# Innovative oral PrEP service delivery models and the policy, legal, and regulatory barriers to their implementation

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on behalf of the NSW HIV PRISM Partnership

UNSW Kirby Institute

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HIV PRISM PARTNERSHIP

**Acknowledgement of Country**

We acknowledge the Traditional Owners and their custodianship of the lands on which the University of New South Wales and all our participants live and work. UNSW is located on the unceded territory of the Bidjigal (Kensington campus), Gadigal (City and Paddington campuses) and Ngunnawal peoples (Canberra), who are the Traditional Owners of the lands where each campus of UNSW is situated. We pay respect to all Aboriginal and Torres Strait Islander peoples, the First Australians, whose lands, winds, and waters we all now share. We also pay respect to their unique values and their continuing and enduring cultures, which deepen and enrich the life of our nation and communities.

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# Acronyms

| | |
|---|---|
| **ART** | Antiretroviral therapy |
| **ARTG** | Australian Register of Therapeutic Goods |
| **CAB-LA** | Cabotegravir long-acting injectable PrEP |
| **ED-PrEP** | Event-driven PrEP (also known as PrEP on-demand) |
| **EPIC-NSW** | Expanded PrEP Implementation in Communities-New South Wales study |
| **F/TAF** | Emtricitabine/tenofovir alafenamide |
| **GBMSM** | Gay, bisexual, and other men who have sex with men |
| **LHD** | Local Health District |
| **MBS** | Medicare Benefits Schedule |
| **PBAC** | Pharmaceutical Benefits Advisory Committee |
| **PBS** | Pharmaceutical Benefits Scheme |
| **PoCT** | Point-of-care test (also known as a 'rapid' test) |
| **PrEP** | Pre-exposure prophylaxis |
| **TD*/FTC** | Tenofovir disoproxil/emtricitabine (TD* is used to represent tenofovir disoproxil fumarate and other biosimilar molecules)[1] |
| **TGA** | Therapeutic Goods Administration |

# Executive summary

To ensure HIV pre-exposure prophylaxis (PrEP) is accessible to all, it is imperative that the Australian HIV response be informed by the global shift towards more person-centred, innovative models of oral PrEP service delivery.[2]

This report provides an overview of innovative PrEP service delivery models, and considerations for their implementation in Australia. The report complements and expands on the findings presented in the 2023 report produced by the federally-established HIV Taskforce.[3]

Cost can be a significant barrier to PrEP access, particularly for those who are ineligible for subsidised healthcare.[4-6] Individuals can currently reduce these costs by sourcing medication through online overseas suppliers (personal importation), and utilising publicly funded sexual health clinics; however these avenues have their own access barriers.[7, 8] Costs could be further reduced by: enabling the issue of 60-day PrEP prescriptions, implementing 6-12 month PrEP follow-up consultations, expanding coverage and capacity of publicly funded sexual health services, increased promotion of personal importation as a cost-efficient source of PrEP, seeking additional funding from government, and promoting the use of non-daily regimens by amending the government licensing documents of PrEP medications.[3, 9, 10]

Shifting tasks from medical practitioners to other healthcare workers could increase service reach, capacity, and cost-effectiveness; in conjunction with appropriate clinical oversight, clearly defined protocols, and additional training and education.[3, 11-13] Registered nurses in NSW have recently been permitted to supply PrEP without a prescription; however, for this model to be scaled up and implemented state-wide, a sustainable payment model needs to be developed.[14] Pharmacists cannot supply PrEP without a prescription; however, there are trials being conducted in NSW and other states allowing other medications to be supplied this way.[15] Peers also cannot supply PrEP; however peer-led sexual health testing services are an example of the important role peers can play in service delivery, and other peer-led opportunities should be explored further.[13, 16, 17]

New technologies – such as telehealth, HIV point-of-care tests, HIV self-tests, and self-collected sample kits – can streamline routine PrEP consultations in clinical and non-clinical settings.[2] Telehealth services are already being used widely in Australia.[18] The sustainability of private PrEP telehealth models can be supported by making time-limited MBS items permanent.[3] The reach of public telehealth PrEP models could be increased with additional funding.[19] HIV point-or-care tests (PoCTs), HIV self-tests, and self-collected sample kits can simplify testing; however, self-tests and PoCTs are not as sensitive as laboratory tests when detecting recent HIV infections or infections acquired after commencing PrEP.[20-26] Creating Medicare Benefits Schedule (MBS) items would support integrating these devices into PrEP service delivery models.[1, 3]

## Recommendations:

1. Reduce the cost of PrEP and associated consultation and pathology fees, particularly for Medicare-ineligible individuals. HIV Taskforce Recommendation #1
2. Increase the time between PrEP follow-up appointments to 6-12 months to reduce consultation and testing costs for all individuals. HIV Taskforce Recommendation #2
3. Implement 60-day PrEP prescriptions to reduce medication costs for Medicare-eligible individuals.
4. Develop a state-wide model that enables registered nurses to supply PrEP in publicly funded sexual health services. HIV Taskforce Recommendation #3
5. Explore the feasibility and potential impact of pharmacy-led and peer-led models. HIV Taskforce Recommendation #3
6. Establish, fund, and support the expansion of public and private telehealth PrEP services.
7. Retain MBS telehealth items that exempt sexual and reproductive telehealth consultations from needing a previous in-person consultation with patients to be eligible for MBS subsidy. HIV Taskforce Recommendation #7
8. Explore the viability of using point-of-care tests, HIV self-tests, and HIV and STI self-collected sample kits to initiate and continue PrEP use.
9. Create MBS items for HIV point-of-care testing devices and consultations to ensure their feasible integration in testing and PrEP service delivery models. HIV Taskforce Recommendation #10
10. Advocate for the amendment of Australian Register of Therapeutic Goods TD*/FTC listings to include event-driven PrEP.

Our recommendations to policy makers, researchers, and other HIV sector workers reaffirm and build on those presented by the HIV Taskforce.[3]

# Introduction

Australia's response to the HIV epidemic in the 1980s was world leading.[27] It involved partnering with key population groups, investing in research and surveillance, decriminalising sex work and homosexuality, establishing needle and syringe programs, and providing access to safer-sex tools (e.g. condoms) and testing and (later) treatment services.[27]

A major advancement since 2016 has been the introduction and then scale-up of pre-exposure prophylaxis (PrEP), a highly effective biomedical HIV preventative.[28] PrEP has contributed to a decrease in HIV diagnoses over the last decade, and is seen to be a powerful tool to help meet the government's goal of ending HIV transmission by 2030.[29, 30]

However, the decrease in diagnoses has not been shared equally across the population. There are still disparities, with smaller decreases seen in gay, bisexual, and other men who have sex with men (GBMSM) born overseas, women, and those living outside of inner-city areas.[29]

From 2018 to 2023, over 30,000 individuals in NSW have been dispensed PrEP through the Pharmaceutical Benefits Scheme (PBS).[31] But uptake remains lower among GBMSM living outside of inner Sydney, younger GBMSM, men who have sex with men who do not identify as gay or bisexual, and some overseas-born GBMSM.[32, 33] Uptake of PrEP among women is low (2% of all prescriptions), and surveillance data of PrEP use among trans and gender diverse communities is lacking.[34]

The drivers of HIV diagnoses and PrEP use disparities are multifaceted. For individuals these include stigma, cost, lack of PrEP knowledge, limited access to low-cost or free public sexual health services, and limited access to PrEP prescribers.[4-7, 35-39] To address healthcare access barriers there has been a global shift towards more person-centred, differentiated models of healthcare delivery.[2] Differentiated service delivery commonly involves tailoring four key components to meet the needs of individuals: where the service is located, who is providing the service, service frequency, and what innovation is being implemented.[2]

To ensure we continue to provide a world-leading HIV epidemic response for all, we should consider how learnings from national and international innovative, patient-centred healthcare models can inform our local response.[40] This report explores examples of these models, and how they may be implemented to increase access to PrEP. These include models that reduce or remove cost barriers, shift tasks from medical practitioners to other healthcare workers and trained key population peers, leverage telecommunication tools to shorten PrEP appointments and increase access and convenience, and technologies that simplify diagnostic testing.[41] While this report focuses on policies, legislation, and regulations that influence PrEP access in NSW, many findings are likely to be relevant to other Australian jurisdictions.

This report complements and expands on the findings of the 2023 HIV Taskforce report, which provides guidance on how Australia can virtually eliminate HIV acquisition by 2030.[3]

# Research design and methodology

A working group of professionals from the health, research, and community sectors was established to provide direction and feedback on the content of this review. The topic areas explored included:

- The current policy, legal, and regulatory environment governing the provision of PrEP in NSW.
- Case studies of medication provision programs in Australia that differ from standard practice, which could inform the design of innovative PrEP service delivery models. These included s100 medication programs, STI treatment in publicly funded sexual health services, pharmacy-led medication trials, telehealth models, point-of-care testing programs, and HIV self-testing vending machine trials.
- Innovative PrEP service delivery models that have been implemented in Australia and internationally.
- Barriers to implementing these models presented by the NSW policy, legal, and regulatory environment, and how these barriers may be addressed, were also explored.

While there are many definitions for the term 'policy', in this report we conceptualise it as the guidelines and principles adopted by governments or organisations to guide decision-making processes (e.g. Australian PrEP Guidelines).[1, 42] We refer to 'legislation' as the bills passed in both state and federal parliaments that become law, in the form of Acts and statutory instruments (e.g. Therapeutic Goods Act 1989 (Cth)).[43] The term 'regulation' is used in this report to refer to the statutory instruments that government agencies and regulatory bodies use to specify rules or requirements (e.g. Poisons and Therapeutic Goods Regulation 2008 (NSW)).[43, 44]

A preliminary review of literature was conducted, and involved searching for journal articles and grey literature (Australian and NSW legislation, health policies, clinical guidelines, and news articles). Additional data were then collected by conducting semi-structured interviews with six key informants. Selection criteria for key informants were based on their professional background. Eligible key informants included GPs, sexual health physicians, nurses, pharmacists, state and federal health department staff, Primary Health Network staff, Local Health District staff, non-government organisation staff, community sector workers, research sector stakeholders, intergovernmental organisation staff, professional body staff, and other relevant stakeholders. Findings from the interviews were used to direct the collection of additional data, which were integrated into the final version of the review.

# Policy, legal, and regulatory context

In this section of the report, we first contextualise how access to medication is determined by the Australian policy, legal, and regulatory environment, and outline the mechanisms that are in place to support community members to obtain affordable and essential medication. We also include information about how private medical services, such as consultations and pathology tests, are subsidised. An overview of how medication is accessed and subsidised in Australia is illustrated in Figure 1. We then discuss how the policy, legal, and regulatory environment shapes the way individuals obtain PrEP. An overview of how PrEP is accessed and subsidised is illustrated in Figure 2.

## Access and supply

### Australian Register of Therapeutic Goods (ARTG)

Established by the Therapeutic Goods Act 1989 (Cth) as part of the Australian Government Department of Health and Aged Care, the Therapeutical Goods Administration (TGA) is responsible for regulating the supply, importation, exportation, manufacturing and advertising of therapeutic goods, including medicines and medical devices, in Australia.[45] The sponsor (the importer, exporter, manufacturer, or a third party that arranges for any of these three activities to occur) can apply to the TGA to have the therapeutic good approved for use in Australia or for export. This application is required to include information such as the efficacy of the drug, dosing requirements, drug interactions, and other safety information.[46] The Advisory Committee on Medicines is the independent committee that provides the Minister for Health and Aged Care and the TGA advice on these applications, as well as other therapeutic goods that have already been approved for use in Australia.[47] If approved, the therapeutic good is listed in the Australian Register of Therapeutic Goods (ARTG). Sponsors can follow a similar process to amend a listing.

