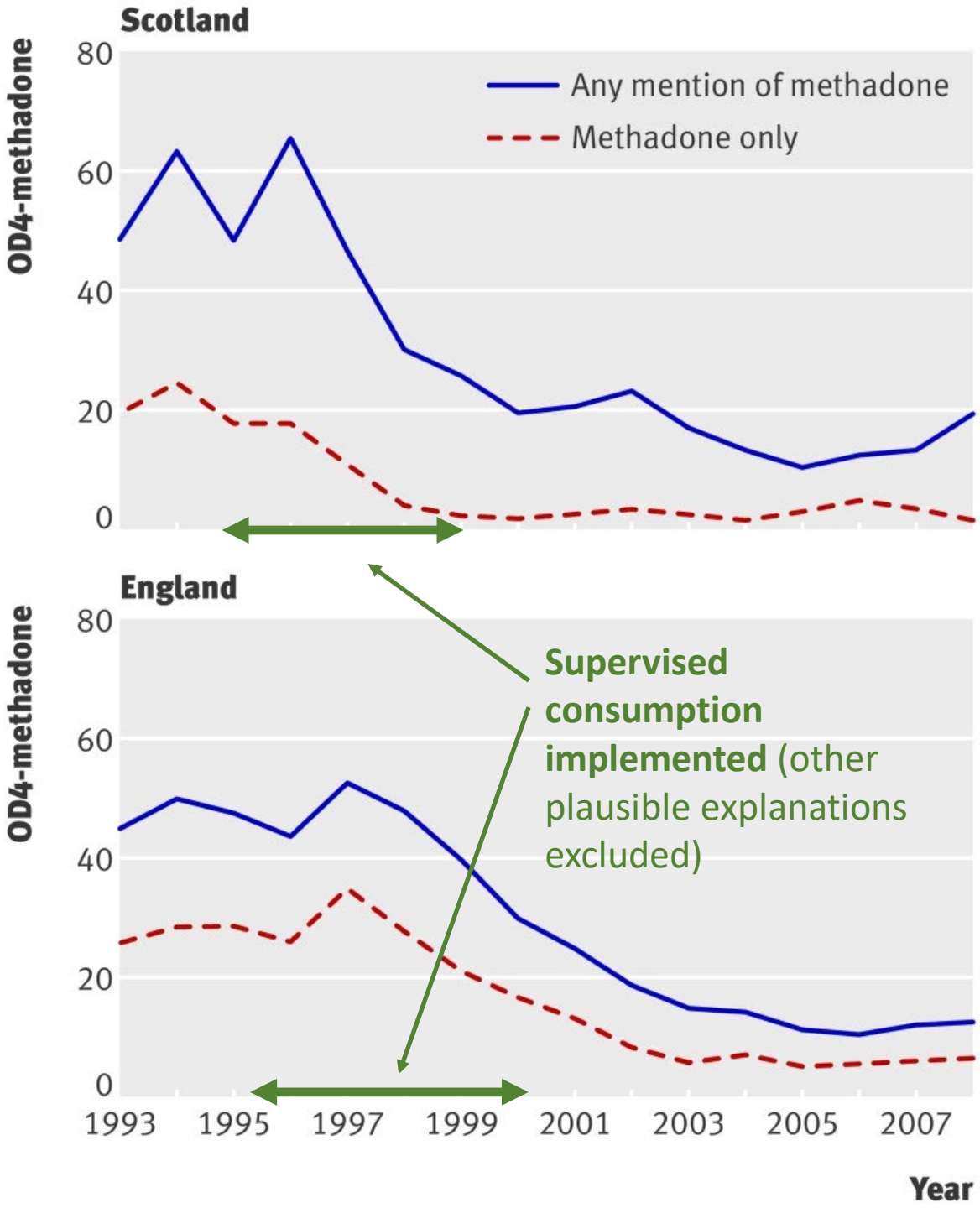
Safety: Supervision

Supervision of dosing, particularly early in treatment

- Study in Scotland clearly demonstrated that the introduction of supervision (Strang et al 2010)[9]

