

NEW GLOBAL APPROACHES TO HIV PREVENTION

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BACKGROUND

HOLA (HIV Online Learning Australia) is a workforce development program by Health Equity Matters (formerly AFAO) and the National Association of People with HIV Australia (NAPWHA). HOLA aims to increase the knowledge and skills of staff within HIV organisations around Australia.

HOLA commissions papers investigating emerging knowledge, technology and practice to ensure Australian community practice remains at the global cutting edge and inform future strategies. This paper focuses on new international approaches to HIV prevention, particularly in high-income settings that have the elimination of HIV transmission as a goal, and their application in Australia.

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Aldo Spina has 22 years of experience as a consultant and has worked with government, health services, UN agencies and non-government organisations in Australia and developing countries. His main areas of work include evaluating health programs and services, policy, planning and strategy development, facilitation, and stakeholder engagement.



OVERVIEW OF CONTENT

The first section of this paper summarises science and medical advances in biomedical prevention and treatment, particularly injectable pre-exposure prophylaxis (PrEP) and long-acting injectables for HIV treatment, as they have many potential benefits for treatment and prevention.

The second section of this paper summarises insights that can be drawn from how HIV prevention programs have been implemented in comparable jurisdictions overseas that are working towards ending HIV transmission. In particular, it identifies how PrEP is provided in several comparable countries and strategies to increase HIV testing through HIV self-test (HST) kits. It briefly touches on early exploration of how technological advancements may complement HIV prevention programs. One gap in this section is that U=U (undetectable equals untransmittable) initiatives that could provide relevant insights into Australia were not identified during the paper's development.

The paper was informed by a desktop review of online information posted by HIV programs and organisations. A limitation of this approach is that it may not have captured programs that do not provide up-to-date information online. This was supplemented by reviewing recent conference abstracts and reports (such as Sevilla Fast Track Cities 2022 and the 24th International AIDS Conference 2022). A reference group with representatives from Health Equity Matters and NAPWHA member organisations and the consultant's professional networks suggested programs that could be included.

HIV PREVENTION IN AUSTRALIA

Australia has made significant efforts towards its national goal of ending HIV transmission. In Australia, as of the end of 2021, approximately 29,460 individuals were living with HIV.¹ Among them, an estimated 91% had received an HIV diagnosis. Of those diagnosed, 96% were engaged in care and receiving antiretroviral therapy (ART). Within the group receiving ART, 98% achieved a suppressed viral load. Overall, it is estimated that 82% of people living with HIV in Australia have achieved a suppressed viral load. Australia is probably only one of a select number of countries in the world for which the end of HIV transmission is possible. Consequently, the lessons that could be drawn from HIV prevention programs in comparable countries were mostly incremental changes.



ADVANCES IN HIV TREATMENT AND PrEP

INJECTABLE PrEP

PrEP is a highly effective HIV prevention option available in Australia as an oral tablet that can be taken daily or on-demand. However, a new development is the introduction of injectable PrEP.

Injectable PrEP using cabotegravir has been found to prevent HIV in multiple clinical trials. Two large-scale clinical trials, HPTN 083 and HPTN 084, were conducted to test the efficacy of bimonthly injections of cabotegravir as PrEP. The trials found that cabotegravir was superior to daily oral PrEP in reducing the risk of HIV transmission among at-risk cisgender men who have sex with men, transgender women who have sex with men, and HIV negative women in sub-Saharan Africa.² This is not because oral PrEP is ineffective but because injectable PrEP addresses the issue associated with adherence to taking daily PrEP. The trials were stopped early due to the positive efficacy outcomes, and both confirmed that cabotegravir is well-tolerated, has an acceptable safety profile, and can increase adherence.² The US Food and Drug Administration has approved cabotegravir as PrEP for cisgender and transgender men and women in the USA with no limitations based on the type of sex they have.

The main benefit of injectable PrEP is that it only needs to be taken every few months, rather than daily, like oral PrEP, which may improve adherence and convenience. Additionally, injectable PrEP may offer greater protection against HIV compared to oral PrEP. However, injectable PrEP has some drawbacks, such as the need for healthcare professionals to administer the injections and potential side effects, mostly pain at the injection site, but during the trial, few participants discontinued treatment due to this side effect.²

According to the PrEPARE study, long-acting injections would be the preferred form of PrEP (40%) among HIV-negative and untested/unknown men, including current PrEP users, followed by daily pills (22%), event-based dosing (19%), and implants (18%). Current PrEP users¹ were more inclined towards long-acting injections than non-users, with 51% preferring this method. However, even among non-PrEP users, non-injectable PrEP was still the most preferred option (33% among non-users).