### Scheduling

Some medicines and other chemicals are deemed to need further regulatory safeguards to protect public health and safety. These substances are classified into Schedules 1 to 10, with regulations restricting access generally corresponding to an increase in schedule number, as stipulated in the Therapeutic Goods Act 1989 (Cth).[48] The substances are listed and regularly updated in the Poisons Standard (Cth); however, this needs to be ratified by each state to take effect. In NSW, it is ratified through the Poisons and Therapeutic Goods (Poisons List) Proclamation 2016 (NSW), under the Poisons and Therapeutic Goods Act 1966 (NSW).[49] The most relevant schedules of substances for this review are Schedules 2 (also known as pharmacy-only, off-the-shelf medication), 3 (also known as pharmacy-only, over-the-counter medication), and 4 (also known as prescription-only medication). Schedule 3 substances can also be listed under Appendix M of the Poisons Standard (Cth.), requiring pharmacists to meet additional safeguards before supplying medication to the patient. Appendix M has not yet been utilised by the government. When applying to register a drug with the TGA, the applicant can suggest which schedule the drug should be listed in. An applicant can submit a separate application to reschedule a drug. However, a strong case would have to be made as to why this drug meets the criteria for an alternative schedule.[50] Examples of schedule criteria can be seen in Table 1.

**Table 1:** Criteria for classifying schedule 3 and schedule 4 medication.[50]

| Schedule 3 Criteria | Schedule 4 Criteria |
|---|---|
| 1. The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately. | 1. The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention. |
| 2. The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at supratherapeutic doses. Where risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist-consumer consultation. | 2. The use of the substance requires adjunctive therapy or evaluation or specialised handling for administration. |
| 3. The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist. | 3. The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use. |
| 4. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber. | 4. The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance. |
| 5. The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition. | 5. The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical, veterinary or dental intervention to minimise the risk of using the substance. |
| Note: Additional controls over access and training for drugs in Schedule 3 may be required by medications listed in Appendix M of the Poisons Standard (Cth.).<br><br>Appendix M is intended for drugs that have the potential for severe and irreversible injury without the user being aware of exposure or where the pattern of use of the drug poses a significant risk from direct or indirect public exposure. | 6. The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner. |
| | 7. The use of the substance has contributed to, or is likely to contribute to, communal harm. |
| | 8. The experience of the use of the substance under normal clinical conditions is limited. |

## Prescribing, dispensing, and supplying

Each state in Australia regulates who can prescribe, dispense, and supply medication within their borders. The Poisons and Therapeutic Goods Act 1966 (NSW), and its associated Poisons and Therapeutic Goods Regulation 2008 (NSW), allow medical practitioners, nurse practitioners, midwives, dentists, optometrists, podiatrists, and veterinary practitioners to prescribe medication in NSW (if within their scope of practice). Dispensing involves "the review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient."[51] Generally, Australian pharmacists can only dispense prescriptions, including interstate prescriptions, provided the information in the prescription conforms to the legal requirements of the state the medication is being dispensed in.[51] The Poisons and Therapeutic Goods Regulation 2008 (NSW) also allows the NSW Secretary of Health to produce an authority to allow prescribers and other persons, as authorised by the

Secretary of Health of NSW, to supply Schedule 4 medications directly to their patients in specific circumstances without a prescription. Some of these unique cases are explored in this report, and include the supply of STI treatment and PrEP in publicly funded sexual health services, the supply of naloxone by non-government organisations, and the supply of low-risk oral contraception by pharmacists. Supplying medication through these mechanisms is not classified as dispensing.[51]

# Subsidisation

State and federal governments subsidise many aspects of healthcare in Australia. These include: free, publicly funded hospital services (state-funded); access to subsidised private hospital services (federally funded); access to subsidised health professional services provided by private practitioners through the Medicare Benefits Schedule (federally funded); and access to medication at a subsidised cost through the Pharmaceutical Benefits Scheme (federally funded).[52] Generally, Australian citizens, permanent residents, and visitors from countries that have a reciprocal healthcare agreement with Australia can access government-subsidised healthcare.[53]

## Medicare Benefits Scheme

Australia's universal health insurance scheme, Medicare, was established in 1984, under the Health Insurance Act 1973 (Cth).[52] The Medicare Benefits Schedule (MBS) contains a list of services administered by private practitioners for which patients can be reimbursed for.[52] The Medication Services Advisory Committee, an independent advisory body, provides recommendations to the federal Department of Health and Aged Care regarding new medical services proposed to be listed on the MBS. The MBS Review Advisory Committee, another independent committee, reviews and provides recommendations to amend MBS listings.[52, 54] MBS listings stipulate the amount the federal government will subsidise healthcare consultations, procedural/therapeutic services, and diagnostic services (such as pathology tests). The MBS lists the 'schedule fee', the rate of which the Medicare benefit for each of these services will be calculated: 100% of the scheduled fee for general practitioner services, 85% of the scheduled fee for other out-of-hospital services, and 75% of the schedule fee for in-hospital services for private patients. Whilst the federal government sets the schedule fee, private health professionals providing these services set their rates. The MBS will only reimburse patients the amount as determined by the MBS, meaning there may be a gap between it and the actual private service fee the patient will need to pay. An example of this shortfall between the MBS and private healthcare practitioner fees can be seen in the growing number of general practice clinics charging a gap fee to their patients.[55] Medicare-ineligible patients are not able to access reimbursement through the MBS and so are required to pay the full-service fee, which can present a financial barrier to healthcare access.[4, 56]

## Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS), established by the National Health Act 1953 (Cth), is a federally funded program that provides free and subsidised medication to Medicare-eligible people.[57] For medications to be subsidised under the PBS, they must be recommended to the Department of Health and Aged Care by the Pharmaceutical Benefits Advisory Committee (PBAC; an independent committee comprised of clinicians, economists, and pharmacists).[57] PBAC conducts a cost-benefit analysis and can only recommend that a medication be included in the Pharmaceutical Benefits Schedule if the proposed restrictions and formulation are within the scope of the drug listing found on the ARTG.[57]

Most medications available through the PBS fall under the general schedule (section 85 of the National Health Act 1953 (Cth), or s85); however, some medications are also subsidised under special arrangements (section 100 of the National Health Act 1953 (Cth), or s100). It is important to note that while medications subsidised under s85 require a co-payment, some medications subsidised under s100 do not (such as those in Case Studies 1 and 4). Eligible medications can be subsidised through the PBS, under s85, if prescribed by medical practitioners, or nurse practitioners/midwives/optometrists (within their scope of practice), and dispensed by pharmacists. Medications subsidised through s85 are further stratified into three categories, indicating in what circumstances the medicines will be subsidised:

1. Unrestricted benefits: no restrictions on the subsidised prescription of these medications.
2. Restricted benefits: these medications are only subsidised when they are prescribed for specific therapeutic uses or when a patient meets certain criteria, as noted in the medication's listing on the Pharmaceutical Benefits Schedule.
3. Authority-required benefits: like restricted benefits, these medications are only subsidised when they are prescribed for specific therapeutic uses or when a patient meets certain criteria, as noted in the medication's listing on the Pharmaceutical Benefits Schedule. These prescriptions need prior authorisation via telephone or in writing from Services Australia or the Department of Veterans' Affairs. Alternatively, some medications have been permitted to be provided by 'streamlined authority', where prescribers only need to record a known authority code on the authority prescription. These medications have additional reporting, filing, and tracking requirements for the prescriber and Services Australia/Department of Veterans' Affairs.

### Pharmacies

Prescriptions for PBS-subsidised medications are generally filled at community pharmacies. The Australian Government and drug manufacturers negotiate the cost of the medication supplied through the PBS, and the customer pays the medication cost and pharmacy dispensing fees up to the maximum co-payment amount. If the price of dispensing the prescription is above the maximum co-payment amount, the government reimburses the pharmacy for the remaining balance. The maximum co-payment for s85 medications in 2024 was $31.60; Pension Concession Card, Veteran White Card, and Health Care Card holders (for those who meet social welfare requirements) can access these medications at a further subsidised rate ($7.70).[57] Aboriginal and Torres Strait Islander community members who qualify for the 'Closing the Gap' initiative can also have their co-payment reduced to $7.70, or to $0 if they qualify for a Health Care Card. If individuals are ineligible for Medicare, or if the PBS does not subsidise a medication, Medicare-ineligible individuals can still have their prescription filled as a 'private prescription'. The private prescription price is set by the pharmacy and is influenced by the price at which the pharmacy purchases the drug from the supplier.

When a pharmacy processes a prescription to dispense medicine, a dispensing fee forms a part of its total price. If pharmacists are dispensing a PBS-eligible medication where the price is below the co-payment they can also charge other fees agreed to by the government, up to the fee limit or co-payment amount (whichever comes first).[58] In 2023, the Australian Government increased the prescription limit for certain medications to 60 days (previously 30 days).[9] This change allowed those who were Medicare-eligible to obtain two months' worth of PBS-subsidised medication for the maximum co-payment amount or less, avoiding incurring multiple dispensing fees for the same quantity of medication and potentially reducing overall medication costs.

### Personal Importation Scheme

Individuals can import most medicines from overseas suppliers (usually online pharmacies) under the 'Personal Importation Scheme', including those not listed on the ARTG.[59] The scheme was established through an exemption provided in the Therapeutic Goods Regulation 1990 (Cth).[59] Medications sourced this way are not eligible for PBS subsidy. However, overseas suppliers may offer the medication at a lower cost when compared to what is available locally, even with a PBS subsidy. This might make the scheme an appealing avenue for Medicare-ineligible individuals to obtain medication. However, accessing medication using the personal importation scheme presents other barriers, such as a lack of awareness of the scheme, complicated ordering processes, significant upfront costs for bulk medication purchasing, and delays in medication delivery.[8] While medications sourced this way can be safe and effective, this cannot be guaranteed. The Therapeutic Goods Regulations 1990 (Cth), sets out the conditions under which a drug can be imported into Australia: they must comply with customs and quarantine law and cannot be an injectable drug (except for insulin) or other prohibited substance; a maximum of three months' supply per import can be ordered (with no more than 15 months of medication ordered over 12 months); and the purchaser must hold a valid prescription for the imported drug if it is a prescription-only medication in Australia.[8]

Under the Therapeutic Goods Act 1989 (Cth.), permission must be sought from the TGA before advertising medication used for serious diseases that are not self-treatable.[8] The meaning of the term 'advertising' in this act was broadened in 2018. It now includes "any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods." This includes healthcare providers or organisations recommending, outside of a private medical consultation, or advertising the sourcing of medications through the personal importation scheme.[8] An example of permission to advertise being granted by the TGA was that given to the Australian Federation of AIDS Organisations (now Health Equity Matters) and its member organisations for PrEP in 2020; any advertisement of PrEP beforehand was in breach of the Act.[8, 60]

### Public hospitals

NSW Health allocates funds to Local Health Districts (LHDs) to provide free or subsidised medical services to individuals, usually through hospitals.[61] NSW Health funding also allows medicines to be supplied for free or subsidised at these hospitals, at the discretion of the LHD or NSW Health; otherwise, a prescription can be provided to be filled at the individual's pharmacy of choice. Free sexually transmissible infection (STI) and HIV testing services provided at publicly funded sexual health services throughout NSW are an example of this.[61] NSW Health has made it a priority to provide this service to individuals, regardless of Medicare eligibility, for free. These services do not claim PBS or MBS reimbursement for medications or services provided, as this would mean the public healthcare services would be funded twice (once through the state health system and once through the federally funded MBS/PBS). Therefore, these clinics are dependent on the level of funding allocated to their service by their LHD, and so may need to prioritise those who are most at risk of STIs and HIV, and who experience access barriers to sexual healthcare services.