Recent **increases in unsupervised** dosing (up to 6 unsupervised doses per week) with COVID-19

- no evidence of increased methadone-related mortality or diversion (Victorian Coroners report)[10]



Unsupervised dosing – risk mitigation

- Weak evidence → **Dilution** may reduce injection, and **more unsupervised doses** may be linked to diversion/injection → but other factors also key (e.g. drug markets, treatment access & quality) (diversion often for therapeutic reasons[20,21])

Risk mitigation

- Careful patient selection / assessment for unsupervised dosing
- Stability confirmed with dosing pharmacist
- Confirm **storage** requirements
- Child proof lids & single dose packed per bottle

› Addiction. 1999 Aug;94(8):1175-8. doi: 10.1046/j.1360-0443.1999.94811757.x.

Methadone injecting in Australia: a tale of two cities

N Lintzeris [1], M Lenné, A Ritter

Affiliations + expand

PMID: 10615732 DOI: 10.1046/j.1360-0443.1999.94811757.x

Caution examining outcomes by dosing site →confounded by patient/treatment characteristics

Naturalistic Australian study[6]: ***improved retention in community pharmacy*** compared to clinics

- **32% less likely to leave treatment** at in first 9mo compared to clinic
- 14% less likely to leave treatment after 9mo

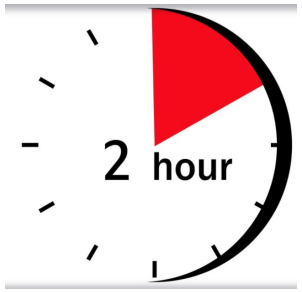
Canadian study found with higher retention in clinics (**77% less likely to withdraw from treatment with onsite pharmacy**)[18]

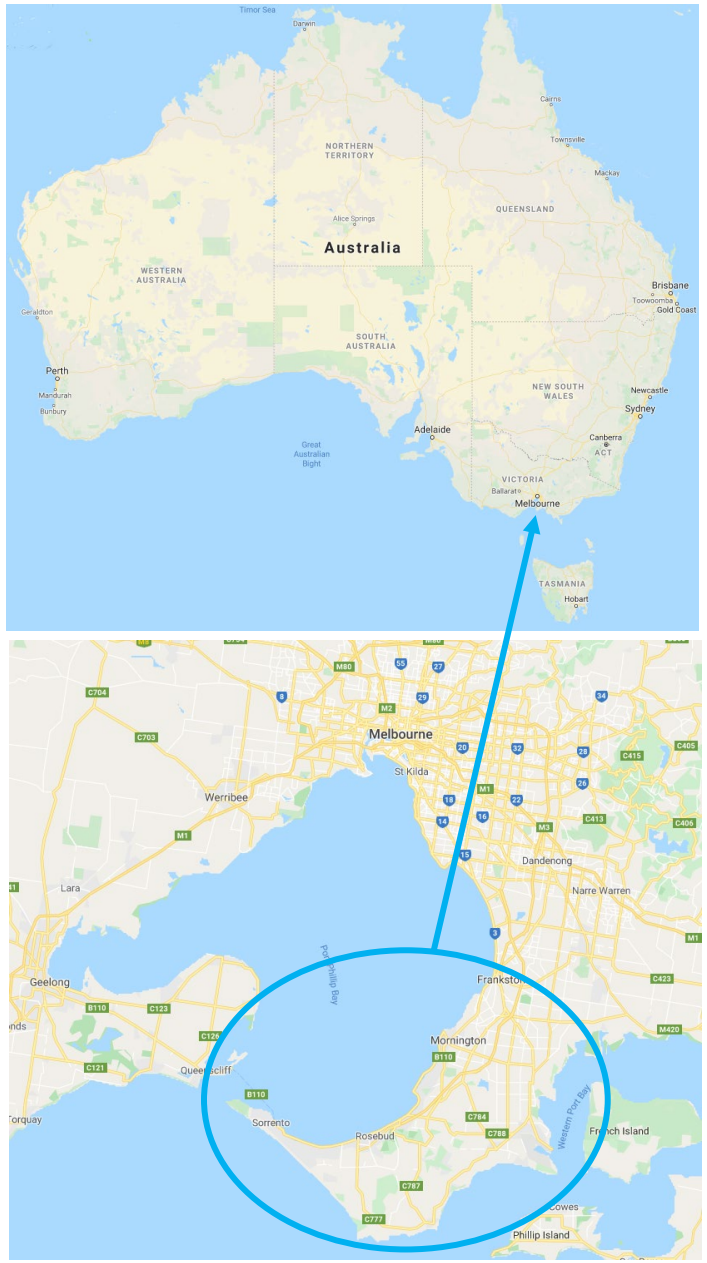
Important caveats:

