

Understanding how long-acting depot buprenorphine impacts the high-risk post-release period- Protocol for The Release Study

ADRIAN J DUNLOP^{1,2,3}, BETHANY WHITE^{3,4,5}, JILLIAN ROBERTS^{3,6}, ROBERT GRAHAM^{3,7}, NADINE EZARD^{3,8}, LISA MAHER⁹, ELIZABETH MCENTYRE¹⁰, MICHAEL DOYLE¹¹, KYPROS KYPRI², NICHOLAS LINTZERIS^{3,12}, PAUL S HABER^{3,4,5}

¹Drug & Alcohol Clinical Services, Hunter New England Local Health District; ²School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle; ³Drug & Alcohol Clinical Research & Improvement Network; ⁴Edith Collins Translational Research Centre, Drug Health Services, Sydney Local Health District; ⁵Specialty of Addiction Medicine, Faculty of Medicine and Health, The University of Sydney; ⁶Justice Health and Forensic Mental Health Network; ⁷Western Sydney Local Health District; ⁸St. Vincent's Hospital Sydney, Alcohol & Drug Service; ⁹Kirby Institute, University of NSW; ¹⁰Independent Aboriginal Researcher, NSW; ¹¹Australia Centre of Research Excellence Indigenous Health and Alcohol, Central Clinical School, The University of Sydney; ¹²Drug and Alcohol Services, South Eastern Sydney Local Health District

Presenter's email: bethany.white@sydney.edu.au

Introduction: People with opioid use disorder are at elevated risk of overdose following release from custody. Opioid agonist treatment (methadone and buprenorphine) is protective against overdose but resource intensive to administer safely in custodial settings. Long-acting depot buprenorphine (depot-BPN) has been shown to be safe with low risk of diversion in correctional settings and effective in NSW community settings. While prescription in NSW prisons is increasing, it is unknown whether depot-BPN will be as effective as methadone when people return to community-based opioid treatment. There are concerns that depot-BPN may allow patients to disengage from treatment, increasing the risk of relapse and reincarceration.

Design and Methods: The Release Study is a prospective observational multisite study that will follow opioid dependent patients released from custody and compare outcomes for patients released on depot-BPN to patients released on methadone to determine the comparative effectiveness of both forms of treatment. The primary endpoint is retention in drug treatment in the community (primary endpoint). Secondary outcomes include substance use, overdose, mortality, health service utilisation, return to custody, and the costs consequences of these interventions. As depot-BPN is being increasingly prescribed in prisons it is important and timely to understand if retention in treatment is acceptable.

Ethics and dissemination: Ethical approval will be sought from the Justice Health and Forensic Mental Health Network Human Research Ethics Committee (HREC), the NSW Population and Health Services HREC, the Hunter New England HREC, the Aboriginal Health and Medical Research Council HREC, and the Corrective Services NSW Ethics Committee.

Implications for Practice: These findings will build on emerging research regarding the positive impact of more flexible OAT programs.

Implications for Translational Research: As depot-BPN is being prescribed in prisons, especially due to recent demand for treatment during COVID-19, it is important and timely to understand if retention in treatment is acceptable (like methadone) or poor (like sublingual-BPN).

Disclosure of Interest Statement: No pharmaceutical grants were received in the development of this study. AD, PH and NL have received funding to their institutions from Braeburn Pharmaceuticals (North American partners of Camurus AB) to support a previous

community trials of Buvidal. No funds were provided directly to these individuals and none of the investigators or their families hold shares in Camurus or Braeburn pharmaceuticals or stands to make financial gains through their involvement with Camurus AB. NL has received funding for advisory boards from Mundipharma and Indivior.