The Therapeutic Goods Administration (TGA) approved cabotegravir as PrEP (brand name Apretude) on 11 August 2022.² It is unlikely that the full-price cabotegravir will be accessible to most people in Australia without subsidies on the Pharmaceutical Benefits Scheme (PBS). The PBS approves new medicines for public funding based on cost-effectiveness.

If taken daily, the oral PrEP available in Australia currently costs users with a Medicare card A\$360 per year for those without a concession card and A\$87.60 per year for those with a concession card. The cost of listing cabotegravir on the PBS is likely higher than that of existing oral PrEP options. The cost of the drug cabotegravir is not yet known in Australia, but a Kirby discussion paper reported that in the US, one dose costs US\$3,700, or US\$22,200 per year per individual (assuming six doses), which is approximately A\$5,500 for one dose or A\$33,000 for one year.

The Kirby paper identifies that it is unlikely that the government will be advised to approve the subsidy of cabotegravir for everyone who wants it. It is more likely that it will be proposed as an option for people who cannot take oral PrEP or those for whom withholding cabotegravir would result in a high probability of HIV transmission.

i The preferences identified in this study may reflect the men who were recruited and participated in the study, so there may be some limitations in interpretation of these preferences across all populations among these men. The analysis revealed no significant associations between current PrEP use and factors such as country of birth (Australia versus overseas) or education level.



LONG-ACTING INJECTABLE HIV TREATMENT

Long-acting injectable HIV treatment is now available in Australia. In February 2021, Cabenuva, a drug combination treatment of cabotegravir and rilpivirine, was the first long-acting injectable approved in Australia. It was added to the PBS in April 2022. Cabenuva is approved for those with an already undetectable viral load and without known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva is given as an injection every four to eight weeks.

One of the main advantages of long-acting injectable HIV treatment is that it eliminates the need for daily pill-taking and may help with adherence. It can reduce the stigma associated with HIV and provide greater convenience for people living with the virus. However, one of the disadvantages is that it requires regular visits to a healthcare provider for the injection. Between 6-12 or more appointments per year.

A combination of lenacapavir, an investigational long-acting HIV drug, and broadly neutralising antibodies could offer a twice-yearly HIV treatment, according to new findings from a small study.³ Participants received an oral loading dose of lenacapavir, two subcutaneous (under the skin) injections of lenacapavir, and an intravenous infusion of teropavimab (broadly neutralising antibodies). They were randomly assigned to receive 10mg/kg or 30mg/kg of zinlirvimab. At 26 weeks, 90% of participants in both groups maintained viral suppression. A phase II clinical trial will assess whether viral suppression can be maintained when the regimen is continued for a longer time with multiple twice-yearly doses.

Another study conducted in San Francisco found that long-acting cabotegravir and rilpivirine could be feasible options for people living with HIV who have not achieved viral suppression on oral antiretroviral therapy.⁴ Participants received monthly injections at the start, but individuals who consistently achieved viral suppression for six months could transition to receiving injections every other month. Overall, 74% of participants received their injections on time, and 55 of the 57 people with a detectable viral load achieved viral suppression. Most study participants were men reporting active substance use and unstable housing. The study researchers commented that reaching and supporting these participants required intensive resourcing. The study suggests that long-acting cabotegravir and rilpivirine may be feasible treatment options for people living with HIV who cannot achieve and maintain viral suppression with oral antiretroviral therapy.

GLOBAL APPROACHES TO HIV PREVENTION THAT CAN PROVIDE INSIGHTS FOR HIV PREVENTION IN AUSTRALIA

This section explores approaches in comparable jurisdictions to initiate PrEP for eligible individuals, promote regular HIV testing, particularly through HST kits, and how technological advancements may complement HIV prevention programs. However, generally there was limited detail publicly available regarding program outcomes. It is crucial to acknowledge that strategies may vary in effectiveness and appropriateness when working with distinct population groups, such as culturally and linguistically diverse individuals and those born overseas, with tailoring of approaches required.



THREE INITIATIVES TO INCREASE PREP INITIATION

With a similar healthcare system and regulatory environment, New Zealand has implemented two initiatives to streamline access to PrEP. In California, USA, the government has taken concrete steps to 'de-medicalise' PrEP and PEP access by passing legislation to make it available at community pharmacies.