- Not randomised to dosing condition
- Differences in clinic and pharmacy populations (demographics, stability in treatment, methadone doses)

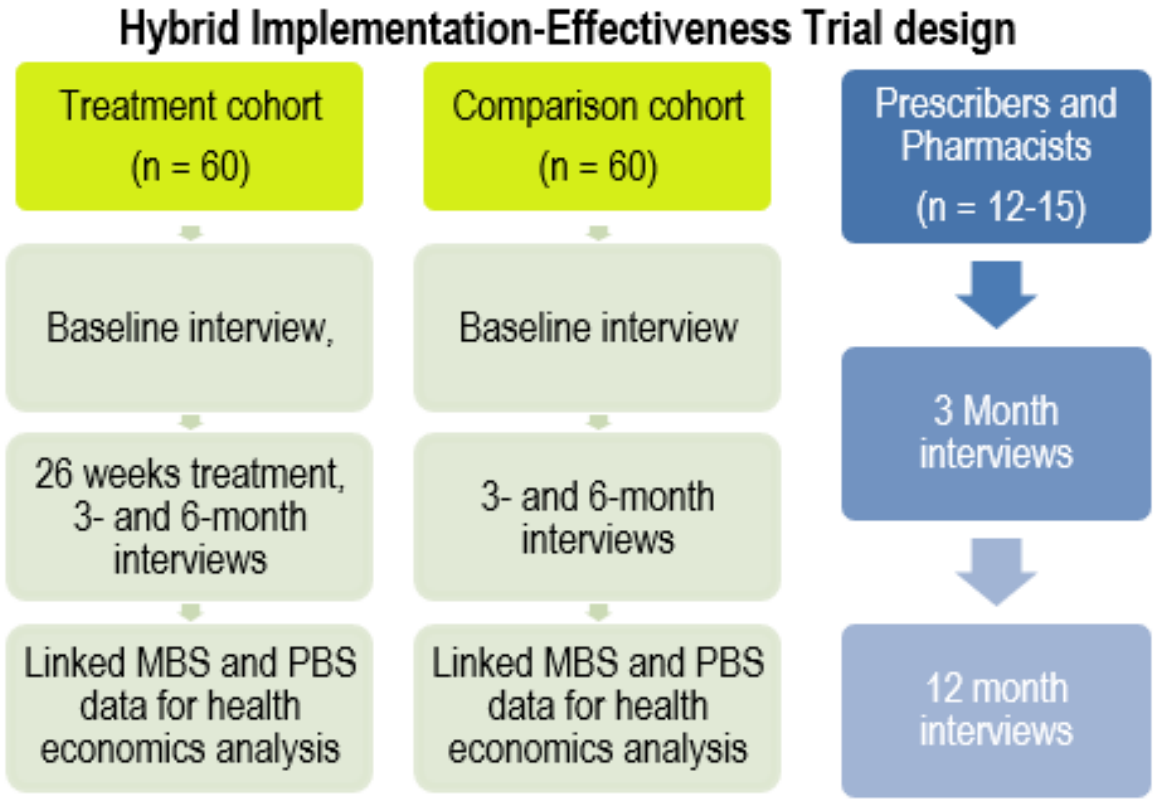
New models: EPIC-MATOD
Frankston Mornington Peninsula

