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Developing a sustainable HIV,
viral hepatitis & sexual health workforce

Implementing long-acting injectable HIV pre-exposure prophylaxis using Cabotegravir-LA: Recommendations to support the Australian Health Sector

Workshop Summary Report

June 2024

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1. Background

In recent years, Australia has made significant progress in HIV prevention, thanks to comprehensive public health initiatives, widespread access to HIV testing and treatment, HIV pre-exposure prophylaxis (PrEP) and community-led advocacy efforts. These efforts have contributed to significant reductions in rates of new HIV diagnoses.

The introduction of long-acting injectable cabotegravir (CAB-LA) as HIV PrEP adds a new dimension to Australia's HIV prevention toolkit, offering an innovative and highly effective option for individuals at risk of HIV acquisition. Unlike daily oral PrEP, which requires strict adherence to daily medication, CAB-LA offers protection with one injection administered every two months, providing longer duration of action.

CAB-LA supports clinicians in adopting person-centred approaches to care by having choices to offer patients that most fit their needs. The introduction of CAB-LA in Australia would support other low-and middle-income countries in the region to secure their own regulatory approvals by using the Therapeutic Goods Administration (TGA) approval as a regulatory reference market.

As Australia hopes to introduce CAB-LA into clinical practice, it is essential to engage in proactive discussions and planning to ensure a smooth transition and optimise the benefits of this new prevention modality.

The TGA's positive recommendation of CAB-LA for HIV PrEP last year represents a significant milestone in Australia's ongoing efforts to combat HIV transmission. This approval highlights the nation's commitment to advancing HIV prevention strategies and improving the health outcomes of at-risk populations. At the time of writing however, CAB-LA has not been subsidised on the Pharmaceutical Benefits Scheme (PBS) as a pricing agreement between ViiV Healthcare and the Pharmaceutical Benefits Advisory Committee (PBAC) has not been reached.

2. Workshop Overview

On the 6th of April 2024, ASHM Health organised a national workshop, funded by ViiV Healthcare, to convene a select group of key stakeholders from each Australian State and Territory. The primary objective was to facilitate discussions around how to successfully implement the use of CAB-LA throughout Australia and to identify the requisite support needed within the healthcare sector to navigate this transformative change in HIV biomedical prevention.

The Steering Committee comprised co-chairs Professor Edwina Wright, and Associate Professor Vincent Cornelisse and Robert Wisniewski and Rebekah Lamb who represented the ASHM secretariat. The Committee designed the program and oversaw the invitee list. ViiV Healthcare gave feedback on the program design and the invitee list, but all final decisions were made by the Steering Committee.

Objectives:

1. Provide a comprehensive understanding of ASHM's CAB-LA PrEP guidelines.
2. Optimise the process of identifying patients suitable for CAB-LA across diverse healthcare settings.
3. Explore implementation considerations and models of care for specific populations, within diverse healthcare settings.
4. Identify and explore educational needs and models that will support providers over the next 12 months.

Program

The workshop program (see appendix) spanned a full day and encompassed a series of interactive sessions designed to foster collaboration and knowledge exchange among participants. Most sessions were facilitated by the workshop attendees, promoting a peer-led approach to learning and discussion. Case-studies were used to explore the pathways of delivering CAB-LA to different populations across diverse healthcare settings and were designed by the session facilitators.

Participants

The workshop attracted a diverse cohort of 32 participants, which included medical practitioners, nurses, researchers, and community representatives, ensuring a comprehensive representation of perspectives and expertise.

Participant Feedback: Feedback from participants was collated from an evaluation survey providing valuable insights into the workshop's effectiveness, areas of improvement, and future directions. *See the detailed survey responses available in the appendix.*

Snapshot Summary of Key Recommendations

Key Recommendations & Takeaways	
Use CAB-LA as a tool to discuss recommencement of PrEP to eligible patients	<ul style="list-style-type: none">• Leverage the novelty factor of CAB-LA to discuss recommencing PrEP, either oral or CAB-LA, with eligible patients who have ceased PrEP.
Target Specific Populations	<ul style="list-style-type: none">• Tailor educational materials and outreach strategies to meet the diverse needs of specific populations for more effective engagement in HIV prevention.
Address System Considerations	<ul style="list-style-type: none">• Develop tailored implementation strategies that include consideration of varying healthcare systems.
Learn from Oral PrEP Rollout	<ul style="list-style-type: none">• Use insights from the successes and challenges of the oral PrEP rollout to guide and optimise CAB-LA implementation.
Centralise Patient Priorities	<ul style="list-style-type: none">• Align educational efforts with patient needs and preferences, prioritising patient-centric approaches for greater relevance and effectiveness.
Expand PrEP Delivery	<ul style="list-style-type: none">• Explore innovative delivery models and collaborate broadly with diverse healthcare providers and systems to enhance PrEP accessibility and reach.