• The Burnett Foundation Aotearoa (formerly the New Zealand Aids Foundation) provides an easy option to access PrEP online.¹ The Burnett website provides comprehensive PrEP information, but embedded within this information is a call-to-action to 'Get PrEP online for \$19.95', with the tagline emphasising 'cheap virtual PrEP appointments'. The service is for those not currently on PrEP. The service is a partnership with an online GP telehealth service, MedOnline.¹¹ Users answer six screening questions and, if eligible, are directed to the MedOnline website to book a virtual appointment. The cost to users is NZ\$19.95, as they receive a \$30 discount subsidy from the Burnett Foundation Aotearoa. The consultation includes lab test forms and forwarding the prescription to your pharmacy if the results mean you can go ahead and get PrEP. The significant advantage of this approach is that it allows people to take action immediately without leaving their homes. It reduces the time between deciding on a course of action and taking that action by making it as easy as possible.

Two private providers in Australia have established similar services. One is **PrEP.Health**ⁱⁱⁱ and the other **PrEP Connect.**^{iv} The services do not appear to be promoted by HIV NGOs, though there are links to the services on the PrEP Access Now website.

- The Body Positive in New Zealand, a peer support organisation for people living with HIV, has a PrEP initiative called iPrEP^v that commenced in May 2020. It provides immediate PrEP access (modelled on a New York program) and is delivered in partnership with a GP clinic. A quick assessment and HIV rapid test occur at Body Positive, functioning with its drop-in clinic, to check for eligibility before being provided with a PrEP starter pack. Eligible individuals are given a 10-pill starter pack for NZ\$25. To continue on PrEP, additional laboratory tests are required within 72 hours to maintain a supply of PrEP. Laboratory results are reviewed and additional payments are needed for PrEP to be couriered to your home. By September 2021, the initiative reported that 36 people had commenced PrEP.⁵ The significant advantage of this initiative is that it reduces barriers to access by enabling eligible individuals to start PrEP immediately.
- In September 2019, California became the first state in the US to pass legislation allowing pharmacies to initiate PrEP and PEP without a prescription.⁶ This was seen as an effort to remove barriers that prevent people from obtaining PrEP and PEP. Pharmacies can initiate and furnish PrEP for up to 60 days and PEP for 30 days. News reports indicated that some medical groups initially opposed the bill due to the concern of patients taking PrEP without medical supervision. The compromise to address this concern was to provide PrEP for 60 days without a doctor's prescription.⁷ One of the requirements that must be met before providing PrEP is that person must be HIV negative and documented within seven days prior. This can include laboratory HIV tests or rapid HIV tests. If a test has not occurred in the past seven days, a point-of-care fingerstick blood test can be administered in the pharmacy. Before providing access to PEP, pharmacies assess that the HIV exposure occurred within the past 72 hours and that the patient meets clinical eligibility for PEP consistent with guidelines. The San Francisco Department of Health recommends that pharmacists notify the patient's primary care provider unless the patient does not have one or refuses to consent. In this case, the pharmacist provides a list of physicians and clinics for PrEP and PEP.
- i https://www.burnettfoundation.org.nz/learn/staying-safe/prep/cheap-virtual-prep-appointments
- ii https://medonline.co.nz
- iii https://prep.health you complete a form, pay for your evaluation (\$39.99), and are referred to pathology.

iv https://www.prepconnect.com.au – you book an online appointment with a nurse practitioner, receive a digital pathology form (used at any pathology service).
 Once the results are reviewed, you are sent a script that can be used at a community pharmacy. The initial consult is \$60 (\$24.30 out-of-pocket after the Medicare rebate).
 v https://bodypositive.org.nz/PrEP



INCREASING UPTAKE OF HIV TESTING THROUGH THE USE OF HIV SELF-TESTING KITS

Overview of HIV self-testing in Australia

The National HIV Strategy aims to increase the frequency and regularity of HIV testing. In April 2019, an HST kit (Atomo) was approved for use in Australia, a valuable addition to HIV testing options. The TGA eased initial restrictions on the distribution and advertising of the kits in October 2021, allowing the kits to be purchased in community pharmacies, removing requirements to watch an instructional video and changing advertising permissions.

The uptake of HST is still reasonably low in Australia. In 2022 the Sydney Gay Community Periodic Survey reported that 3% of non-HIV-positive participants had used an HIV self-test in the previous 12 months and 2.5% in the Melbourne Gay Community Periodic Survey.^{8,9} This presents an opportunity to consider how access and use of HST kits could be expanded.

Research has found that gay and bisexual men prefer accessing kits from online distributors or community pharmacies, with getting kits from the staff at community organisations and sexon-premises-venues less preferred.¹⁰ The research found participants preferred free or cheap oral tests and that cost was more important for men born in countries with non-reciprocal healthcare agreements with Australia.

