

# PHARMACEUTICAL CHALLENGES OF THE QUEENSLAND PRE-EXPOSURE PROPHYLAXIS DEMONSTRATION (QPREPD) PROJECT

## Authors:

ELISSA L SUTCLIFFE<sup>1</sup>, MELINDA DE LUCA<sup>1</sup>, SARA YEGANEH<sup>1</sup>, SIMON DOYLE-ADAMS<sup>1</sup>, SANDRA DOWNING<sup>1,2</sup>, SIMONE J LUKIES<sup>1</sup>, ROSEANNE MCNELLEY<sup>1</sup>, DARREN RUSSELL<sup>1,3</sup>

<sup>1</sup>Cairns Sexual Health Service, Cairns, Australia, <sup>2</sup> College of Public Health, Medical & Veterinary Sciences, James Cook University, Cairns, Australia, <sup>3</sup>College of Medicine and Dentistry, James Cook University, Cairns, Australia

## Background/Purpose:

QPrEPd began in 2016 and now has 24 provider sites and 2231 active participants across both metropolitan and regional Queensland. The Sexual Health pharmacy team at the sponsor site, Cairns Sexual Health Service, are responsible for the procurement, distribution and management of the trial drug. Innovative and flexible solutions have been required to balance logistical and clinical practicalities to comply with trial guidelines.

## Approach:

Site initiation visits included a member of the pharmacy team who assessed the suitability of drug storage facilities, provided training on stock management and are always available to answer clinical or stock related questions. Trial drug is procured and managed by the pharmacy team and distributed to all clinical sites. Sites store the trial drug so that treating clinicians can issue directly to participants. An online stock management system was developed in REDcap, the software platform being used for all trial data. Regular self-assessment and site audits are organised by the pharmacy team to ensure trial drug is managed according to the protocol.

## Outcomes/Impact:

Key issues have included requests for deviations from protocol, loss of trial drug due to inadequate temperature control during transit and temperature breaches at sites. Temperature monitoring during transit is now required for all trial drug received or dispatched. Selection of incorrect batch numbers when issuing drug was a common issue for many sites. REDcap was modified to prompt correct selection of batch numbers and sites are notified weekly if problems are identified. Site audits have increased from annually to 6 monthly to ensure better compliance of sites with guidelines.

## Innovation and Significance:

We have demonstrated that implementing and managing a state-wide, multi-site project from a Sexual Health service has been successful, although not without considerable challenges. Prompt identification of issues and implementation of solutions that work for both clinical sites and the sponsor pharmacy team is vital.

## Disclosure of Interest Statement:

No interest to declare