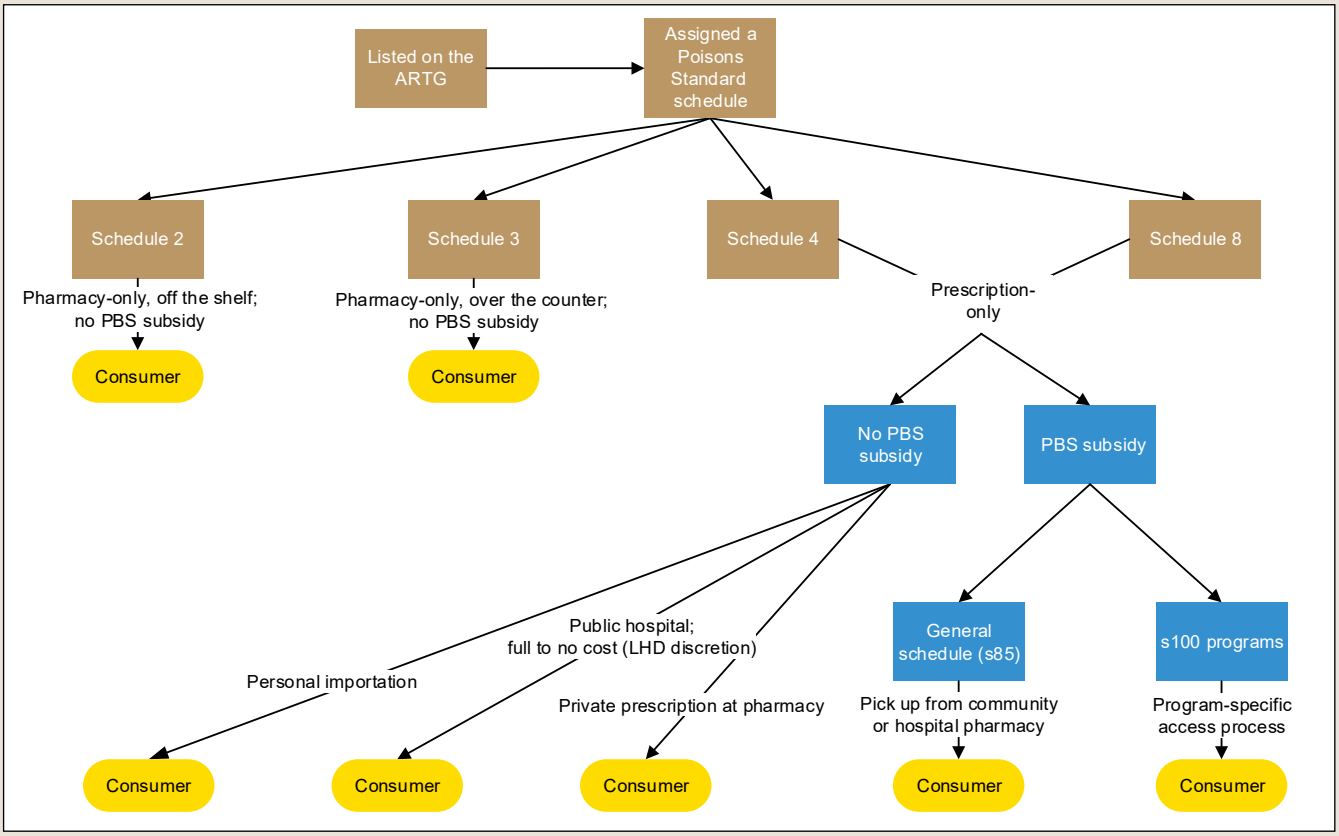


**Figure 1:** A general overview of how medication is accessed and subsidised in Australia.

# Pre-exposure prophylaxis

## Being prescribed PrEP

In Australia, tenofovir disoproxil fumarate/emtricitabine and bioequivalent drugs (TD*/FTC) are approved for daily oral use in the ARTG, listed as a prescription-only medication (Schedule 4) in the Poisons Standard (Cth), and are subsidised through the general schedule of the PBS.[1]

Clinical guidance for healthcare providers is provided through the Australian PrEP Guidelines, and the accompanying clinical decision-making tool. The guidelines include guidance for determining the suitability of PrEP for patients, testing and monitoring requirements, endorsed dosing regimens, and information about how patients can safely cease PrEP use.[1] The endorsed dosing regimens include daily pills and on-demand dosing, also known as event-driven PrEP (ED-PrEP; a specific, short-term dosing regimen that is currently only recommended in Australia for cisgender men).

The ARTG entry only lists the daily dosing regimen, meaning that ED-PrEP can only be prescribed as an 'off-label prescription'. Off-label prescribing is when "a drug is prescribed for an indication, a route of administration, or a patient group that is not included in the approved product information document for that drug".[62] Medication practitioners prescribing off-label may increase risk of prescriber liability, as the onus is on the prescriber to justify why they think the medication is suitable.[63] This could impact a prescriber's confidence in recommending ED-PrEP to their patients. The TGA guidance has not changed since TD*/FTC was listed on the ARTG in 2016. Updating the ARTG listing would help support prescriber confidence in ED-PrEP.[7] However, updating each TD*/FTC listing requires an application from a sponsor (either the parent pharmaceutical company or another party), who must also finance writing of the application and any processing costs.[63]

The Australian PrEP Guidelines state that for PrEP to be prescribed, the patient must either have a negative test result no older than four weeks or have evidence that a test has been conducted with the result forthcoming.[1] Medicare-eligible individuals who attend general practice clinics to access PrEP will be able to use the MBS to cover all or part of the consultation cost and any associated testing fees. Medicare-ineligible individuals accessing PrEP through this avenue will need to cover the total cost of the consultation and test/s. Those deemed as key populations by NSW Health, regardless of Medicare eligibility, can access free testing services at publicly funded sexual health services. However, many of these clinics encourage Medicare-eligible individuals to access PrEP prescriptions through general practice to maintain the clinic's capacity to prioritise those Medicare-ineligible individuals who may not be able to afford it otherwise.[7]

Whilst the Australian PrEP Guidelines were developed to guide clinicians prescribing PrEP, they also inform TGA and PBS listings for TD*/FTC. Following a review by the PBAC in September 2020, the PBS TD*/FTC prescribing requirements were aligned to those in the Australian PrEP Guidelines. The amended prescribing requirements removed the need for patients to be above the age of 18 and meet specific risk criteria.[1] The review also resulted in the reclassification of TD*/FTC in the Pharmaceutical Benefits Schedule from a 'streamlined authority' medication to a 'restricted benefit' medication (meaning prescribing practitioners do not need to include an authority code on an authority prescription form).[64] PrEP was not a medication eligible for a 60-day prescription as of the end of 2023.[9]

Whilst TD*/FTC is the focus of this review because it is the most commonly used medication as PrEP, other drugs have also been approved by the TGA: tenofovir alafenamide/emtricitabine (F/TAF), taken as an oral pill, approved in 2021; and cabotegravir, taken as a long-acting injectable (CAB-LA) or an oral pill, approved in 2022.[65, 66] Whilst F/TAF is not subsidised by the PBS, in September 2023, the PBAC recommended CAB-LA to be subsidised by the PBS for those not suitable for TD*/FTC, although as of April 2024, it has not yet been listed on the PBS.[67] The Australian PrEP Guidelines were updated on 1st December 2023 to include CAB-LA guidance.

### Obtaining PrEP

There are currently three methods to obtain PrEP:

1. Pharmacy: a prescription can be dispensed at a pharmacy, and if the individual is eligible for Medicare, they are supplied the medication at a subsidised price through the PBS (this cost is further reduced for Pension Concession Card and Health Care Card holders). If they are ineligible for Medicare, they can still have their PrEP prescription filled as a 'private prescription' for ~$50.00 as of the end of 2023.[68] (In the 2023 Sydney Gay Community Periodic Survey, 85% of current PrEP users reported getting PrEP from a pharmacy).[69]
2. Personal Importation Scheme: a prescription can be used to import up to 3 months' supply of PrEP for personal use. The PBS does not subsidise medication sourced through the Personal Importation Scheme. However, it is currently the least expensive way to purchase PrEP (costing as little as $18 per 30 pills as of April 2024).[70] PrEP sourced this way has been found to be legitimate and safe for use.[71] (In the 2023 Sydney Gay Community Periodic Survey, 8% of current PrEP users reported getting PrEP via personal importation).[69]
3. Publicly funded sexual health services from registered nurses (NSW only, added in late 2022): a registered nurse at a publicly funded sexual health service in NSW can supply PrEP to their patients without a prescription.[14] Funding is being sought to develop a standardised and sustainable approach to scale up this model across the state, as PrEP

supplied in this way is not subsidised by the PBS. As such, there is currently limited utilisation of this model.

