

Understanding NSW Long-acting Opioids in Custody-Treatment (The UNLOC-T study)

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Trial of depot buprenorphine in NSW custodial settings

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- Funding: NSW Ministry of Health

- Depot Buprenorphine (Buvidal/CAM2038): Camurus AB

- Disclosures:

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NSW Australia

- Population: 7.54 million (30% Australian population)
- 20,057 patients on methadone & buprenorphine treatment 2016
- Incarceration NSW: 222/100,000 population
 - 32 prisons in NSW
 - Daily average number in prison 13,740 (2017)
 - Aboriginal 27% (3.3% population)
 - Women 8% jail population
 - 1/3 not yet sentenced (on remand)
 - Most stays in jail: 3-6 months
 - General poor mental health, social problems, substance use very common of prisoners
 - E.g. 81% history of injecting drug use (heroin, other opioids, amphetamines, alcohol...)

Opiate treatment in prison NSW

- Opiate treatment – at any one time approx. 1500-1600 being treated
 - Methadone ~91%, buprenorphine ~9%
- Over 12 months, 3180 patients treated 2017/2018 in jails
 - 384 commenced in treatment in jail 2017/2018
- If enter jail on opiate treatment, remain on treatment
 - If not on treatment, unless pregnant, significant medical/psychiatric problem, only offered treatment 1-2 weeks before release
 - Significant under-treatment of opioid dependence in NSW jails (lack of resources)

Policy challenges

- Significant problem with diversion/injection illicit buprenorphine in jails
 - >44,000 findings of diversion attempts of buprenorphine in prisoners in NSW 2017/2018
 - includes buprenorphine smuggled into jails
 - Violence/threats associated with buprenorphine – common
- More jails being built in NSW
- No significant increases in health resources for jails (or post release)

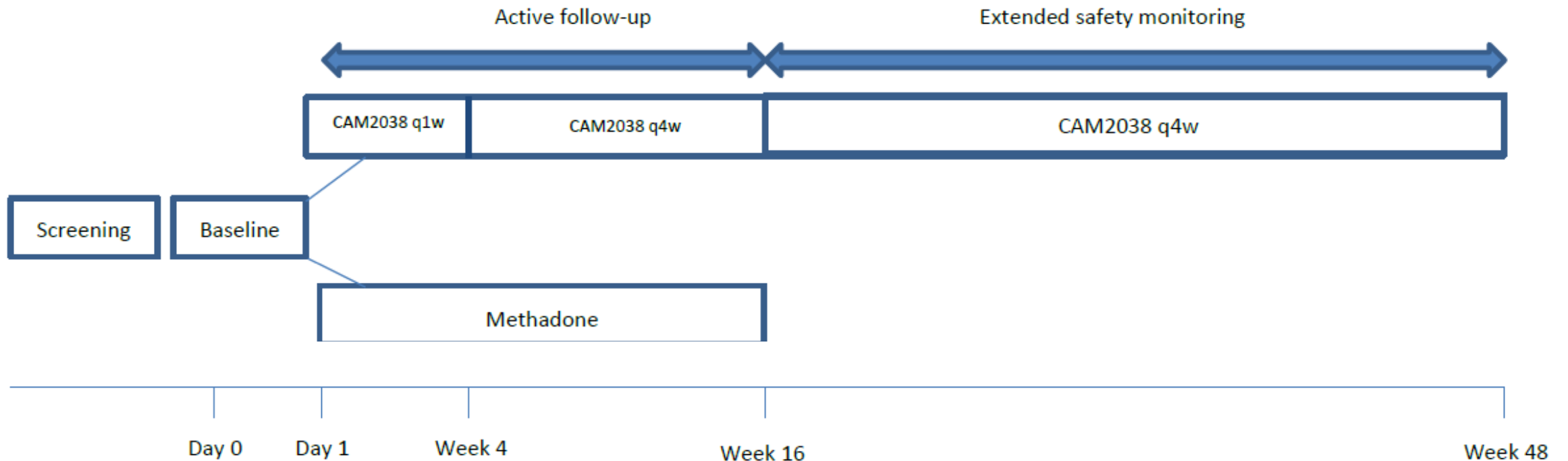
Primary objectives NSW jail study

1. To identify any unexpected *safety* and *tolerability* considerations of depot buprenorphine specific to the adult custodial population with moderate to severe opioid use disorder.
2. To assess *diversion* and other *non-medical use* of depot buprenorphine and impact of these activities on *risk of violence compared to standard of care* (methadone and sublingual buprenorphine- naloxone film) in custodial settings.
3. To compare the *time and cost* associated with administration of *depot buprenorphine compared to standard of care* (methadone and sublingual buprenorphine- naloxone film) in custodial settings.