Research has reported that HST kits particularly appeal to infrequent and first-time testers.¹¹ Among men born overseas, they were three times as likely to want to use self-testing as those born in Australia. The paper highlighted that this might be due to the financial burden of HIV testing (if they are without health insurance), limited knowledge of HIV testing facilities, cultural stigmatisation linked to HIV diagnoses, and concerns about being judged by healthcare providers. Given the high rate of late diagnosis for overseas-born men who have sex with men, promoting HST kits should be a greater focus in our HIV prevention strategy.¹² Research has emphasised the importance of TGA approval for an oral-based HIV self-test kit.¹² Currently, no oral-fluid rapid test for self-testing in Australia is regulatory approved. Uptake of HST has probably been low in Australia due to limited test choice, availability, lack of advertising and cost.¹²

Currently, the main options to obtain an HST kit in Australia are:

- Atomo online purchase:ⁱ HST kits can be bought online for \$40.99 from the manufacturer, Atomo, and include shipping and handling costs and GST.
- ACON you[TEST]:ⁱⁱ A peer educator provides a 30-minute video appointment outlining the testing options for free Atomo HST or dried blood spot testing (self-collection sample the client sends to a laboratory for testing), with the preferred kit posted to the client.
- SAMESH/Thorne Harbour Health CONNECT Vending Machines:ⁱⁱⁱ Five vending machines in Adelaide distribute HST kits for free targeted at students from culturally and linguistically diverse backgrounds after answering four questions.^{iv}
- Queensland Positive People Rapid:^v After answering several demographic and HIV testingrelated questions, users can watch an instructional video before a kit is posted, with a choice to speak to a peer before or after the test, and the service contacts users for their results.
- Community pharmacies and HIV organisations: Respondents can obtain an HST kit from community pharmacies and HIV organisations, with 53 sites currently listed on the Atomo website. However, availability is limited in some areas, with only four pharmacies listed in Queensland and eight in Victoria.

i intepo.,/ initialitapia.org.do



i https://www.atomodiagnostics.com/products/hiv_tests

ii https://endinghiv.org.au/test-often/book-a-test-at-youtest

iii https://samesh.org.au/connect-free-hiv-test-kits iv https://healthequitymatters.org.au/article/connect-hiv-self-testing-in-the-community/

v https://neaitnequitymatters.org.av

Key insights from the online distribution of HST kits in other jurisdictions

- Users must answer demographic and screening questions to ensure eligibility before accessing an HST kit. Example: I'm Ready to Know (Canada)ⁱ requires users to create a profile and answer survey questions before receiving up to three HST kits.
- Many HST kits are provided free of charge. Example: Take Me Home (USA).ⁱⁱ provide free HIV and STI tests with users asked a few questions to see if they are eligible and if yes, they can order their kit in less than five minutes. An exception to the free provision of kits is Terrence Higgins Trustⁱⁱⁱ (UK), which allows you to order online (A\$26) but only offers free kits in specific geographic areas where they are locally funded.
- Reporting test results are sometimes required or encouraged, and different approaches to
 providing support exist. Example: HIV Self-Test (HIV Scotland)^v allows users to enter their results
 online and request support if needed. However, Get a Kit (Ontario, Canada)^v users register to
 access the service and participants are encouraged to report their results by logging into their
 accounts. If they report a positive result, the service will contact them to discuss the next steps.
- Services do not require contact with program staff or peer workers to access the kit, allowing users to maintain privacy and control over the testing process, but often have this option available if requested by the user. Example: I'm Ready to Know has an option available to speak to a peer navigator at any point.
- Services provide users with a choice of HST kit, such as oral or blood; occasionally, they offer self-collection kits (with blood samples sent to a laboratory for testing). Example: Terrence Higgins Trust users can choose blood or oral test. Test Now, Stop HIV (56 Dean Street London sexual health clinic)^{vi} users are provided with a self-collection kit and return their samples by post, with test results arriving by text several days later. In a previous service (Dean Street Express), if clients are symptom-free, they could use a touch screen, collect a self-test kit and move to a private booth to collect their samples and then use a vacuum chute to send the samples to the onsite laboratory, and again test results by text, within six hours.^{vii}
- Various delivery options are available, including home delivery or pickup at a designated location. Example: Test Now, Stop HIV allows users to order a free home sampling kit that can be delivered by post or picked up.
- All programs identified during the review have good online and easy-to-use online websites; one initiative uses an app to manage orders and report results. Example: I'm Ready to Know has an information website but requires users to download an app to order tests.