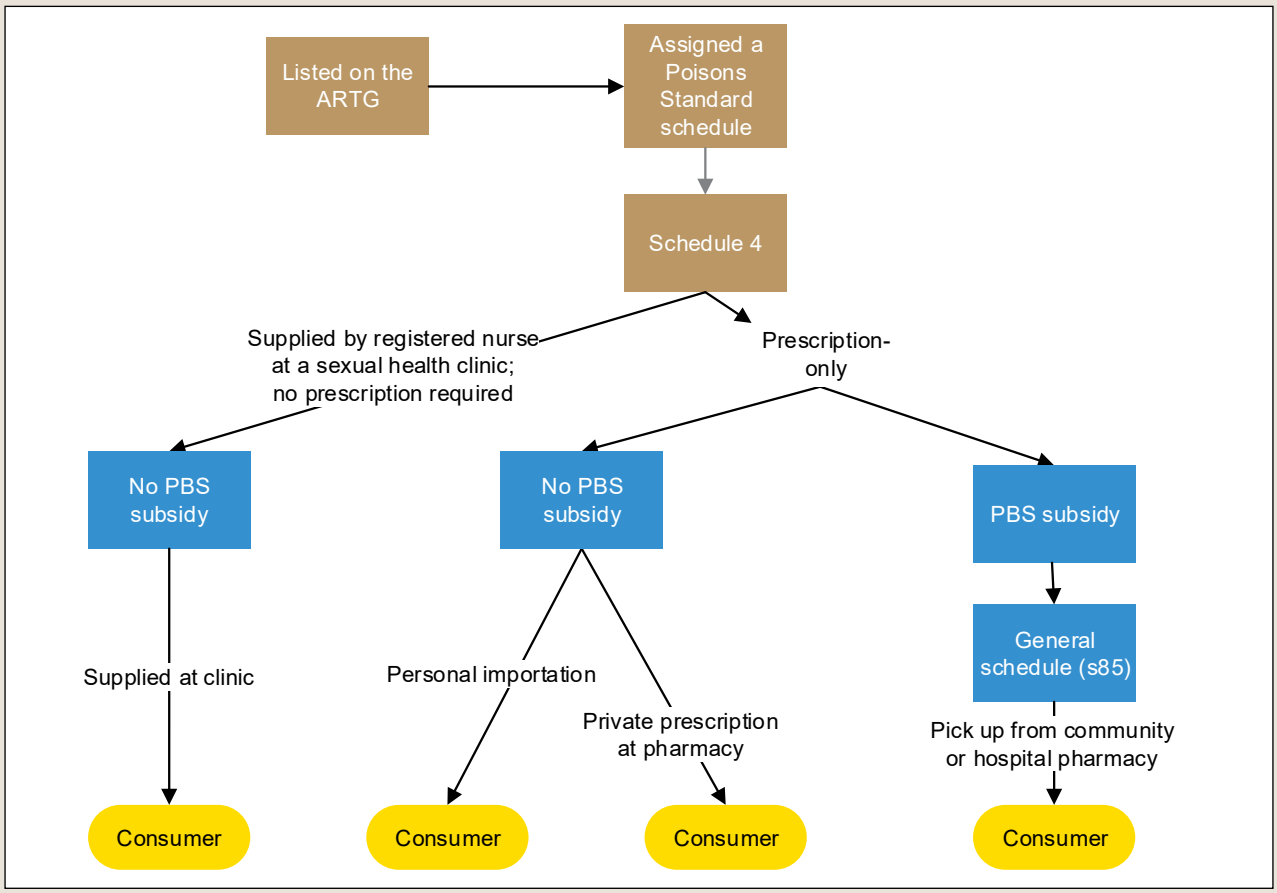


**Figure 2:** An overview of how PrEP is accessed and subsidised in NSW.

# Innovative PrEP programs

The World Health Organization has emphasised the importance of a patient-centred, decentralised, differentiated service-delivery approach to improve access and uptake of PrEP.[2] Globally, innovative PrEP service delivery models have been developed to enhance accessibility, scalability, and cost-effectiveness. These models include providing PrEP at no cost; shifting tasks from doctors to others, such as nurses, pharmacists, and peers from key (priority) populations (specific to each local context); telehealth models; and self-test and self-collected sample technologies. We explore innovative PrEP service delivery models from other countries, present case studies of notable Australian medication and healthcare programs, and evaluate how these might inform future innovative PrEP service delivery model designs.

## Free PrEP

The cumulative expense of medication, ongoing consultations and testing services is a significant PrEP access barrier for individuals in Australia, especially for those who are younger or Medicare ineligible.[4-6] The simplest innovative service delivery models are those that offer PrEP and the associated consultation and testing services at a low or no cost. Many countries provide PrEP and consultation and testing services at no cost, however many of these models have restrictions on who is eligible and where these services are provided. Some examples are shown in Table 2.

**Table 2:** Examples of countries that give eligible individuals access to free PrEP.[72-77]

| Country | Eligibility | Access location |
|---|---|---|
| **Africa** | | |
| **South Africa** | Key populations | Certain public health services |
| **Asia** | | |
| **Thailand** | Key populations who are eligible for public health insurance | Publicly funded hospitals |
| **Europe** | | |
| **Belgium** | Citizens and documented migrants | HIV reference centres |
| **Denmark** | Residents and documented migrants | Publicly funded hospitals |
| **France** | Residents and documented migrants | Any prescribing physician |
| **Germany** | Residents with public health insurance | Public health services |
| **Ireland** | Key population citizens and migrants who have government documentation | Certain public health services |
| **Portugal** | Everyone | Public health services |
| **United Kingdom** | Everyone | Sexual health clinics |
| **South America** | | |
| **Brazil** | Key populations | Public health services |

Participants of the NSW-based PrEP implementation trial, the Expanded PrEP Implementation in Communities-New South Wales (EPIC-NSW) study, were able to access PrEP and the associated consultation and testing services at publicly funded sexual health clinics and select GP clinics at no cost.[78] Access to free PrEP ceased after the completion of the trial, and Medicare-ineligible people now need to pay the private prescription price to purchase PrEP locally.[7] Individuals can continue to access free appointments and testing at NSW sexual health clinics; however due to capacity constraints, those who are Medicare-eligible and not a part of a high-priority group are encouraged to access PrEP through private GP clinics.[7]

Reducing cost barriers for Medicare-ineligible individuals is a recommendation of the Australian HIV Taskforce.[3] Further expanding this recommendation to all individuals, regardless of Medicare eligibility, has the potential to support more of those who are deterred by the cost of PrEP.[69] This could be achieved by:[33, 9, 10]

- Increasing MBS reimbursements to reduce GP gap fees
- Including PrEP on the 60-day prescription program (I.e. reducing PBS co-payment costs; by petitioning the government and PBAC to be included in this new initiative)
- Increasing the length of time between clinical visits in the PrEP monitoring cycle to 6-12 months (a recommendation of the HIV Taskforce; achievable now for those on non-daily dosing regimens needing 90 tablets in this period by amending the Australian PrEP Guidelines. If on a daily dosing regimen or needing more than 90 pills, this may require amending the PrEP PBS listing to increase the number of repeats allowable on a single PrEP prescription)
- Promoting the use of ED-PrEP to reduce medication costs (by updating TGA PrEP listings)
- The federal government covering PrEP costs via a federation funding agreement (for Medicare-ineligible individuals)
- Creating a PrEP s100 program to take advantage of the NSW s100 co-payment initiative (for Medicare-eligible individuals), as detailed in Case Study 1
- Establishing funded targeted services provided by state government or community organisations for key populations.

## Case Study 1: Antiretroviral therapy for people living with HIV

Antiretroviral therapy (ART) is free for everyone in most*# parts of Australia. This is achieved through a patchwork of federal and state initiatives. Medicare-eligible individuals have access to free# ART through a PBS s100 treatment program.[79] These medications have the same maximum co-payment amount as s85 medications; however, state governments pay this on the individual's behalf, effectively making ART free* through the PBS.[10] In NSW, Medicare-eligible individuals can collect their medication at public hospitals or community pharmacies.

ART is also freely available to Medicare-ineligible individuals through a separate federal funding mechanism called a 'federation funding agreement'.[80, 81] This agreement stipulates that the federal government will reimburse state or territory governments for the cost of providing ART to Medicare-ineligible individuals.[80, 82] In NSW, medication must be collected from a publicly funded hospital pharmacy, and this agreement does not subsidise consultations or testing services.[82] The agreement is due to be reviewed in 2026.[80]

Of note is the fact that these ART programs mean TD*/FTC is free when it is used to treat HIV, but not when it is used as PrEP to prevent HIV acquisition.

**What might this mean for PrEP access?**

This case study shows government funding instruments can reduce the cost of PrEP. Initiatives using these mechanisms may opt for a targeted approach to support the most vulnerable. Outside of federal funding agreements and s100 programs, direct additional funding to community-based organisations or publicly funded sexual health clinics (from either state or federal sources) could also be used to provide no or low-cost PrEP to individuals most in need.

* Medicare-eligible individuals may be charged a copayment in South Australia, Tasmania and Victoria.[79]
# Medicare-ineligible individuals may be charged a copayment in Tasmania and Victoria.[81]

# Task shifting

Task shifting involves the transfer of clinical tasks from medical practitioners, such as assessing PrEP suitability and prescribing, to others.[83] This section will focus on models that shift tasks to registered nurses, pharmacists, and trained peers from key populations (overview provided in Table 2).

## Nurse-led PrEP

Enabling nurses to provide PrEP to their patients could potentially increase the accessibility of PrEP (especially for rural and remote communities), reduce the likelihood of loss to follow-up, and be more cost-effective.[11] Examples of this can be seen internationally:

- In Canada, a medical practitioner or nurse practitioner sees the patient for their initial appointment to prescribe PrEP. Subsequent appointments can be conducted by registered nurses, who could issue PrEP or direct a pharmacy to dispense PrEP through a medical directive.[84-86]
- Since 2020, nurses in Brazil have been permitted to prescribe medication. By the end of 2021, nurses accounted for ~18% of all PrEP prescriptions.[87]
- In Africa, many countries allow nurse-led provision of PrEP (e.g. South Africa, Uganda, Zimbabwe, and Kenya).[11]

Nurse-led PrEP provision was a key component of the EPIC-NSW study.[28, 88] Standing orders from the NSW Secretary of Health permitted registered nurses to – as part of the trial – independently supply their patients with PrEP or dispense PrEP prescriptions obtained from medical practitioners.[89] It was only at the end of 2022 that registered nurses in NSW publicly funded sexual health services were again permitted to independently supply PrEP to their patients, as detailed in Case Study 2.[14] This provision does not apply to registered nurses operating outside of these settings.

### Case Study 2: STI treatment provided by registered nurses

Task shifting to nurses in sexual health clinics allows resources to be utilised more efficiently and provides greater access to healthcare for patients (especially those living in rural and regional areas who only have access to nurse-led clinics). In NSW, registered nurses in public sexual health services can provide treatment to their patients without a prescription for specific presentations, such as uncomplicated gonorrhea and chlamydia. This practice is made possible through a policy directive* made by the NSW Secretary of Health (or one of their representatives), enabled by the Poisons and Therapeutic Goods Regulation 2008 (NSW). Nurse-led treatment must strictly follow a treatment protocol#, as set out by the policy directive*. All presentations that fall outside of the protocol# must be referred to a medical or nurse practitioner. To provide STI treatment, registered nurses undergo further training and accreditation, as stipulated in the NSW Health Sexual Health Services Standard Operating Procedures Manual. Publicly funded sexual health services provide some STI treatments to their patients at no cost. This means LHDs must budget to offer this free medication.

**What might this mean for PrEP access?**

Nurse-led provision of PrEP was included in an updated version of this protocol# in December 2022; however, providing it to patients through this mechanism means the PrEP supplied is not subsidised by the PBS.[14] The logistics of registered nurses supplying PrEP in NSW publicly-funded sexual health services are still being established at the time of writing this review. State funding or a user-pays system could help ensure this model is sustainable. Once instituted, nurse-led PrEP has the potential to streamline routine appointments, increase access, and utilise the time of nurses and doctors time more effectively.