3. Workshop Sessions

The workshop commenced with opening remarks from the co-chairs, setting the tone for the day's discussions. They emphasised the significance of CAB-LA as a major paradigm shift for clinicians and healthcare workers in the field of HIV prevention and acknowledged the crucial role of industry partnerships in advancing public health initiatives and facilitating knowledge exchange within the healthcare community.

3.1 HIV seroconversion rates in PrEP users and non-PrEP users in Australia

Presented by Dr. Nick Medland, The Kirby Institute

Below are the main insights and recommendations generated from the session:

Success of Australia's PrEP roll-out: Australia's highly accessible and successful government-subsidised PrEP roll-out, initiated in 2018, has been instrumental in reducing HIV transmission rates. By providing affordable access to PrEP, Australia has seen a steady increase in uptake since its inception, with strong adherence to HIV testing guidelines among PrEP users.

Challenges and Questions: To achieve the goal of eliminating HIV transmission, several questions need to be addressed, including the long-term effectiveness of PrEP when scaled up, methods for measuring HIV incidence outside of controlled studies, and appropriate comparators for assessing PrEP efficacy.

Research Study Objectives: To estimate HIV incidence among PrEP users and predictors of HIV acquisition utilising linked de-identified government prescription/dispensing data. The study aimed to assess the population effectiveness of PrEP and identify factors associated with discontinuation.

Key Findings: Individuals with high adherence to PrEP, defined as $\geq 60\%$ days covered by PrEP, experienced a significant reduction in HIV incidence (79%). Even those with lower adherence ($< 60\%$ days covered) still saw a considerable decrease in HIV incidence (62%), highlighting the overall effectiveness of PrEP programs.

Areas for Improvement: While the results were promising, there were areas identified for potential improvement, such as providing additional support to certain demographics, including young people, individuals with hepatitis C risk factors, and those living outside inner urban gay areas. Identifying and addressing barriers to PrEP continuation is essential to maximise its impact on HIV prevention.

Implications for CAB-LA: The presentation raised questions about the role of CAB-LA in preventing HIV acquisition among previous users of oral PrEP. While the data suggested low HIV incidence rates among ongoing PrEP users, further research is needed to assess the potential benefits of transitioning to CAB-LA and its impact on HIV prevention.

Conclusion: Dr. Medland emphasised the importance of longitudinal research into PrEP and HIV incidence to inform future prevention strategies effectively, including evaluating the role of CAB-LA.

3.2 Overview of PBAC listing of CAB-LA for PrEP

Presented by Clinical Professor Louise Owen, Sydney Sexual Health

PBAC Submission Outcome (September 2023):

- CAB-LA for PrEP received a positive recommendation for listing on the PBS as a General Schedule, Authority required (Streamlined) listing. Clinical criteria were established to identify individuals who may benefit from CAB-LA, including those with current or likely suboptimal adherence to oral PrEP or contraindications to tenofovir disoproxil fumarate/emtricitabine (TDF/FTC).
- The revised restriction allows for a simpler clinical assessment of eligibility, broadening the population eligible for CAB-LA beyond those with contraindications to TDF/FTC.

PBAC Supportive Claims:

- PBAC supported claims regarding the efficacy, safety, and cost-effectiveness of CAB-LA compared to standard of care.
- While CAB-LA was deemed at least as effective as TDF/FTC, the extent of any incremental benefit was uncertain.
- Cost considerations favoured CAB-LA over the long term, with potential increases in PrEP coverage and reductions in HIV infections.

Discussion Points:

- CAB-LA was considered as an adjunct to existing PrEP options, offering an alternative for individuals with suboptimal adherence to oral PrEP.
- The cost-effectiveness of CAB-LA, despite requiring more frequent appointments initially, was highlighted as outweighing the risk of HIV infections associated with oral PrEP.
- Nurse practitioners were identified as suitable prescribers, potentially increasing access to CAB-LA for patients.
- It was noted that it will be important to observe how overseas data will be translated to Australian settings, specifically lower infection rates for cisgender women compared to gay and bisexual men and women with trans experience.