Secondary objectives NSW jail study

4. To examine *effectiveness* of depot buprenorphine *compared to methadone* for patients with opioid use disorder.
5. To assess changes in *general physical, mental and psychosocial functioning* compared to methadone.
6. To examine *patient satisfaction* and experiences of treatment with depot buprenorphine compared to methadone.
7. To identify *other safety considerations* of depot buprenorphine specific to the adult custodial population with opioid use disorder.
8. To assess *staff satisfaction* and acceptability
9. To identify *system requirements for implementation* of depot buprenorphine products as a routine treatment in the custodial setting.

Study design



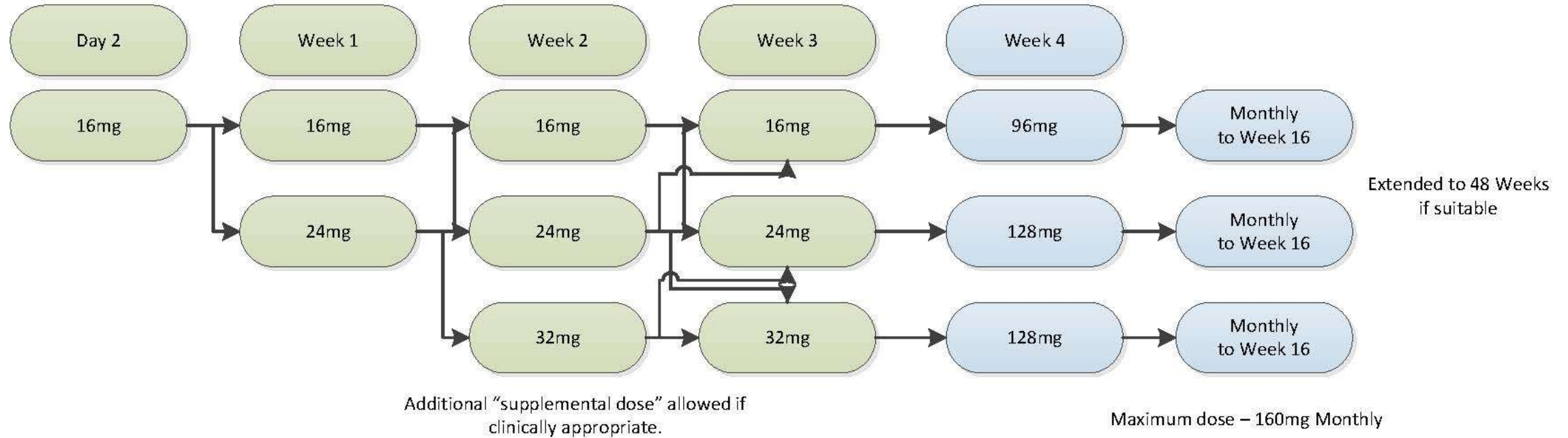
- 2 arm, case-comparison study (n=120):
 - Methadone (standard care) already on treatment
 - Opiate dependent, non currently on methadone/buprenorphine – depot BPN (may be currently injecting illicit BPN in jail)

Medication – flexible doses

- Methadone: standard care
 - Typically >60mg in custody (often 100mg/+)
- Buprenorphine
 - Patients who request pre-release Suboxone
 - Suboxone
 - 4 mg day one ('test' dose), may have additional doses (8mg)
 - Buvidal
 - Weekly (weeks 1-4)
 - 16mg weeks 1-4, may be titrated up (24mg, 32 mg doses)
 - Monthly (weeks 5-16)
 - 96 mg, may be titrated up or down (64mg, 128mg, 160mg doses)
 - Can continue up to 48 weeks if participant elects

n.b. Buvidal 160 mg doses not available in Europe

Depot buprenorphine



Eligibility - Inclusion criteria

1. Adult (male and female) prisoners (≥ 18 years old) sentenced in full-time custody
2. Demonstrating sufficient English language ability and willing to provide written informed consent
3. Sentenced for all charges, with **at least six months** remaining on sentence
4. Willing and able to comply with requirements of the study
5. Meets the criteria for opioid dependence as defined by Diagnostic and Statistical Manual of Mental Disorders – 5th Edition (DSM-5) for **moderate to severe opioid use disorder (a.k.a ICD 10 ‘dependence’)**
6. Appropriate candidate for medically assisted treatment with partial/full opioid agonist treatment as determined by the Principle Investigator