*RN Supply and Administration of STI Therapies in Publicly Funded Sexual Health Services 2020
#Medication Protocols under NSW Health Policy Directive: RN Supply and Administration of STI Therapies in Publicly Funded Sexual Health Services 2022

### Pharmacy-led PrEP

Pharmacy-led PrEP aims to increase accessibility and cost-effectiveness through the supply of PrEP at local pharmacies without the need for a prescription. It has the potential to increase the number of locations where PrEP can be accessed, and promote same-day initiation by supplying PrEP during the appointment. Examples of pharmacy-led PrEP can be seen in some settings in the USA, where pharmacists can provide certain prescription medications and order tests, independent of a medical practitioner, under collaborative practice agreements or in conjunction with a medical practitioner using collaborative drug therapy agreements.[90]

- In the USA, the allowance of collaborative practice agreements varies by state, and the states that do have these mechanisms in place for PrEP include California, Oregon, and Colorado.[12] California, as an example, allows an initial supply of 30-60 PrEP pills from the pharmacy after a negative result from a HIV point-of-care test (PoCT).[91] The individual is then expected to visit a primary care provider for ongoing care.
- Collaborative drug therapy agreements, on the other hand, are recognised in most states in the USA.[92] They are unique agreements developed by medical practitioners and pharmacists. Pharmacists can initiate, modify, and discontinue treatment using clinical guidelines established by these agreements; and treatment is reviewed by a medical practitioner as required. Using this mechanism, two pharmacy chains have committed to take part in collaborative drug therapy agreements in participating states. For example, utilising a collaborative drug therapy agreement in Washington State, a pharmacy pilot program called 'One-step PrEP' has been established. The pilot program involves a pharmacist conducting the intake assessment, collecting necessary samples for the required tests, and issuing a prescription – all in the same appointment.[93] Apart from providing another PrEP access point, the pharmacist is also able to minimise out-of-pocket costs (by helping navigate insurance requirements and apply for cost-saving programs), monitor adherence (through medication refills), and provide adherence counselling.[93] It should be noted that this program is implemented in a state that has an established expanded scope of practice for pharmacists, in a progressive city (Seattle) with access to public insurance and cost-saving programs, and in a metro area that already has a high rate of PrEP users.[93] Nevertheless, the fact that the initiation rate in a study of this program was high (97% of those eligible), and the discontinuation rate was 5-15% lower than other PrEP studies cited in the paper.[93]

The PrEP APPEAL study found that the Australian participants' most preferred location to access PrEP was a pharmacy (followed by a peer-led clinic and then a GP clinic).[5] Multiple pilot studies are planned or are being conducted in Australia, such as that described in Case Study 3, that allow pharmacists to prescribe or independently supply certain medications.[94] The active studies do not currently include PrEP. In NSW, pharmacists are permitted to provide certain medication through authorities issued by the NSW Secretary of Health through the Poisons and Therapeutic Goods Act 1966 (NSW) and Poisons and Therapeutic Goods Regulation 2008 (NSW).[15] Depending on the findings of these pilot programs, it could be possible in the future for PrEP to be included in the list of eligible medications to be supplied or prescribed by pharmacists. PrEP could also be listed under Schedule 3, allowing pharmacists to supply PrEP without a prescription. If additional safeguards were required before pharmacists were to supply PrEP to their customers, these could be listed using Appendix M of the Poisons Standard (Cth.) (see Table 1 for more details). Currently, there are no MBS items that allow for the subsidisation of consultations provided by pharmacists, nor is the medication they provide eligible for PBS subsidy.

## Case Study 3: NSW pharmacy trial for oral contraception

Emergency contraceptive pills were successfully rescheduled from prescription-only (Schedule 4) to over-the-counter (Schedule 3) at pharmacies since 2004; however, similar applications to downgrade daily oral contraceptives have repeatedly been rejected by the PBAC.[95] The ramifications of daily contraceptive treatment interruption are significant, leading to increased rates of unplanned pregnancy, morbidity, and mortality.[96] Many access barriers to daily oral contraception medication are similar to those of PrEP, including a lack of suitable GP appointment times, gap payments for GP consultations, and limited access to GPs in rural and regional areas.[97]

As of July 2023, pharmacists participating in a 12-month, NSW-based pharmacy trial are permitted to continue the supply of low-risk contraception for individuals.[98] This trial also allows pharmacists to supply antibiotics to treat urinary tract infections among women. This trial aims to increase contraception continuation rates by increasing contraceptive access points and hours, and streamlining follow-up consultations.[99] These prescription-only medications are permitted to be supplied by pharmacists through authorities issued by the NSW Secretary of Health.[15] Participants pay for their medication at the private prescription price, and the $20 consultation fee is paid to the pharmacy by the NSW Government.[100]

There are safeguards in place to limit the risk of harm to individuals who participate in the trial:

- The trial provides access to four low-risk contraception medications.[99]
- Individuals must have been prescribed one of these four medications in the last two years, and have not ceased taking their contraception for longer than a month before presenting for their pharmacy consultation.[99]
- Pharmacists undertake additional training, follow a clinical protocol co-designed by community pharmacists and GPs, and use specialised software to guide their consultation.[99]
- There are strict exclusion criteria, and the clinical assessment includes screening for health complications and drug interactions.[99]

A similar pharmacy trial for urinary tract infections in women was conducted in Queensland from June 2020 to December 2021.[101] The trial included 6,513 participants across 817 participating pharmacies.[101] 2,409 (35.7%) participants were available for follow-up, and of those, the majority (87%) reported having their symptoms resolved, had sought further care (7.6%), or were referred to their GP (3.6%).[101] Only a small number of follow-up participants (2.8%) completed the evaluation survey sent to their email; however, those who did fill out the survey reported being very satisfied (92.7%) or satisfied (7.4%) with the service they received. There has been opposition to this trial from Australian professional medical bodies, who have flagged concerns about the study's design, and the quality of care participants were receiving from their pharmacist.[102] Following the outcomes of the trial, pharmacy prescribing has been made permanent in Queensland, and has been expanded to include low-risk oral contraception and other medications.

### What might this mean for PrEP access?

These trials involve pharmacy-led supply of daily oral contraception medication. The similarities between oral contraceptives and PrEP mean the trial findings will be particularly relevant to inform the design of pharmacy-led, daily (or ED-PrEP) oral PrEP service delivery models. Further consideration would need to be made to determine if these pharmacy consultations could be for only initiating, only continuing, or both initiating and continuing PrEP use. Unlike contraception, pharmacists will likely need to confirm the HIV status of the individual. This may be difficult if pharmacists are not permitted to order pathology tests, or if clinical guidelines continue to not recognise PoCTs as providing suitable results. Learnings from the expansion of PrEP access to GP clinics should also be considered (e.g. ensuring participating pharmacies are culturally competent, staff are able to conduct comprehensive sexual health screenings, and individuals are easily able to locate which pharmacies offer pharmacy-led PrEP access).[7, 103]

### Peer-led PrEP

Peer-led, or key population-led, PrEP provision involves shifting certain tasks to trained individuals who are part of a service's targeted population. The service design usually involves a strong partnership between a community-based or peer-led organisation and other medical bodies, clear and specific clinical protocols, and specialised training for peer workers.[16] Peer-led service delivery models can increase healthcare access for those who may not feel safe to utilise mainstream services due to fear of stigma and discrimination, and previous poor experiences.[16,104] Examples of peer-led PrEP services can be seen internationally:

- Prior to 2022, Thailand allowed peers employed by community organisations to distribute oral PrEP directly to an individual after conducting a HIV PoCT and other associated tests.[26] The peer-led service's clinical partner would then review these data. PoCTs enabled HIV testing services to be provided by these peer-led clinics, and allowed for same-day initiation of PrEP. If an individual returned a reactive result for HIV or any STIs, they would be referred to a medical practitioner at the clinic or elsewhere for treatment. PLHIV could also access these peer-led services for ongoing, routine maintenance of ART after the establishment of a treatment plan by a medical practitioner.[26] This was Thailand's primary strategy for their PrEP rollout and accounted for ~70% of new initiations, and helped facilitate the increase of PrEP initiations from 15,000 in 2020 to 62,000 in 2023.[105, 106] In late 2022 the government changed the policy, so that only government doctors could prescribe PrEP and only government pharmacies could supply PrEP.[107] The policy change meant that only those peer-led services that partnered with doctors employed by the public health system were able to prescribe PrEP.[107] Though even these government-associated peer-led services would not be able to continue to stock PrEP to provide to their patients.[107] This policy change also removed PrEP subsidies for those not covered by Thailand's main insurance scheme.[107] While PrEP initiations still increased after this new policy was implemented, its impact on PrEP uptake and continuation is currently unknown.[105]
- Vietnam used Thailand's peer-led PrEP model as a guide for their own, called Prepped for PrEP (P4P).[108] There are multiple clinics with differing models operating in Vietnam.[109] However, these clinics generally employ medical practitioners who are also peers, who conduct any required testing (including a HIV PoCT) and provide a prescription for PrEP in the same appointment.[109] This has been Vietnam's primary PrEP rollout strategy and helped facilitate 66,000 initiations up until 2023, a sizeable increase from the 6,700 initiations recorded up until 2020.[105] A study of this model found that the retention rates for GBMSM and transgender women were 83% after 12 months at peer-led clinics, compared to 45% at public sector clinics.[109]

A planned peer-led PrEP trial in Victoria, called 'Buddy PrEP', will involve trained peers providing information about PrEP with their peers, offering a starter pack of PrEP and a point-of-care HIV test, and referring them for ongoing care.[3] More information about this trial is unknown at this stage. A current example of shifting tasks to peers in NSW is the peer-led HIV testing service, a[TEST], operated by ACON (Case Study 6).[13, 16]

A barrier to implementing peer-led PrEP service delivery models is that peer workers are not authorised to supply or prescribe medication under the Poisons and Therapeutic Goods Act 1966 (NSW). However, peers could potentially be incorporated into a PrEP service model under the supervision of medical or nurse practitioners, or registered nurses in publicly funded sexual health services. Other pathways include the Secretary of NSW issuing an Authority allowing peers to provide PrEP under certain circumstances (the same mechanism used in Case Studies

2, 3, and 5), or reclassifying PrEP from a Schedule 4 to an unscheduled drug. Changing PrEP to an unscheduled or Schedule 2 medication would remove the ability to require HIV testing to access PrEP. This change is unlikely, as accessing PrEP without need of a HIV testing may lead individuals who have unknowingly acquired HIV prior to their PrEP use to remain undiagnosed and develop medication resistance.[110] It is also unlikely that these models would also be subsidised through the PBS unless an s100 program (with the co-payment being paid for by the NSW Government) or federation funding agreement was established (such as in Case Studies 1 and 4).

## Case Study 4: S100 'Take Home Naloxone' program

Ensuring convenient and simplified access to medication that can save a person's life is important. Naloxone is a medication that can temporarily reverse an opioid overdose, allowing more time for medical assistance to reach that person. Naloxone is both a Schedule 3 and Schedule 4 medication, which means it can be purchased over the counter for a fee, or subsidised by the PBS when prescribed by a medical or nurse practitioner.[111] Additionally, since 2022, it can also be accessed through the s100 'Take Home Naloxone' program.[112] This program allows those who are at risk of, or who may witness, an opioid overdose access to naloxone for free and without a prescription at participating pharmacies, needle and syringe programs (NSPs), and alcohol and other drug services.[112]

This program is the result of a successful pilot study conducted in NSW, SA, and WA.[17] The study enrolled 1,480 sites across NSW, SA, and WA; which supplied 28,000 units of naloxone over 18 months, at no cost to participants.[17] This was in contrast to 3,500 units of naloxone through the PBS in the two years preceding the study.[17] It states that the program enabled at least 1,649 overdose reversals (equivalent to 3 per day of the pilot program). The establishment of the pilot program required federal legislation to be passed to fund the supply of naloxone through the PBS, under section 100 of the National Health Act 1953 (Cth); and the Secretary of Health in NSW to issue an authority to recognise non-government and other private services as approved suppliers of Naloxone.

### What might this mean for PrEP access?

Any peer-led model would require clinical oversight, clearly defined protocols, and specialised training for peer workers. This case study shows that the barriers to peer-led PrEP service delivery models are not insurmountable in the right circumstances. Lessons from the Take Home Naloxone program can inform a peer-led PrEP model in NSW. Like this program, the Secretary of Health in NSW can authorise non-government and other private services to supply PrEP, and funding for the program could be provided by the PBS or another federal or state source. And, like the Take Home Naloxone program, there would have to be a strong cost/benefit case put forward to achieve support from government.