3.3 Long-Acting PrEP Summary & Guidelines

Associate Professor Vincent Cornelisse

A/Prof Cornelisse provided an overview of [ASHM's CAB-LA PrEP Guidelines](#)

Effectiveness Trials:

- The effectiveness of CAB-LA was assessed in two multicentre randomised controlled trials (HPTN-083 and HPTN-084). HPTN-083 enrolled cisgender men who have sex with men (MSM) and women of trans experience, while HPTN-084 enrolled cisgender women in sub-Saharan Africa. Both trials demonstrated significant reductions in HIV risk with CAB-LA compared to oral TDF/FTC.
- There was a total of 43 trial sites worldwide, however, some participants with high adherence to injection visits acquired HIV infection, warranting further discussion.

Safety Profile:

- Instances of HIV acquisition occurred during the oral lead-in phases of the trials. Notably, there was a 50% incidence of integrase strand transfer inhibitor (INSTI) mutations, likely due to delayed diagnoses resulting from viral load suppression during CAB-LA use. Late diagnoses contributed to the development of INSTI resistance mutations.
- Permanent discontinuation of PrEP due to adverse effects was uncommon in both trials, with similar rates between CAB-LA and TDF/FTC arms.
- Adverse events rated grade 2 or higher were common but similar between active CAB-LA and TDF/FTC arms.
- Adverse events, including weight gain, were observed with CAB-LA use compared to TDF/FTC. However, the implications of weight gain need to be carefully evaluated considering TDF/FTC's known impact on weight suppression.

Clinical Considerations:

- The ASHM PrEP guidelines recommend informed patient decision-making when selecting a PrEP regimen, including daily oral PrEP, on-demand oral PrEP, and CAB-LA injectable PrEP.
- CAB-LA is suitable for individuals at risk of HIV who may have difficulties adhering to oral PrEP or have contraindications to oral TDF/FTC.
- Several key factors were discussed in assessing a patient's suitability for CAB-LA:
 - **Adherence Challenges:** Patients who have demonstrated difficulty adhering to the oral PrEP regimen may benefit from the less frequent dosing schedule of CAB-LA.

- **Recurrent Side Effects:** Individuals experiencing recurrent side effects with oral PrEP may benefit from switching to CAB-LA.
- **Willingness to Receive Injections:** A patient's willingness to undergo an intramuscular injection every two months is necessary in determining their suitability for CAB-LA.
- **Patient Life Circumstances:** Consideration should be given to the patient's life circumstances, including medical, mental health and psychosocial factors that may impact adherence. Other potential factors such as frequent travel, competing priorities in life, unstable housing, privacy concerns and intimate partner violence should be considered. Patients who frequently travel to countries with restrictive HIV laws may prefer the option of receiving an injection before their travels, providing temporary protection against HIV transmission.
- **Bridging Non-Attendance:** Patients should be informed about the option of bridging non-attendance of appointments with oral PrEP to maintain protection against HIV transmission.
- **Understanding of Pharmacokinetics:** Patients should be educated about the pharmacokinetics of CAB-LA, including the period during which the drug remains detectable in the blood. This information is essential in discussing the risk of HIV acquisition and the potential development of resistance to INSTIs following cessation.

Initiation and Monitoring:

- CAB-LA initiation typically involves two appointments, with ongoing monitoring including laboratory tests and STI screening at relevant intervals. Patients should continue or commence oral PrEP for one week after the first CAB-LA injection if they are at current HIV risk.
- Questions raised by the group highlighted the importance of communication between healthcare providers and patients and patient-provider relationships and trust in assessing perceived risk of HIV when initiating PrEP. Discussions were also raised regarding the duration and efficacy of protection of CAB-LA through vaginal fluid after injection. Time to protection and oral lead in were concerns raised by the group seeking clarification on when protection begins, especially for those who undergo a 4-week oral lead in before transitioning to injections. The queries reflect strong interest in understanding the safety, efficacy and long-term implications of CAB-LA as a PrEP option.

Other Considerations and Cessation:

- Safety considerations include renal impairment, hepatic impairment, elderly patients, pregnancy, and breastfeeding. Participants raised questions about the occasional disturbance in renal and liver function observed during the trials, seeking clarification

on whether these issues were related to CAB-LA or other factors such as fatty liver, hepatitis, or alcohol consumption. Participants questioned potential long-term impacts of CAB-LA on renal function, and whether there was evidence of renal function issues emerging over longer periods of time, beyond the duration of existing studies.