- High relative levels of opioid-related harm for the state
- Some of the most disadvantaged suburbs in the country
- Poor public transport (2 hrs to get to a prescriber)
- No specialist clinics
- Very few prescribers centralised in one clinic
- High pharmacy participation in methadone provision





The EPIC-MATOD study protocol[17] (ACTRN12621000871842)



Key features:

- **Delegation** of care to pharmacist (6-mth Rx)
- Co-designed **clinical practice guideline**
- **Regular structured pharmacist review** sent to prescriber (validated assessment tools to detect deterioration in substance use, mental health, psychosocial stability etc.)
- **Flags for prescriber consult**
- Pharmacist **adjusts dose**, **takeaways**, **restart** after missed doses

GOALS

- Extend pharmacist roles beyond **dosing**
- Increase **treatment capacity** (better use of prescriber time)
- Addresses **geographic barriers**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A prospective, multisite implementation-efficacy trial of a collaborative prescriber-pharmacist model of care for Medication Assisted Treatment for Opioid Dependence: Protocol for the EPIC-MATOD study

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Best practice: community pharmacy methadone

1. Clear state / national **guidelines** (e.g. limits on induction dosing, missed doses, clear indicators for unsupervised dosing suitability)
2. Pharmacist trained & confident to assess and respond to **intoxication/clinical deterioration**
3. Two-way **communication** with prescriber (e.g. confirm with pharmacist before increasing unsupervised dosing, pharmacist contacts prescriber with concerns)
4. Funded **consumer mediation** roles → support pharmacist & consumers
5. Patient **overdose prevention**: supervised dosing where clinically indicated, monitor missed doses/intoxication, drug-methadone interactions, naloxone provision
6. “Others” overdose prevention, single packed methadone doses with child-proof tops, safe storage for take home doses

Thank you!

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References

1. Sheridan J et al prevention and drug treatment services for drug misusers: a national study of community pharmacists' attitudes and their involvement in service specific training. Addiction. 1997 Dec;92(12):1737-48. PMID: 9581006.
2. Fonseca J, et al. Perceived Barriers and Facilitators to Providing Methadone Maintenance Treatment Among Rural Community Pharmacists in Southwestern Ontario. J Rural Health. 2018 Dec;34(1):23-30. doi: 10.1111/jrh.12264. Epub 2017 Sep 5. PMID: 28872697.
3. Neale, J et al, J. (2018). Patient views of opioid pharmacotherapy biodelivery systems: Qualitative study to assist treatment decision making. Experimental and Clinical Psychopharmacology, 26(6), 570–581. https://doi.org/10.1037/pha0000217
4. Neale J. Drug users' views of substitute prescribing conditions. International Journal of Drug Policy, 1999. 10(3):247-258. doi: 10.1097/01.adt.0000210713.80198.d1
5. Drucker, E. et al The Lancaster Office Based Opiate Treatment Program: A Case Study and Prototype for Community Physicians and Pharmacists Providing Methadone Maintenance Treatment in the United States, Addictive Disorders & Their Treatment: 2007, 6(3): 121-135 doi: 10.1097/ADT.0b013e31802b4ea1
6. Burns, L. et al Opioid agonist pharmacotherapy in New South Wales from 1985 to 2006: patient characteristics and patterns and predictors of treatment retention. Addiction,104, 1363–1372 https://doi.org/10.1111/j.1360-0443.2009.02633.x
7. Joudrey, PJ et al. Pharmacy-based methadone dispensing and drive time to methadone treatment in five states within the United States: A cross-sectional study, Drug and Alcohol Dependence, 2020. 211, Volume 211, 107968. https://doi.org/10.1016/j.drugalcdep.2020.107968.
8. Sheridan J. et al. Health problems and help-seeking activities of methadone maintenance clients at Auckland Methadone Service (AMS): potential for community pharmacy service expansion?. Harm Reduct J 2, 25 (2005). https://doi.org/10.1186/1477-7517-2-25
9. Strang J, Hall W, Hickman M, Bird S M. Impact of supervision of methadone consumption on deathsrelated to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland BMJ 2010; 341 :c4851 doi:10.1136/bmj.c4851
10. Victorian overdose deaths, 2011-2020 (Coroners report) https://www.coronerscourt.vic.gov.au/sites/default/files/2021-07/CCOV%20-%20Overdose%20deaths%20in%20Victoria%202011-2020%20-%2029Jul2021.pdf