It is important to note that PrEP and Naloxone are used differently and treat different conditions. Naloxone is used on an ad hoc basis to reverse a discrete overdose incident, while PrEP is used in either an ad hoc (ED-PrEP) or an ongoing manner (daily PrEP) to prevent the acquisition of HIV. Adopting a similar approach to the Take Home Naloxone program, peer-led PrEP distribution may not involve ongoing care, but instead engage individuals using a one-off PrEP starter pack, in conjunction with PoCTs or HIV self-tests and referrals for ongoing care.

**Table 3:** A summary of task shifting models, cost implications, and their status in NSW

| Healthcare worker | Description | Cost implications | Status in NSW |
|---|---|---|---|
| **Nurses** | The nurse conducts the HIV and STI screening, and provides the bottle/s of PrEP during the same appointment. | PrEP and associated tests are not able to be subsidised without a medical or nurse practitioner embedded in the model.<br><br>If providing this service through a publicly funded sexual health service, additional funding will be needed to provide PrEP for free, or a payment system will need to be created to facilitate the purchasing of PrEP by patients. | Limited access to publicly funded sexual health services. |
| **Pharmacists** | The pharmacist conducts the HIV and STI screening, and provides a prescription for PrEP. | PrEP and associated tests are not able to be subsidised without a medical or nurse practitioner embedded in the model.<br><br>Consultation fees may apply. | Currently not available. |
| **Peers** | The peer, who is a trained community organisation staff member, conducts the HIV and STI screening, and the medical or nurse practitioner provides PrEP, or a prescription for PrEP.<br><br>Other models:<br>Peer-to-peer clinical distribution, where a trained community organisation staff member, conducts the majority of clinical testing and sample collection, and also supplies PrEP (Thai model)<br><br>Peer-to-peer starter pack distribution, where a trained peer (community organisation staff member or volunteer) distributes PrEP starter packs (a small number of pills), and provides a follow-up referral with a clinical service. | PrEP and associated tests are not able to be subsidised without a medical or nurse practitioner embedded in the model.<br><br>If providing this service through a publicly funded sexual health service or peer-led clinic, additional funding will be needed to provide PrEP for free, or a payment system will need to be created to facilitate the purchasing of PrEP by patients. Additional funding may have to be sourced.<br><br>Peer-to-peer starter pack distribution through a community organisation would require funding to set up the program, buy starter packs, and supervise/ support the peers involved. | Currently possible with medical and nurse practitioners, although there are no active examples of this.<br><br>Peer/ registered nurse and peer-to-peer models are not currently available. |

# Telehealth services

Telehealth services are healthcare services that are provided remotely through information and communication technologies.[18] Examples of telehealth include telephone, video and internet consultations, electronic messaging between healthcare providers and their patients (over a mobile network or internet), and electronic prescriptions.[18] Integrating telehealth services into innovative PrEP service delivery models can streamline appointments, enable service delivery in new or under-resourced settings, and increase access to those who may not otherwise access health services (e.g. due to geographical access barriers, concerns about stigma, or their regular GP is not confident prescribing PrEP).[18, 113]

Many telehealth services were introduced or expanded during the COVID-19 pandemic.[18] The Australian Government supported private enterprise innovation by temporarily listing additional telehealth services on the MBS; many of which have now been made permanent.[18] Additionally, patients do not need to have an established relationship with a GP when seeking care for sexual and reproductive health services (usually, one in-person appointment in the last 12 months is required to access Medicare-subsidised telehealth appointments), due to temporary MBS items that are in place until 30 June 2024.[114, 115]

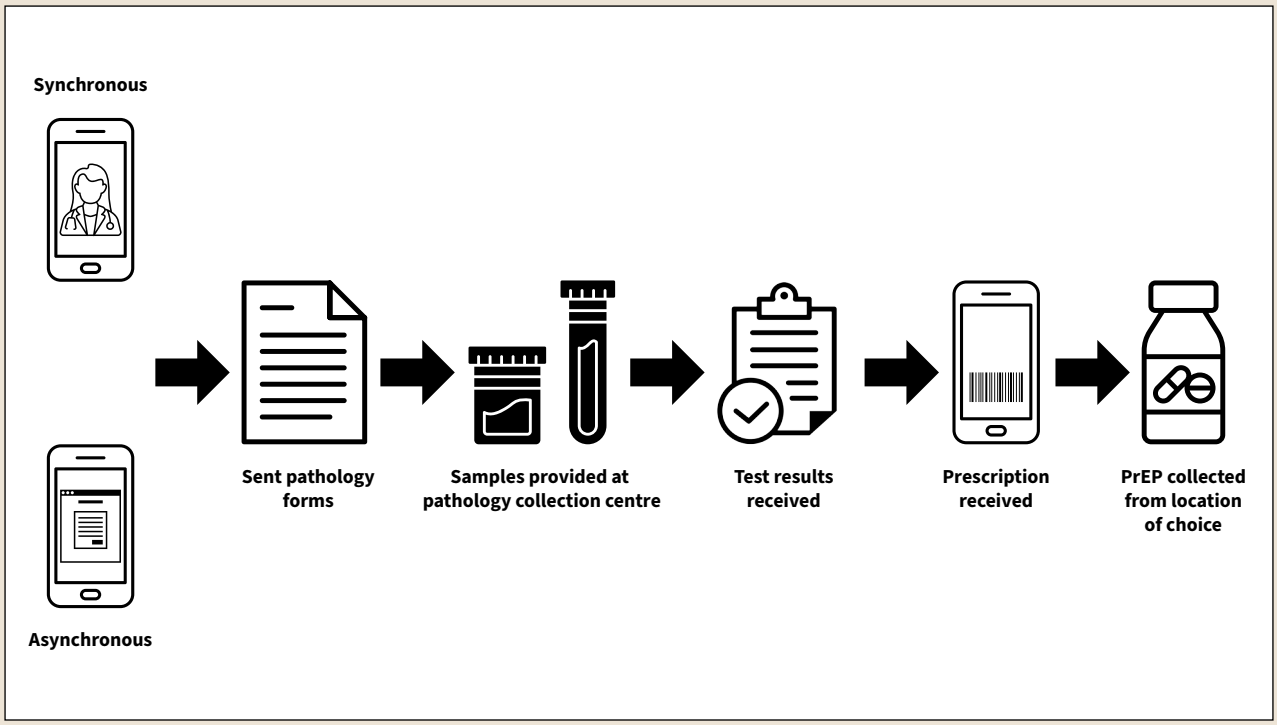


**Figure 3:** Telehealth PrEP pathway: (synchronous) a videoconferencing or telephone call-based consult is attended by an individual with their GP, or (asynchronous) an individual completes an online request form which a medical practitioner reviews; a pathology form is sent to the patient electronically; the patient attends a pathology collection centre of their choice to provide their sample; results are received; the GP sends the patient a PrEP prescription, either electronically, by post, or has it faxed to their pharmacy; and the patient collects their medication from a location of their choosing.

Many GP clinics in Australia offer synchronous (real-time) phone and video conferencing-based PrEP appointments, using similar pathways mapped out in Figure 3. This means it is easier for individuals to access PrEP from knowledgeable medical practitioners based anywhere in the country, in conjunction with local pathology services and pharmacies. Some healthcare providers also offer asynchronous healthcare services.[18] These services allow patients and healthcare providers to send and receive communications at different times (not in real-time), through online messaging applications and webforms (Figure 3). Australian professional guidelines require patients to have at least one synchronous consultation (either face-to-face, or via phone call or video) with their healthcare provider a year to access subsidised healthcare and prescriptions through asynchronous healthcare services.[116] Private, online synchronous and asynchronous telehealth services that specialise in PrEP prescribing, such as 'PrEP Health' and 'HeyFella', now see thousands of patients across Australia.[117, 118] Synchronous and asynchronous telehealth services are also available in the USA and Canada, where they also provide self-collected sample kits to replace the need to attend pathology services.[21, 22, 119-121]

Some considerations need to be made when integrating telehealth into innovative PrEP service delivery models:

- To initiate PrEP, under the Australian PrEP Guidelines a venous blood sample is required for laboratory testing.[1] Therefore, individuals wanting to access PrEP currently need to attend a pathology collection centre in person.
- Face-to-face appointments are still required for those presenting with complications.
- Some STI treatments need to be provided in person. If an individual is accessing telehealth PrEP services out of area, they may have to be referred to a local GP or sexual health service for treatment.
- There may be privacy concerns about conducting telehealth appointments in a shared space or having sample kits or medication mailed to a home address.
- Individuals may experience or be perceived to be the subject of stigma at pathology collection centres.[19]
- The temporary MBS items that exempt sexual and reproductive telehealth consultations from needing a previous in-person consultation with patients to be eligible for subsidy are due to expire on 30 June 2024. As of September 2023, a draft review of these items from the MBS Review Advisory Committee recommended that they be retained.[122] This has also been recommended by the HIV Taskforce.[3]

### Case Study 5: MyCheck telehealth HIV and STI testing service

MyCheck, a pilot telehealth testing service run by publicly funded sexual health services in NSW, presents a valuable opportunity to expand access to PrEP. This service allows nurses in publicly funded sexual health services to conduct ad hoc, routine, sexual health consultations with individuals via phone call. Nurses use the electronic MyCheck form to guide conversation and collect required information. When the form is submitted, it then automatically sends a pathology request form to the patient. Similarly, an asynchronous version of MyCheck allows nurses to send their patients a link to the MyCheck electronic form; after the form's completion, a pathology request form is automatically generated and sent to the patient. The individual can then attend a nearby pathology collection centre to provide their samples. The notification of HIV and STI results follow standard procedures. Clinics that also offer PrEP prescribing in conjunction with MyCheck can either mail the prescriptions to patients, or have them faxed to a pharmacy of their choosing.

MyCheck is still in pilot phase, and is currently only being conducted in a few LHDs. It is also only available for current sexual health clinic patients (i.e. those who have previously attended the clinic before) with uncomplicated presentations. Complicated presentations still need to attend the clinic in person to see a doctor. Preliminary findings from one pilot site found that the majority of participants and clinical staff had a positive experience using the MyCheck service.[19] However, a small number of participants recorded negative experiences when accessing pathology collection centres (such as perceived stigma and lack of sensitivity towards their needs). The service was particularly helpful in supporting clinical operation continuity during COVID-19 pandemic lockdown periods, and increasing clinic capacity by streamlining routine sexual health consultations.

**What might this mean for PrEP access?**

This method is already being used to distribute PrEP in NSW; however, PrEP may not be accessible at all publicly funded sexual health clinics that use MyCheck as each LHD decides how they would like to utilise the MyCheck platform. For those services that do allow access to PrEP this way, after the results of the tests are received, a doctor at the sexual health clinic either sends a script to the patient's address, or faxes it directly to a pharmacy of their choosing. MyCheck was designed to streamline the appointment process for patients with uncomplicated presentations, thereby freeing up doctors' time to see complicated presentations, and increasing testing rates by making it easier for individuals to access sexual health services. There is still an emphasis on encouraging individuals to access PrEP through GPs, due to sexual health clinic capacity constraints; for PrEP access to be expanded using the MyCheck service, these constraints would have to be addressed.