- Cessation of CAB-LA should be followed by oral PrEP or consistent condom use if ongoing HIV risk is present. Discussions were raised on the difficulty navigating a management plan for HIV risk for 12 months with patients.

Pharmacokinetics and Monitoring:

- Pharmacokinetic studies have shown rapid onset and sustained plasma concentrations of CAB-LA, supporting its efficacy as PrEP.
- Monitoring during CAB-LA use includes regular HIV serology, renal and liver function tests, and STI and blood-borne virus (BBV) screening.

3.4 Round Table Panel: Pathways and challenges to bringing novel HIV treatment and prevention therapeutics to PBS listing

A round table panel discussion, chaired by co-chair Edwina Wright, was convened to address the pathways and challenges associated with bringing novel HIV treatment and prevention therapeutics to PBS listing in Australia.

The panellists addressed various issues, including patient populations and PrEP use, community knowledge dissemination, introduction of new science, PBAC's decision-making process, pharmaceutical companies' motivations, and considerations for drug prescribing and access.

Professor Darren Russell, A/Professor Vincent Cornelisse, and Dr. Melanie Bissessor provided insights into the diverse patient populations they serve and the barriers they face accessing PrEP, particularly marginalised groups and those ineligible for Medicare.

Chris Williams from Thorne Harbour Health, and Deputy Director of NAPWHA, Brent Clifton highlighted the importance of community engagement and peer interactions in spreading awareness about PrEP.

The discussion also touched upon the challenges of informing patients about new treatments and the regulatory aspects of sharing information with healthcare practitioners.

Chair of PBAC for the Australian Department of Health and Ageing, Professor Andrew Wilson shed light on PBAC's role in evaluating drugs for PBS listing, emphasising the need to balance cost, quality, and access.

The panel concluded with a discussion on pharmaceutical companies' motivations and the complexities of prescribing restrictions and access considerations. Overall, the panel highlighted the multifaceted nature of the challenges and considerations involved in bringing

novel HIV treatments and prevention methods to PBS listing and ensuring equitable access for all populations.

3.5 Identifying potential users of CAB-LA in diverse healthcare settings: Optimal models of injectable PrEP care delivery to different populations in diverse healthcare settings

These sessions focused on exploring optimal models of injectable PrEP care delivery for diverse populations across various healthcare settings. Case studies were presented to illustrate different scenarios, prompting participants to engage in discussions and share insights on effective approaches to deliver CAB-LA.

3.5.1 Session: Gay, Bisexual, Men who have sex with men (GBMSM), young MSM, people with medical contraindications.

Facilitated by Dr Melanie Bissessor, MSHC and Alfred Hospital.

Case Study 1

- 60 y/o cisgender MSM has not had sex for 10 years. Had an AMI 6 months ago.
- He has DM with diabetic nephropathy with hypertension and gout.
- His eGFR=52. His creatinine has been creeping up in the last two years with more than a 20 % drop in the last two years.
- He has erectile dysfunction and, in the past, has condomless sex.
- He has been hearing about PrEP and is considering exploring the possibility of sex again.

Case Study 2

- Tom is a 25 y/o cisgender MSM sexually active who has been on PrEP for 6 years. He has had 4 STIs in the last 4 months.
- He has a long history of irritable bowel syndrome and finds oral PrEP makes his IBS worse.
- He started taking event-driven PrEP, but he is concerned that he is having more sex recently and wants to go onto daily PrEP but is also concerned about the exacerbation of his GI symptoms.

Case Study 3

- 40y/o heterosexual cisgender man, George has schizophrenia, is non-adherent to his anti-hypertensives, currently injects heroin occasionally, and uses methamphetamine.
- He is on a depot anti-psychotic through a community treatment order.
- Asking about PrEP as he often has “chem sex”.

Discussion

Discussion revolved around the patients' suitability for CAB-LA and the timing of initiating the conversation. Participants highlighted challenges such as cost for people without Medicare, and access through compassionate access schemes.

Participants discussed possible strategies for identifying patients suitable for CAB-LA, managing their linkage to care, and addressing logistical challenges such as follow-up and adherence.