Eligibility - Exclusion criteria

1. General clinical contraindications for partial/full opioid agonist treatment (see National Guidelines for Medication-Assisted Treatment of Opioid Dependence, 2014)
2. Current, **severe medical condition** (e.g. hepatic failure or respiratory insufficiency) assessed by Principle Investigator
3. Any known hypersensitivity to methadone or buprenorphine
4. Participants with a **serious untreated psychiatric comorbidity** at the discretion of the Principle Investigator
5. Recent history of suicidal ideation or active suicidal behaviour, in the opinion of the Principal Investigator
6. **Forensic mental health patient** not guilty by reason of mental illness
7. Clinically significant laboratory abnormalities, which in the opinion of the Investigator may prevent the patient from safely participating in trial
8. History of risk factors of Torsades de Pointes heart arrhythmia (e.g., heart failure, hypokalemia, family history of long QT syndrome) or an electrocardiogram (ECG) demonstrating a clinically significant abnormality, as judged by the Investigator
9. Requires chronic use of agents that are strong inhibitors or inducers of cytochrome P450 3A4 (CYP 3A4) such as some azole antifungals (e.g. ketoconazole), macrolide antibiotics (e.g. clarithromycin), or protease inhibitors (e.g. ritonavir, indinavir, and saquinavir)
10. Currently **breastfeeding or pregnant**
11. Patients who have had an investigational new drug or device within the last 30 days
12. Patient is on his/her parole period (past earliest date of release)
13. Patient is **enrolled in a residential or intensive treatment program** (Intensive Drug Treatment Program, Intensive Sex Offender Treatment Program, Compulsory Drug Treatment Program and Drug Court Program)

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Cost consequences measures

- Time measured:
 - Corrective services time: dosing parade (collection from cells, dosing, return)
 - JH&FMHN staff time (dose preparation and administration)
- 3 arms:
 - Methadone, buprenorphine depot
 - Also a sublingual buprenorphine comparison
- Related staff (x time) costs
 - Corrective services
 - JH&FMHN staff

Recruitment sites

	Gender	Security level	Location
Metropolitan Special Programs Centre	Male	Minimum & medium	Long Bay, Sydney
Dillwynia	Female	Minimum & medium	Windsor, Sydney
Emu Plains	Female	Minimum	Emu Plains, Sydney
Cessnock	Male	Minimum	Cessnock
Shortland	Male	Maximum	Cessnock
Bathurst	Male	Minimum & medium	Bathurst
Lithgow	Male	Maximum	Lithgow
Mid North Coast	Male	Minimum & medium	Kempsey

Baseline data – total sample

	Depot BPN n=67	Methadone n= 62	Overall n= 129
Mean age, years (SD)	34 (7.5)	38 (8.6)	36 (8.4)
Male (%)	82	86	84
Australian born (%)	94	94	94
Aboriginal/Torres Strait Islander (%)	45	34	39
Did not complete high school (%)	48	68	57
History of overdose (%)	37	52	44
Drug use, last 28 days			
Non-prescribed opioids (%)	95	0	50
Methamphetamine (%)	25	8	17
Injecting drug use, any (%)	81	6	45
Diverted methadone/BPN in jail	17	15	17
Aware of 'standover' in jails	67	77	71

Discussion

- 2 different groups enrolled
 - 'Stable' on methadone – remain on methadone
 - No treatment group – high prevalence of illicit buprenorphine use (and methamphetamine use)
- Able to adequately enrol women, Aboriginal people, across range of security levels across jails
- Follow up for 16 week (main) comparison – November 2019
- Buvidal weekly and monthly now available in Australia from 1 September
 - Scale up in jails now possible – planning commenced

Possible policy implications

- Reduce risk of diversion and related violence related to sublingual buprenorphine in jails in NSW
- Time and cost savings-> increase treatment places-> increased coverage among the inmate population requiring treatment
- Increase in the availability of other clinical services in custody