## Point-of-care testing

A point-of-care test (PoCT) is a diagnostic test that provides results in a short timeframe (~15 minutes), thus informing care provided during the same healthcare consultation.[123] While there are numerous types of PoCT technologies, each with its advantages and disadvantages, the focus of this report is on visually-interpreted lateral flow tests, which are routinely used to detect HIV and other infectious diseases in many settings.[123] Lateral flow PoCTs incorporate a strip of cellulose and dyes that react with antigens and/or antibodies when present in blood or oral fluid samples, producing a visual signal.[123]

PoCTs have many benefits – they can allow diagnostic services to be offered in resource scarce or remote locations, can expedite results that would otherwise be received from a laboratory, and can be used by a wide variety of healthcare workers.[124, 125] While newer PoCTs have increased in sensitivity (3rd generation antibody-only and 4th generation combination antibody and antigen tests), they still are not as sensitive as a laboratory test (especially if an individual is already taking PrEP), and have a longer window period (the time period after someone has been exposed to HIV) before they can reliably detect a HIV infection.[20, 126]

Using PoCTs in PrEP service delivery models have been successful in studies in the USA and Africa.[124, 125] In the USA, their clinical PrEP guidelines allow PrEP to be initiated using a combination antibody and antigen test, with follow-up appointments requiring laboratory testing.[20] Pharmacists in a USA-based study provided a 6-week supply of PrEP to low-income black GBMSM after performing a PoCT and STI screen, and scheduled a follow-up appointment with a medical practitioner; leading to an increase in PrEP use in this population.[125] In a South African study of pregnant women in antenatal care, PoCTs reduced the time to PrEP initiation to 0, from 26 days in the laboratory testing arm.[124] For those that acquired HIV, it reduced the time from testing to treatment from 38 days to 3 days.[124]

The Australian PrEP Guidelines currently recommend that PoCTs must be accompanied by laboratory tests in PrEP service delivery models.[1] Further research into the feasibility of integrating PoCTs in PrEP models will likely be needed.[1] Given the lower sensitivity of PoCTs detecting a recent HIV infection compared to laboratory-based tests, these models may only be feasible when PoCTs are used to initiate PrEP (like the clinical PrEP guidelines in the USA); or they could be integrated across the PrEP monitoring cycle.[20] As PoCTs are not currently subsidised under Medicare, advocacy for the establishment of PoCT MBS items will assist program feasibility and access for those who are Medicare-eligible. If these programs did rely on MBS subsidies, they should also consider how to ensure accessibility for those who are Medicare-ineligible.

## Case Study 6: HIV point-of-care testing

In NSW, the 'NSW Framework and Standard Operating Procedure for HIV Point of Care Testing' sets out operational requirements for sites offering PoCTs, which allows them to be used in clinical and non-clinical settings.[127] HIV PoCTs are used at a[TEST] sites – peer-led, nurse-supervised sexual health clinics run by ACON in partnership with NSW Health.[13, 16] a[TEST] utilises trained GBMSM peers to conduct the majority of a sexual health screen, including PoCT (4th generation), and offer support and advice to the patient; the only routine task performed by nursing staff is venepuncture. PoCTs are used to provide preliminary results during the consultation, which allows for prompt referrals for any necessary follow-up testing and treatment.

Using PoCTs at a[TEST] has been shown to be highly acceptable, promote access to sexual health for vulnerable community members, and increase individuals' testing frequency.[16, 128]

**What might this mean for PrEP access?**

If PoCTs were endorsed in the Australian PrEP Guidelines, they have the potential to expand PrEP access in a variety of settings. Possibilities include being used by registered nurses to provide PrEP in regional and rural areas, or while conducting outreach at community events; pharmacists could use it to allow for same-day initiation of PrEP (in conjunction with pharmacist-led PrEP initiatives); or by peer-led clinics to allow greater access for key populations (most likely supported by registered nurses or medical practitioners). Given that PoCTs have lower sensitivity compared to laboratory tests, they may be found to be suitable for initiation-only or continuation-only PrEP programs.

# HIV self-tests and self-collected sample kits

Instead of attending a pathology collection centre, self-tests or self-collected sample kits allow individuals to either complete a test at home or collect their samples at home and send them away to a laboratory for testing. For this reason, HIV self-tests and self-collected sample kits may complement telehealth services.

There have been some international examples of how self-collected sample kits have been incorporated into telehealth PrEP models. These examples include:

- 'One-Step PrEP', a USA-based telehealth PrEP service, provides the option for a self-collected sample kit to be mailed to individuals, which is posted to a laboratory for testing.[21]
- 'PrEP@Home', another USA-based PrEP pilot program, followed a similar format that allowed individuals to replace three out of the four in-person appointments a year with telehealth appointments and self-collected samples.[22]
- SH:24, a HIV and STI telehealth service based in the UK and Ireland, sends self-collected sample kits to individuals' homes, which are posted to a laboratory for testing.[23]

Some international programs have also utilised self-tests to support their PrEP programs. These examples include:

- In Vietnam, HIV self-tests were temporarily used to support PrEP monitoring during the COVID-19 pandemic, in conjunction with telehealth PrEP consultations and mail-delivered PrEP.[24]
- A Brazilian service used a similar model to Vietnam during the pandemic, to ensure continuity of access to PrEP.[25]
- A Kenyan study found that 6-monthly in-person appointments for PrEP monitoring and 6-monthly PrEP prescriptions that were supplemented by HIV self-tests were non-inferior to 3-monthly in-person visits.[129]

In NSW, self-collected sample kits are available for HIV and hepatitis C through the Dried Blood Spot testing program (funded by NSW Health), and HIV self-tests are available in select pharmacies or can be ordered online. Due to the longer window period of available self-tests (Australia has one TGA-licensed 3rd generation self-test), current PrEP guidelines require laboratory testing to confirm HIV status for PrEP initiation and ongoing care.[20, 130] Additionally, whilst these options are currently available for HIV, there are yet to be chlamydia, gonorrhoea, or syphilis self-tests approved by the TGA. While self-collected sample kits could still qualify for MBS subsidisation (as the laboratory tests are the same as those conducted on samples collected in person), self-tests cannot.

New self-collected sample kits and self-tests may face adoption challenges due to a lack of funding and the need to obtain the necessary market authorisation from the TGA. Also, self-tests and self-collected sample kits are not able to determine an individual's eligibility for PrEP, as per the Australian PrEP Guidelines.[1] Using self-tests come with other caveats, such as potential difficulties linking individuals to care after returning a reactive result; however, this may be an acceptable risk if it results in increased PrEP use and testing frequency.[131] Further research, funding, and regulatory approvals are needed to assess the feasibility of integrating self-collected sample kits and self-tests into innovative PrEP service delivery models.

## Case Study 7: HIV self-test vending machines

In July 2023, the Centre for Excellence in Rural Sexual Health in Victoria launched STI-X, an HIV and STI test vending machine trial, in multiple rural and regional locations.[132] The vending machines dispensed HIV self-tests and STI self-collected sample kits (to collect samples for chlamydia and gonorrhoea testing), which individuals used to collect their samples to send to the Melbourne Sexual Health Centre for testing. Individuals received care in-person at a suitable location if they returned a reactive test result.

Similarly, HIV self-tests have been available via vending machines in Adelaide and Brisbane.[133, 134] In these cities, individuals completed an online screening form, after which they were sent an SMS code that could be scanned at their closest vending machine to obtain the self-test. A short time later, the individual was prompted to enter their test result online, and further care was provided if they returned a reactive test result.

**What might this mean for PrEP access?**

These programs provide the opportunity to normalise HIV and STI testing in locations that may have had limited access to them previously. They also allow testing to be conducted discreetly, and may appeal to those who may not feel comfortable accessing these services through their local GP or sexual health clinic. Incorporating PrEP access into these services may provide access to individuals that current programs have not yet reached. Following up self-test results with a mailed prescription or e-script could be a simple add-on for these programs. This is not currently possible, as the current self-test available in Australia is 3rd generation, which has a 3-month window period, and is not endorsed by the Australian PrEP guidelines to access PrEP (for either PrEP initiation or continuation).[1] Similar to PoCTs, innovations may be more feasible if self-tests are used for initiation-only or continuation-only programs. Also, these innovations may be found to be more acceptable if newer 4th generation self-tests, which have a shorter window period, were licensed to be used in Australia by the TGA.[131]

# Discussion

Experience within and outside of Australia shows that there are many opportunities to implement innovative PrEP service delivery models aimed at increasing PrEP uptake, particularly for underserved and key populations. However, the policy, legal, and regulatory environment governing access to and subsidisation of medication in Australia is complex. PrEP can be accessed through a PBS-subsidised prescription, but only when it is prescribed by a medical or nurse practitioner; a private prescription, by those who are Medicare-ineligible (however not at a PBS-subsidised price); personal importation at lower private cost, however, patients may have to wait weeks for it to arrive in the mail; and a registered nurse working at a publicly funded sexual health clinic (in NSW), though this model is yet to be scaled up. [1, 7, 8, 14]

Not all innovations require significant changes to legislation or policy, or large amounts of funding. It would be relatively simple to amend the PrEP TGA listings to allow ED-PrEP to be prescribed on-label, allowing medical professionals to provide access to this increasingly common regimen more confidently.[63] Our current system does not incentivise pharmaceutical companies to update their listings to include new patient groups and indications, or allow other parties, such as professional bodies or consumer-representative organisations, to do so in their stead.[63] A symptom of this flaw in our medication licensing system is that off-label prescribing is common in Australia.[63, 135] Whilst system reform would be beneficial, in the short-term the HIV sector could work in partnership with pharmaceutical companies to amend their TGA PrEP listings to include ED-PrEP. Also, while ED-PrEP is currently only recommended for cisgender men in Australia, an updated UK PrEP-user guide (produced by community advocates and sexual health physicians) informed by recent research recommends that ED-PrEP be considered suitable for everyone.[1, 136-139] It recommends that those participating in anal sex can use the standard ED-PrEP regimen (two PrEP pills 2-24 hours before sex, and then one pill every 24 hours until 48 hours after sex) and an amended ED-PrEP regimen for those participating in receptive vaginal/front hole sex (2:7, two pills 2-24 hours before sex, and one pill each day for seven days after sex). It would be pertinent to consider these new ED-PrEP recommendations if applications were to be made to amend the TGA listings. Amending TGA lists such that ED-PrEP does not need to be prescribed off-label will help medical practitioners prescribe with confidence and consumers more easily access their preferred dosing regimen.[7]

Reducing medication, testing, and consultation fees will assist those wanting to access PrEP, particularly those on low incomes, in unstable employment, and those who are Medicare-ineligible.[25, 44, 45]. The HIV Taskforce has recommended reducing the cost for Medicare-ineligible individuals, and expanding this recommendation also to include Medicare-eligible individuals will help support those who are most vulnerable.[3] Free sexual health screening for everyone, regardless of Medicare eligibility, is available at publicly funded sexual health clinics; however, due to funding constraints, access is limited.[7] Increasing sexual health clinic funding will allow for the expansion of these services to meet the needs of more people in the community. Accessing medication using the personal importation scheme is another way to reduce medication costs; however, its use is limited due to a lack of awareness of the scheme, complicated ordering processes, significant upfront costs for bulk medication purchasing, and delays in medication delivery.[8] Costs could also be reduced by increasing the time between PrEP appointments from 3 months to 6-12 months (a recommendation of the HIV Taskforce), including PrEP in the 60-

day PrEP prescription program (which would half the medication costs for Medicare-eligible individuals), or funding targeted programs to provide low cost/free PrEP to key populations.[3] Many of these cost-saving initiatives could support Medicare-eligible as well as Medicare-ineligible individuals.