11. McCarty D et al. Office-Based Methadone Treatment for Opioid Use Disorder and Pharmacy Dispensing: A Scoping Review. American Journal of Psychiatry 2021 178:9, 804-817. https://doi.org/10.1176/appi.ajp.2021.20101548

12. Laird, A. et al. Community pharmacy-based opiate substitution treatment and related health services: a study of 508 patients and 111 pharmacies. J Public Health 24, 193–207 (2016). https://doi.org/10.1007/s10389-016-0714-y

13. Anstice, S et al. Supervised Methadone Consumption: Client Issues and Stigma, Substance Use & Misuse, 2009, 44:6, 794-808, DOI: 10.1080/10826080802483936

14. Matheson, C. (1998a). Privacy and stigma in the pharmacy: illicit drug users' perspectives and implications for pharmacy practice. Pharmaceutical Journal, 260(6992):639–641.

15. Matheson, C. (1998b). Views of illicit drug users on their treatment and behaviour in Scottish community pharmacies: implications for the harm-reduction strategy. Health Education Journal, 57(1):31–41.

16. Lawrie T et al. Pharmacy customers' views and experiences of using pharmacies which provide drug misuse services. Drug and Alcohol Review(June 2004), 23, 195 DOI: 10.1080/09595230410001704181

17. Nielsen S et al. A prospective, multisite implementation-efficacy trial of a collaborative prescriber-pharmacist model of care for Medication Assisted Treatment for Opioid Dependence: Protocol for the EPIC-MATOD study. Res Social Adm Pharm. 2021 Nov 18:S1551-7411(21)00379-X. doi: 10.1016/j.sapharm.2021.11.007. Epub ahead of print. PMID: 34924314

18. Gauthier G et al. Improved treatment-retention for patients receiving methadone dosing within the clinic providing physician and other health services (onsite) versus dosing at community (offsite) pharmacies. Drug and Alcohol Dependence. 2018 191(1):1-5 https://doi.org/10.1016/j.drugalcdep.2018.04.029

19. Tran AD, Chen R, Nielsen S, Zahra E, Degenhardt L, Santo T Jr, Farrell M, Larance B. Economic analysis of out-of-pocket costs among people in opioid agonist treatment: A cross-sectional survey in three Australian jurisdictions. Int J Drug Policy. 2022 Jan;99:103472. doi: 10.1016/j.drugpo.2021.103472.

20. Hulme, Hughes, Drug sourcing and motivations among a sample of people involved in the supply of pharmaceutical drugs in Australia. Nielsen International Journal of Drug Policy.2019;66:38-47.

21. Hulme, Bright, Nielsen The source and diversion of pharmaceutical drugs for non-medical use: A systematic review and meta-analysis. Drug and Alcohol Dependence. 2018;186:242-56.

Clinical guidelines

UK

https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management

New Zealand

https://www.health.govt.nz/system/files/documents/publications/nz-practice-guidelines-opioid-substitution-treatment-apr14-v2.pdf

Australia (National, Victoria and New South Wales)

https://www.health.gov.au/sites/default/files/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence.pdf

https://www.health.vic.gov.au/drugs-and-poisons/pharmacotherapy-policy-in-victoria

https://www.health.nsw.gov.au/aod/Pages/nsw-clinical-guidelines-opioid.aspx