- i https://www.readytoknow.ca
- ii https://takemehome.org
- iii https://test.tht.org.uk
- iv https://www.hiv.scot/test/self-test

vii https://www.youtube.com/watch?v=X39ih4mD88I



v https://getakit.ca/ontario/ vi https://www.testnowstophiv.com

USING TECHNOLOGY TO COMPLEMENT HIV SOCIAL MARKETING CAMPAIGNS AND SUPPORT SERVICES

HIV organisations in Australia have been at the forefront of using technology to prevent HIV transmission. One practical example is how HIV social marketing campaigns have incorporated advertising on mobile apps and social media, produced short and long-form videos for social media, and developed interactive website tools. Another technology development that has shown potential for complementing HIV prevention messages and supporting services is using chatbots, which are conversational agents that can provide automated support to users.

Chatbots have gained momentum recently due to improvements in artificial intelligence and natural language processing, as well as the availability of off-the-shelf technologies that make it easy and inexpensive to deploy them.¹³ One advantage of chatbots is that as technology improves, they can offer a more personable, accessible, and efficient service. In this context, the ChatGPT chatbot has generated excitement for its ability to provide knowledgeable answers on various topics, including mental health support.¹⁴ One recent study found that ChatGPT responses to patient questions were preferred over doctors' responses and rated significantly higher for quality and empathy.¹⁵

While there is still limited research on using chatbots in HIV prevention, studies have suggested that they can aid in sex education, provide information about STIs, and offer pre-test counselling before using HST kits.¹⁶ However, one limitation of chatbots is their lack of empathy compared to a human counsellor.¹⁷ Nonetheless, reviews of chatbots in healthcare have reported positive evaluations, citing their effectiveness, accuracy, and acceptability.¹⁸

Several examples of chatbots in HIV prevention include: the US Department of Health and Human Services chatbot on Facebook Messenger to help manage its communication during the International AIDS Conference in 2018;¹⁹ UNESCO's chatbot named Eli in 2020 that can answer young people's questions about HIV, health and relationships in eastern Europe and Central Asia;²⁰ and the recent launch of the HIV.gov chatbot tool where users can search for HIV information by asking questions and conversing with the chatbot.¹

While Australian HIV prevention websites do not currently offer chatbot services, it is an area that has potential for development but requires further investigation, including consideration of privacy, data protection and how it can be deployed in a manner that is acceptable to community members.

A CONDOM PROGRAM WITH A NOVEL APPROACH

With advancements in biomedical prevention, there has been a significant shift in focus on PrEP and treatment as prevention. However, one condom promotion program to highlight is The Ending HIV Condom Toolbox (Burnett Foundation Aotearoa). It aims to ensure condoms fit correctly so they are more comfortable and less likely to break. A free package is available to gay and bisexual men and transgender individuals aged 16-20 in New Zealand, containing 12 condoms of various sizes and materials, different lubricants, printed resources, and a fleshlight masturbation sleeve. An online tool, the Ending HIV Condom Masturbation Trainer, can guide users through trying different condoms to find the correct fit. It offers an interactive experience where viewers interact with a 'live' model who masturbates with the user and exploring different condom options until they find the best fit. The user can then receive more of the preferred condom for free.

i bot.HIV.gov



CONCLUSIONS – CONSIDERATIONS FOR HIV PREVENTION IN AUSTRALIA

- It is crucial to acknowledge that strategies may vary in effectiveness and appropriateness when working with distinct population groups, such as culturally and linguistically diverse individuals and those born overseas, with tailoring of approaches required.
- The affordability and accessibility of new long-acting treatment and prevention options should be supported through policy and advocacy efforts to provide individuals with choices that align with their needs.
- Exploring novel strategies to enhance accessibility and reduce the medicalisation of PrEP and PEP could involve initiating PrEP and PEP at community pharmacies or providing starter packs at HIV testing sites.
- Enhancing online platforms for HIV prevention by investigating suitable partners for collaboration to incorporate 'get PrEP online now' options to expand access to this preventive measure further.
- Increasing the availability of HST kits through additional distribution channels and pick-up locations, exploring options that minimise contact with staff or peers to improve privacy, accessibility and convenience.
- Establishing clear criteria and assessment tools for providing free HST kits to individuals facing financial constraints, first-time testers or irregular testing patterns, such as prioritising gay and bisexual men who have recently migrated to Australia, can ensure equitable access.
- Implementing comprehensive social marketing campaigns, leveraging various channels, to effectively promote HST kits and access options and improve their uptake among diverse populations.
- Investigate the feasibility of using chatbot technology within HIV prevention websites to support access to information and links to relevant services.



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HIV ONLINE LEARNING AUSTRALIA A program by Health Equity Matters and NAPWHA