Task shifting offers PrEP service designers a range of options to meet key population needs and ensure our current services are sustainable (a recommendation of the HIV Taskforce).[3] Nurse-led, pharmacy-led, or peer-led PrEP service delivery models present many possibilities to increase PrEP access, even if they are found to be feasible and acceptable by the HIV sector only if they were used for initiation or continuation of PrEP. However, innovative PrEP service delivery models that solely utilise registered nurses, pharmacists, or peers cannot access PBS and MBS subsidies. Therefore, sufficient funding should be provided to these programs to ensure this cost is not passed on to the end user.

Nurse-led PrEP has the potential to increase clinic capacity by streamlining appointments and allowing medical practitioners to see more complicated presentations. We have seen evidence of this locally, during the EPIC-NSW study, and to a lesser extent with the recently updated policy allowing registered nurses to supply PrEP in public clinics.[88] The nurse-led PrEP policy structure is already in place in NSW; however, for implementation, funding and the development of a sustainable, scaled-up model needs to be developed.

Implementing a pharmacy-led PrEP service delivery model in NSW would increase the number of locations where PrEP is available, and could encourage individuals to pick up their medication on the same day as their appointment. Whilst pharmacist-led PrEP service delivery models have been shown to be effective in the USA (e.g. increased number of PrEP access points, lower cost of access, and higher rates initiation, adherence, and retention rates compared to some clinic-based models), these are yet to be implemented in Australia.[91, 93] The feasibility of pharmacy-led PrEP service delivery models in NSW will be informed by findings from the current trials in NSW, Queensland, and Victoria (see Case Study 3); as well as any pharmacy-led PrEP trials that are implemented in the meantime. To ensure the safety and quality of healthcare provided, these service delivery models could utilise Appendix M of the Poisons Standard (Cth.). Listing PrEP medications under Appendix M of Schedule 3 will allow policymakers to include additional safeguards, similar to those set out in the Australian PrEP Guidelines, before pharmacists can supply PrEP.[1] If pharmacy-led PrEP service delivery models are rolled out in Australia, considerations should also be made about how to overcome similar barriers experienced by individuals when accessing PrEP through GP clinics (E.g. stigma, difficulties finding which GPs prescribe PrEP, and being referred to another healthcare provider due to lack of knowledge or confidence prescribing PrEP).[39, 103]

Peer-led PrEP has the potential to allow individuals to access PrEP in safe and welcoming environments. While peer-led PrEP is one of the bolder models explored in this paper, this sentiment was also previously held about peer-led HIV testing services, which are now found in many states and territories.[13] Integrating PrEP into these peer-led testing services could be achieved by using a medical or nurse practitioner to prescribe PrEP in person, or establishing a model that utilises peers in conjunction with telehealth (such as the new MyCheck service, which allows remote medical practitioner oversight and prescribing). Distribution of PrEP solely by peers could be possible through an authority issued by the Secretary of Health of NSW or removing PrEP as a Schedule 4 medication under certain circumstances in the Poisons Standard (Cth). However, if peers were to distribute PrEP, there would need to be other safeguards in place to ensure the safety of individuals. Other peer distribution models of PrEP, similar to the Take Home

Naloxone program, could see peers supply individuals with a PrEP starter pack and refer them to clinics for ongoing care.[17] Ensuring there is sufficient clinical oversight to facilitate high-quality healthcare should be a significant consideration of this and any other peer-led service delivery model.

Integrating new technologies into innovative PrEP service delivery models can automate routine elements of the PrEP access process, enable service delivery in new settings, and increase the reach of healthcare services to individuals who may not otherwise be able to access them. [19, 106, 107] These services are already being widely utilised in Australia, by private in-person and online clinics. [111, 112] Private telehealth providers rely on what are currently temporary telehealth MBS items to make their clinics affordable for Medicare-eligible individuals. To support these private clinics, making these temporary MBS items permanent will help ensure the sustainability of access for their patients. Pilot telehealth services are also being offered by some public sexual health clinics, allowing them to reduce the time of routine PrEP and sexual health appointments by conducting them over the phone or using webform-based forms.[19] This service increases clinic access and can be more convenient for their patients.[19] As more people's lives are increasingly spent online, establishing and expanding these public and private models presents a valuable opportunity for current and future PrEP service delivery models to connect to a wider audience of those who might be at higher risk of HIV acquisition.

Integrating new and existing technologies, such as PoCTs, self-tests, and self-collected sample kits could further simplify access to PrEP. Many of these technologies have been implemented successfully in other countries, and while some are available in Australia, their implementation and integration into PrEP service delivery models have been limited.[21-25, 129] Simplifying sample collection or removing the need for an individual to attend a pathology collection centre could help facilitate nurse-led, pharmacy-led, peer-led, and telehealth models in non-clinical settings. PoCTs and self-tests do come with the caveat that they may not be as sensitive as laboratory tests, or have a longer window period for detecting HIV.[20, 131] There are also additional policy barriers that need to be overcome to integrate these technologies and ensure sustainability. These include licensing with the TGA, endorsement in the Australian PrEP Guidelines, and listing of services using these devices on the MBS to subsidise their costs.

Our recommendations aim to promote the introduction of differentiated service delivery through innovative PrEP service delivery models. These recommendations to policy makers, researchers, and HIV sector workers reaffirm and build on those presented by the HIV Taskforce.[3]

## Recommendations:

1. Reduce the cost of PrEP and associated consultation and pathology fees, particularly for Medicare-ineligible individuals.
   HIV Taskforce Recommendation #1
2. Increase the time between PrEP follow-up appointments to 6-12 months to reduce consultation and testing costs for all individuals.
   HIV Taskforce Recommendation #2
3. Implement 60-day PrEP prescriptions to reduce medication costs for Medicare-eligible individuals.
4. Develop a state-wide model that enables registered nurses to supply PrEP in publicly funded sexual health services.
   HIV Taskforce Recommendation #3
5. Explore the feasibility and potential impact of pharmacy-led and peer-led models.
   HIV Taskforce Recommendation #3
6. Establish, fund, and support the expansion of public and private telehealth PrEP services.
7. Retain MBS telehealth items that exempt sexual and reproductive telehealth consultations from needing a previous in-person consultation with patients to be eligible for MBS subsidy.
   HIV Taskforce Recommendation #7
8. Explore the viability of using point-of-care tests, HIV self-tests, and HIV and STI self-collected sample kits to initiate and continue PrEP use.
9. Create MBS items for HIV point-of-care testing devices and consultations to ensure their feasible integration in testing and PrEP service delivery models.
   HIV Taskforce Recommendation #10
10. Advocate for the amendment of Australian Register of Therapeutic Goods TD*/FTC listings to include event-driven PrEP.

# Conclusion

Australia's response to the HIV epidemic has been world leading. However, there is much to learn from the innovative programs being implemented locally and in other countries. Our system of PrEP access has the potential to meet the needs of more individuals at higher risk of HIV acquisition. Innovative service delivery models can help address barriers experienced by the most vulnerable in our society, such as those who are Medicare ineligible, culturally and linguistically diverse, trans and gender diverse, facing economic hardship, and who are living in regional and rural areas that have limited access to suitable healthcare.

Many innovative service delivery models – such as those that incorporate low cost or free access to PrEP, task shifting, telehealth services, and PoCTs/self-tests/self-collected sample kits – have been found to be acceptable, feasible, and effective at enhancing the accessibility and cost-effectiveness of PrEP. While some of these innovative service delivery models may require changes to legislation, regulations, or policy, many already can be implemented. And while finding mechanisms to fund innovative service delivery models sustainably presents a challenge to implementation, these models provide a valuable opportunity to enhance the public's access to PrEP.

The innovative PrEP service delivery models explored in this report are tools, and, if implemented, should meaningfully address specific PrEP access barriers. There is likely to be no single model that provides equitable access to PrEP; therefore, implementing differentiated service delivery models that meet the needs of key populations provides us with the best chance to end HIV acquisition in Australia.[2]

# Glossary

| | |
|---|---|
| **3rd generation HIV test** | Diagnostic test that detects antibodies specific to HIV. |
| **4th generation HIV test** | Diagnostic test that detects antigens and antibodies specific to HIV. It has a shorter window period than 3rd generation tests. |
| **ACON** | NSW-based, community-led, LGBTQ+ health and HIV prevention and support organisation. |
| **Cisgender** | Individual whose gender aligns with what they were assigned at birth. |
| **Differentiated service delivery** | Tailoring programs to meet the needs of individuals. E.g. where the service is located, who is providing the service, service frequency, and what innovation is being implemented. |
| **Federation funding agreement** | Specific agreement outlining the state-run services for which the Commonwealth will provide financial support. |
| **General Schedule (s85)** | Main list of medication subsidised through the PBS, under the National Health Act 1953 (Cth). |
| **Lateral flow point-of-care test** | Diagnostic test that usually consists of a strip of cellulose and dye that reacts with antigens and/or antibodies in blood or oral fluid |
| **Legislation** | Bills passed in state and federal parliaments that become law, in the form of Acts and statutory instruments |
| **Key (priority) population** | Population that is at higher risk of HIV acquisition. Classification of a 'key population' will vary depending on context. |
| **Peer** | Individual from a key population. Classification of a 'peer' will vary depending on context. |
| **Personal importation scheme** | Government program that allows individuals to source medication from overseas. |
| **Point-of-care-test** | Diagnostic test (usually a lateral flow test) that produces a rapid result, and can be administered by a trained individual. |
| **Poisons Standard** | Federal regulatory instrument that classifies drugs into schedules, which states use to assign access restrictions. (see 'Schedules') |
| **Policy** | Guidelines and principles adopted by government or organisations to guide decision-making processes |

**PrEP regimens**

| | |
|---|---|
| **Daily** | PrEP taken every day (or at least four times a week for cisgender men). |
| **Event-driven** | PrEP taken on an ad hoc basis, and only endorsed for use by cisgender men in Australia. The regimen consists of taking two PrEP pills 2-24 hours before sex, and then one pill every 24 hours until 48 hours after sex. |
| **Private prescription** | Prescription that the PBS does not subsidise. |
| **Provision** | Providing access to medication with or without a prescription. |
| **Registered nurse** | Individual who has met the requirements of the Nursing and Midwifery Board of Australia for registration as a 'registered nurse'. |
| **Regulation** | Statutory instruments that government agencies and regulatory bodies use to specify rules or requirements |
| **s100 programs** | Alternative arrangements that subsidise medications through the PBS, as provided for in section 100 of the National Health Act 1953. |
| **Schedules (2-10)** | Classes of drugs as set out in the Poisons Standard. Access restrictions generally increase the higher the schedule. (see 'Poisons Standard') |
| **Task shifting** | Transfer of clinical tasks from medical practitioners, such as assessing PrEP suitability and prescribing, to others (e.g. nurses, pharmacists, or trained peers from key populations). |
| **Transgender** | Individual whose gender does not align with what they were assigned at birth. |
| **Window period** | Time between a person acquiring HIV and when a test can detect the presence of HIV. |

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