Nurse-led pre-exposure prophylaxis: a non-traditional model to provide HIV prevention in a resource-constrained, pragmatic clinical trial

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Abstract. There is little evidence and no standardised model for nurse-led HIV pre-exposure prophylaxis (PrEP). In 2016, public sexual health clinics in the state of New South Wales (NSW), Australia, participating in the population-scale PrEP access trial Expanded PrEP Implementation In Communities in New South Wales (EPIC-NSW) were authorised to adopt a nurse-led model of PrEP provision in order to facilitate the rapid expansion of PrEP access to more than 8000 participants in under 2 years without additional resources. The model has been implemented successfully in public clinics in 10 of 14 local health districts, with widespread support and no serious safety events reported. With the increasing importance of PrEP as an HIV prevention tool, non-traditional models of care, including nurse-led PrEP, are needed.


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Introduction

Pre-exposure prophylaxis (PrEP) is a necessary, additional HIV prevention tool that has been recommended by the World Health Organization (WHO) for people at substantial risk of HIV infection since 2015. Across the globe, jurisdictions including the US, Australia, New Zealand, Brazil, Scotland and France have started to embed PrEP within their HIV responses.

Before PrEP was funded through Australia’s universal healthcare system in April 2018, state and territory governments facilitated uptake through PrEP ‘access trials’ as part of a comprehensive HIV response. The first and largest of these pragmatic, population-scale clinical trials was EPIC-NSW (Expanded PrEP Implementation in Communities in New South Wales), which enrolled over 8000 participants at 27 clinics between March 2016 and December 2017 in the state of New South Wales (NSW), Australia.

Countries in Africa and the UK have expanded the role of nurses in HIV care, including prescribing antiretroviral therapy (ART) for treatment and PrEP, to overcome doctor shortages and other resource limitations. There are few published studies on nurse-led models of care for HIV, despite WHO recommendations on task shifting from 2008. However, the available evidence from Africa shows that shifting HIV care from doctors to adequately trained and supported nurses does not decrease the quality of care. In Australia, prescribing of subsidised ART is restricted to specially accredited doctors.

This paper describes the innovative authorisation and use of nurse-led PrEP models in EPIC-NSW, which increased the capacity of clinics to rapidly expand PrEP access within existing resources.

Authorising nurse-led PrEP models for EPIC-NSW: a policy approach

The design of the EPIC-NSW trial has been described elsewhere. In brief, EPIC-NSW is a time-limited public health intervention funded by the NSW Government to markedly reduce HIV transmission by rapidly scaling up PrEP access to all people at high risk. The trial provided...
daily coformulated tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) with quarterly follow-up, including HIV and sexually transmissible infection (STI) testing and treatment, to all participants.

To assist participating public clinics to rapidly enrol and follow-up a large number of participants and facilitate access in regional public clinics without a doctor onsite, flexible models of care were encouraged, including nurse-led PrEP. Under this model, trained and authorised registered nurses (RN) at participating public clinics could screen, educate, clinically assess, order tests and manage results for initiation and follow-up visits. Critically, they could then supply PrEP ‘in-clinic’ to eligible participants either: (1) under a standing order; or (2) following a prescription by a doctor authorised under the study protocol (‘dispensing’). However, RNs were not authorised to prescribe PrEP for dispensing at a pharmacy.

RN are not authorised to prescribe federally subsidised ART in Australia. Although the EPIC-NSW protocol allowed for nurse-led PrEP, NSW legislation required a legal instrument issued by the NSW Ministry of Health for the model to be authorised in public clinics. Extensive consultation with key stakeholders, including senior nurses, the Chief Pharmacist, legal services and directors of sexual health clinics, ensured the legality and acceptability to professional organisations, appropriateness and safety of nurse-led PrEP. Coformulated TDF/FTC was considered an ideal candidate for nurse-led PrEP supply because the clinical expertise required is within the scope of practice for an RN working in a participating clinic, there is no dosage variation, parameters for suitable patients (and where nurse-led PrEP is not authorised) are clearly defined and monitoring and follow-up are standardised. To be authorised, RNs must be delegated responsibility by the site principle investigator, complete EPIC-NSW site training and work in a participating public clinic. In addition, a doctor authorised under the study protocol must countersign any standing orders with 24 h and review the patient’s management at least annually. The authorisation did not apply to private clinics, which sit outside NSW Ministry of Health governance. After the legal instrument was issued in December 2016, of 14 participating Local Health Districts (LHDs) adopted a nurse-led model in at least one participating clinic, with most allowing RNs to supply PrEP at follow-up but not initiation visits. In some LHDs, adoption of nurse-led PrEP required additional approval through the local drug and therapeutics committee. Some local pharmacists objected to the task shifting from pharmacist to nurses, raising concerns over scope of practice and competency. These concerns were overcome by local stakeholders and the NSW Ministry of Health, but delayed uptake in some LHDs.