Considerations included leveraging existing clinic resources, incorporating telehealth, and engaging with support services for vulnerable populations. Other considerations included challenges of follow-up and adherence with CAB-LA, particularly for marginalised populations. The need for infrastructure development and collaboration with mental health services to support patients with complex needs was discussed.

The benefits of using consent/agreement forms to ensure understanding of treatment requirements and follow-up obligations was discussed, along with potential self-administration options and future developments in ultra-long-acting PrEP formulations.

3.5.2 Session: Aboriginal and/or Torres Strait Islander peoples, overseas-born populations

Facilitated by Prof. Darren Russell, James Cook University and Dr Melanie Bissessor with case study development input by Prof. Chris Lemoh, Western Health.

Case Study 4

- Barnaby is a 44-year-old cisgender man from the Torres Strait and frequently travels to mainland Australia for business.
- Has chronic kidney disease (eGFR = 68 mL/min/1.73m²).
- He is sexually active on the mainland only and is wary of keeping PrEP tablets at home.

Case Study 5

- Natalie is a 35-year-old sistergirl who has casual sex with cisgender men in Brisbane. Usually receptive anal sex and "sometimes" uses condoms.
- On no medications and in good health.
- Has heard of PrEP from some sexual partners and would like to know more.
- Usually goes to the local Aboriginal Medical Service for health matters but her cousin-sister is at the front desk and Natalie is worried about confidentiality.
- Has decided to attend the sexual health clinic instead.
- Is "terrible" at remembering to take tablets and wants to know if there are any alternatives?

Case Study 6

- 35-year-old cisgender man from sub-Saharan Africa who has lived in Australia for 5 years.
- Works as an insurance agent.
- Lives in the northwestern suburbs of Melbourne.
- No current partner: previous cisgender male and cisgender female partners but does not “self-identify as gay”. Uses condoms with casual partners.
- Occasional use of recreational drugs: smokes methamphetamines and cannabis but does not inject.
- What role might LA-PrEP play in his sexual health?

Discussion

Discussion encompassed various themes around the health of Aboriginal and/or Torres Strait Islander peoples and overseas-born populations, engagement strategies, and barriers to PrEP uptake.

Participants highlighted the need for culturally appropriate healthcare delivery and the importance of involving Aboriginal Healthcare Workers in PrEP administration and care coordination. Additionally, leveraging existing community resources, such as Aboriginal Medical Services and community pharmacies, was highlighted as a way to improve access to PrEP along with utilising financial incentives to enhance engagement with healthcare services.

Prof. Darren Russell spoke to the significance of addressing the multifaceted challenges faced by marginalised populations and illustrated these challenges by examining a recently published Canadian study on the intersectional social determinants for Indigenous peoples who acquired HIV in their youth (diagram below).

Participants highlighted the need for clinicians to understand the unique needs and preferences of overseas-born prospective users. This included clinicians taking a proactive approach in offering a choice of HIV prevention modalities, including CAB-LA. In doing so they would need to be aware of several factors such as cultural beliefs, healthcare experiences and access to resources to enhance accessibility and uptake.

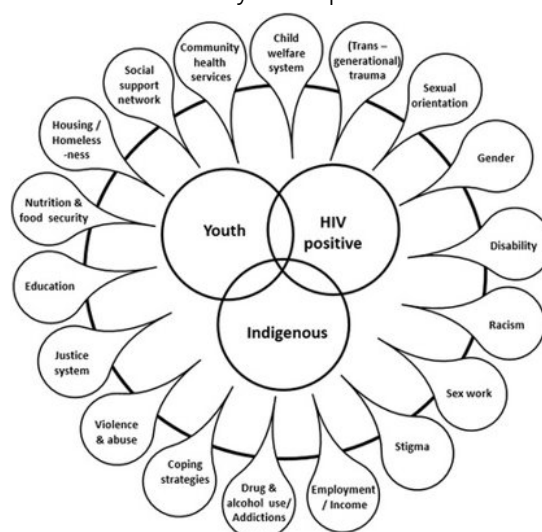


Image: Woodgate et al. *Int J Equity Health*. 2017; 16: 132

3.5.3 Session: Cisgender women, people who identify as heterosexual, fly-in-fly-out workers and people attending travel clinics

Facilitated by A/Prof. Mina John, Royal Perth Hospital and Dr Fergus McCabe, View St Medical.

Case Study 7

- Stella is a 22-year-old heterosexual cisgender woman who is in an open relationship with two bisexual cisgender men.
- She engages in condomless vaginal and receptive anal sex.
- Mirena IUD in situ 2nd to poor adherence to oral contraceptive pill. She has recently been diagnosed with perineal HSV-1 but has never had other STIs.
- Opportunistically started on PrEP at an S100 high caseload GP practice.

Case Study 8

- Mario is a 50-year-old married heterosexual cisgender man from Italy who has 3 adult children and whose marriage he reports, has been asexual since the birth of his children.
- DEXA lowest T-score -1.8 FN (FRAX # risk 3.4%/ Garvan 4%), eGFR 72.
- Vaginal and oral UPSI with unregistered sex workers twice per week and in Italy when visiting his parents – wife aware and insists on him being on PrEP.
- Highly adherent with PrEP, testing and contact tracing.
- STI Hx – urethral gonorrhoea x1 and chlamydia x1 in last 12/12.

Case Study 9

- Brett is a 48yr old cisgender man whose sexual identity is heterosexual. He is a FIFO worker with a 4/4 swing on a rig off the coast of WA.
- On his off-swing lives in Philippines with his 30yr old wife and her 8yr old daughter.
- Spends 1-2 weeks of every alternate off swing in Thailand where he has sex with sex workers including IAI with men with trans experience.
- 01/24 –very unwell prior to flying out to Rig, attended 1/12 later with markedly deranged LFTs and reported intermittent visual disturbance in his peripheral fields - referred to Ophthalmology - Syphilitic infiltrates in his retina – treated 15/7 IV penicillin.

Case Study 10

- Two cisgender men who are real-estate agents in their late 30's, in a same-sex open relationship attend to plan a round-the-world trip through South America including a "Gay Cruise" and then on to Europe and home via the Middle East. Planning to be "very active" on certain stages of their trip including SOP, but not the final period in the Middle East.
- Attended for travel vaccines, Malaria & Altitude sickness prophylaxis, Doxy PEP and their usual PrEP script but are keen to discuss LA PrEP for ease of travel.

Discussion

Discussion included patients who are cisgender female and identity as heterosexual emphasising the importance of individualised care and exploring all available options, considering concerns about risk of PrEP medications during pregnancy.

Participants noted that some cisgender women and other people with a vagina/uterus/cervix may perceive themselves to have a lower HIV risk compared to GBMSM. Furthermore, a recent paper from [Lade et al \(Sexual Health 2023\)](#) was discussed whereupon it suggested that PrEP prescribers in Australia felt that cisgender women had to reach a higher threshold of HIV risk to be offered PrEP compared to GBMSM.

There was consensus that individuals will request CAB-LA if this becomes available, indicating a need for healthcare providers to understand the eligibility criteria and the decision-making pathways when prescribing it.

Discussions highlighted the opportunity for discussing CAB-LA when patients present to discuss doxycycline for use as STI post-exposure prophylaxis; participants thought that patients who request doxy PEP may be particularly interested in CAB-LA.

Participants thought that FIFO workers and patients attending travel clinics will most likely be early adopters of CAB-LA having had experience with oral PrEP, but participants expressed hesitation about these populations using CAB-LA, questioning the practicality of dosing frequency and appointment attendance, especially for patients who travel frequently. However, there was recognition that CAB-LA could enhance ease of travel and overcome barriers associated with carrying oral PrEP during international travel to countries with punitive HIV laws.

Noteworthy suggestions included offering screening and injectable PrEP clinics in GP practices within the broader community, offering first injection of CAB-LA and simultaneously prescribing oral PrEP as a backup in case patients are travelling and can't make the appointment one month later, utilising pharmacy infrastructure for accessibility, and developing robust systems to provide long-acting HIV treatment and prevention.

The session concluded with Dr Fergus McCabe sharing insights from a survey that he undertook just prior to the workshop, of 75 PrEP users in Perth, Western Australia. Survey results indicated a high level of interest in accessing CAB-LA driven by factors including convenience, effectiveness, and recommendations from healthcare professionals. However, awareness of CAB-LA among respondents was limited, suggesting the need for education and outreach efforts in the lead up if CAB-LA becomes available. Additionally, after the survey respondents were informed about the need for one injection every two months and continued HIV prevention measures after discontinuing CAB-LA for 12 months, there was a decrease in the percentage of respondents who would be likely to access CAB-LA.