Model for nurse-led PrEP

Sydney Sexual Health Centre (SSHC) adopted a nurse-led PrEP model in 2016. SSHC employs approximately three times as many nurses as doctors and sees the largest number of homosexual men of any public sexual health clinic in NSW. Nurse-led PrEP augments the sexual health and HIV prevention expertise of the nursing unit with additional training, supervision and support from the multidisciplinary team. It has allowed for efficient, accessible, convenient and cost-effective care to participants with minimal disruption to daily operations and without compromising safety or quality.

PrEP initiation

The initial 30-min consultation includes confirmation of behavioural eligibility, clinical evaluation, education and laboratory assessments, including a fourth-generation HIV antibody and antigen test following the trial protocol and local guidelines. A 1-month PrEP supply is provided at the first appointment, contingent on normal renal function and negative HIV tests. After initiation, follow-up appointments are scheduled at 1 month, month 3 and then at 3-monthly intervals.

PrEP continuation

Asymptomatic patients fluent in English are offered a 15-min ‘Xpress’ follow-up appointment with a RN at either SSHC or a peer-led, community-based testing site. The consult at either site includes a computer-assisted self-interview and a nurse assessment of adherence, side effects, current medications and ongoing behavioural risk, laboratory tests, STI prevention counselling and up to 3 months PrEP supply. Community-based sites provide additional access, including after hours, and peers deliver information, rapid HIV testing and health promotion. There is no doctor at community-based sites, so nurse standing orders are reviewed and countersigned remotely through the electronic medical record by doctors at SSHC.

Patients with symptoms, other issues requiring management or those requiring an interpreter are offered a 30-min appointment with a nurse or doctor according to SSHC scope of practice delegations. Patients must be reviewed by a doctor authorised under the study protocol at least once annually.

Interrupted or discontinued PrEP

As a real-world ‘access trial’, EPIC-NSW allows patients the autonomy to continue, stop and restart PrEP without active follow-up. At each visit, patients are provided with education about the importance of daily PrEP and offered additional support if adherence is less than optimal. Patients are sent automatic SMS reminders 2 weeks before they are due to run out of PrEP, and a missed appointment reminder is sent to anyone who has not attended a scheduled follow-up visit. A nurse-led telephone triage and walk-in service is provided for urgent access.

Patients re-presenting after a break in PrEP are reassessed and restarted on PrEP in accordance with local guidelines, with a recommendation for HIV window-period testing and additional screening or management, depending on risk.

Abnormal results and other complications

A dedicated, specially trained nurse manages all SSHC results daily. Patients testing positive for HIV or another infection and those with abnormal renal function are flagged by an electronic algorithm and urgently recalled for further assessment under clinic guidelines in consultation with a doctor. HIV and renal function results are generally reported the next day.

Patients with impaired renal function, suspected HIV seroconversion or adverse events are referred for medical
review and follow-up. Additional multidisciplinary support is available to patients with chronic viral hepatitis and other medical or psychosocial issues.

Benefits of nurse-led PrEP

The model builds on existing capacity within the nursing workforce while conserving limited doctor appointments for more complex presentations. It has the potential to increase job satisfaction for both nurses and doctors by empowering clinicians to work to their full scope of practice. Although acceptability of nurse-led PrEP has not been formally evaluated, anecdotal evidence from clinics (doctors, nurses and administrators), as well as from the community, suggests the model had broad support; indeed, clinic doctors, the community and government all advocated for its success.

Challenges of nurse-led PrEP

The adoption of a nurse-led model to rapidly expand access to PrEP for the first time in NSW required extensive scoping and planning. It involved a reorientation of existing services to provide safe, accessible and quality care that was acceptable to both patients and staff. It required new competency frameworks, training and support and, at SSHC, significant upgrades to the in-house electronic medical record to support electronic authorisation of standing orders.

Conclusions

The use of nurse-led PrEP for EPIC-NSW was instrumental in facilitating the rapid enrolment of participants and assisting clinics to embed PrEP provision and quarterly follow-up into routine service delivery without additional resourcing. Further, since its introduction there have been no serious safety events reported.

PrEP has been shown to be a safe and effective HIV prevention tool and, with the requirements for clinical care and follow-up, non-traditional models, including nurse-led PrEP, are needed to expand PrEP access. Yet, comparatively little has been published about nurse-led models of ART supply, particularly outside Africa, and there is no standardised model of nurse-led PrEP. Despite the success of nurse-led PrEP in EPIC-NSW and the significant contribution nurses make to sexual health care more broadly, there remain regulatory and other barriers to implementation as part of the universal healthcare system in Australia. The challenge is now to expand and evaluate nurse-led PrEP, including formally assessing the acceptability of nurse-led models compared with other models of PrEP provision, to build the evidence base.

Conflicts of interest

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References