3.6 Identifying educational needs for healthcare providers

Medical Educator, Cherie Bennett led the final session of the workshop, focusing on identifying educational needs for healthcare providers. Ms Bennett summarised the day's sessions and discussions delving into the lessons learned, key considerations and outlining the educational modalities and models for CAB-LA at both the initial stages of roll out and during uptake.

Ms Bennett's key insights and lessons learnt were as follows:

1. **Opportunity for Reintroducing PrEP:** There's a recognition that CAB-LA carries a novelty factor, presenting a great opportunity to reintroduce PrEP into discussions and healthcare practices.
2. **Targeting Specific Populations:** Understanding the diverse populations and their specific needs is crucial. Tailoring education and outreach efforts accordingly can enhance effectiveness.
3. **System Considerations:** Different healthcare systems have varying structures and dynamics. Lessons from various studies provide valuable insights that can inform implementation strategies.
4. **Learning from Oral PrEP Rollout:** Reflecting on experiences from the rollout of oral PrEP offers valuable lessons for the introduction of CAB-LA. Understanding successes and challenges can guide effective implementation strategies.
5. **Patient Priorities:** Prioritising patient needs and preferences is essential. Aligning educational efforts with patient priorities ensures relevance and engagement.
6. **Targeted Education for Beneficial Populations:** Identifying and reaching populations that would benefit most from CAB-LA through targeted education initiatives could enhance uptake and effectiveness.
7. **Expanding PrEP Delivery:** Exploring avenues to expand the delivery of PrEP can increase accessibility and reach. This could involve innovative delivery models and collaborations with broader healthcare providers.
8. **Informed Consent and Toolkit Development:** Developing practical and time-saving tools, such as informed consent forms and toolkits, could streamline the implementation process and ensure compliance with regulatory requirements.

During the initial roll out stage of CAB-LA, suggested educational modalities and models included webinar series, peer support webinars, decision-making tools, on-demand learning opportunities, and toolkits. It was noted that there would be a need for early education preparation for the workforce.

For the implementation phase, there were recommendations for a combination of face-to-face and/or webinar sessions, peer support webinars, and roundtable discussions on service delivery approaches. Additionally, it was proposed that a follow-up session in 12 months could

take place to assess uptake and outcomes, examining population groups, prescribing settings, and geographical differences.

Ms Bennett solicited insights and feedback from the group, resulting in several valuable responses. Participants emphasised the role of early adopters in spreading awareness, the importance of tools and resources for patient advocacy, and the need to address uncertainties around patient demand for CAB-LA. They also discussed the involvement of GP colleges in education, the potential for a train-the-trainer program, and the inclusion of CAB-LA sessions at relevant national conferences.

Other suggestions included leveraging QR codes for patient information, introducing CAB-LA discussions through STI education, and targeting GP registrars through training programs. Participants also considered the feasibility of telehealth for parts of the CAB-LA process, highlighting the need for patient-centred care and innovative approaches to enhance accessibility and uptake.

4. Key Recommendations

Key Recommendations & Takeaways	
Opportunity for Reintroducing PrEP	<ul style="list-style-type: none"> • Recognition of novelty factor provides an opportunity to reintroduce the subject of PrEP to people who have disengaged. • Utilise the novelty factor to engage healthcare professionals and patients in discussions about CAB-LA.
Targeting Specific Populations	<ul style="list-style-type: none"> • Understanding diverse populations' needs is crucial for tailored education and outreach efforts. • Tailor educational materials and outreach strategies to specific populations to enhance effectiveness.
System Considerations	<ul style="list-style-type: none"> • Varying healthcare system structures require tailored implementation strategies. • Incorporate lessons from CAB-LA studies undertaken internationally to inform CAB-LA implementation strategies in Australia.
Learning from Oral PrEP Rollout	<ul style="list-style-type: none"> • Reflect on successes and challenges of oral PrEP rollout to guide CAB-LA implementation. • Apply lessons learned to address challenges and optimise CAB-LA uptake.
Patient Priorities	<ul style="list-style-type: none"> • Align educational efforts with patient needs and preferences for increased engagement. • Prioritise patient-centric approaches to ensure relevance and effectiveness of educational initiatives.
Expanding PrEP Delivery	<ul style="list-style-type: none"> • Explore innovative delivery models and collaborations to expand PrEP accessibility. • Collaborate with various healthcare providers to enhance PrEP delivery and reach.

Next Steps	
Educational Needs	<p>Initial Rollout Stage:</p> <ul style="list-style-type: none"> • Implement webinar series, peer support webinars, decision-making tools, and on-demand learning opportunities. • Develop toolkits to support healthcare providers during the initial rollout stage. Streamline implementation process with practical, time-saving tools like informed consent forms and toolkits. • Initiate early education preparation for the healthcare workforce.
	<p>Implementation Phase:</p> <ul style="list-style-type: none"> • Conduct a combination of face-to-face and/or webinar sessions, peer support webinars, and roundtable discussions. • Plan a follow-up session after 12 months to assess uptake and outcomes, examining population groups, prescribing settings, and geographical differences.
Role of Early Adopters	<ul style="list-style-type: none"> • Leverage early adopters to spread awareness and facilitate CAB-LA uptake.
Tools and Resources for Patient Advocacy	<ul style="list-style-type: none"> • Develop tools and resources for patient advocacy to empower patients in discussions with healthcare providers.
Involvement of GP Colleges	<ul style="list-style-type: none"> • Involve GP colleges and Primary Healthcare Networks in education and training programs to increase awareness and competency among healthcare providers.
Train-the-Trainer Program	<ul style="list-style-type: none"> • Implement a train-the-trainer program to disseminate knowledge and skills among healthcare professionals.
Inclusion in National Conferences	<ul style="list-style-type: none"> • Include CAB-LA sessions at relevant national conferences to reach a wider audience of healthcare professionals.
Innovative Approaches	<ul style="list-style-type: none"> • Explore innovative approaches like leveraging QR codes for patient information and integrating CAB-LA discussions into STI education.
Patient-Centred Care	<ul style="list-style-type: none"> • Prioritise patient-centred care approaches to ensure CAB-LA implementation meets the diverse needs of patients.
Feasibility of Telehealth	<ul style="list-style-type: none"> • Consider the feasibility of telehealth for parts of the CAB-LA process to enhance accessibility and uptake.

5. Appendices

Workshop attendees

- Alexis Apostolellis, ASHM, National
- Professor Andrew Grulich, The Kirby Institute, NSW
- Professor Andrew Wilson, Chair of PBAC, National
- Ashlee Jackson, Royal Prince Alfred Hospital, NSW
- Dr Beng Eu, Prahran Market Clinic, VIC
- Dr Benjamin Bavinton, The Kirby Institute NSW
- Brent Clifton, National Association for People Living with HIV/AIDS, National
- Dr Catriona ooi, Northern Sydney Sexual Health Service, NSW
- Cherie Bennett, ASHM and Sydney Sexual Health, NSW
- Chris Williams, Thorne Harbour Health, VIC
- Dr Clara Tuck Meng Soo, East Canberra General Practice, ACT
- Colin Roberts, Adelaide Sexual Health Clinic, SA
- Professor Darren Russell, James Cook University, QLD
- Dash Heath-Paynter, Health Equity Matters, National
- Dr David Baker, East Sydney Doctors, NSW
- Professor Edwina Wright, Co-Chair
- Elaine Turner, ASHM, National
- Dr Eugene Priscott, Kirkton Road Centre, NSW
- Dr Fergus McCabe, View St Medical, WA
- Dr Fiona Bisshop, Holdsworth House, QLD
- Jude Armishaw, Alfred Hospital, VIC
- Lachlan Gray, ViiV
- Clinical Professor Louise Owen, Sydney Sexual Health, TAS/NSW
- Dr Madhara Weerasinghe, Royal Prince Alfred Hospital, NSW
- Dr Manoji Gunathilake, Clinic 34, NT
- Dr Mark O'Reilly, East Sydney Doctors, NSW
- Matthew Vaughan, ACON, NSW
- Dr Melanie Bissessor, Melbourne Sexual Health Centre and Alfred Hospital, VIC
- A/Professor Mina John, Royal Perth Hospital, WA
- Dr Nick Medland, The Kirby Institute, NSW
- Rebekah Lamb, ASHM, National
- Robert Wisniewski, ASHM, National
- A/Professor Vincent Cornelisse, Co-Chair
- Dr William Donehue, O'Brian St Practice, SA



ashm

Developing a sustainable HIV,
viral hepatitis & sexual health workforce

Long-Acting PrEP Workshop

Date: Saturday 6 April 2024

Time: 9:30am – 4:15pm (AEDT)

Location: Parkview room, The Pullman Hyde Park, Sydney

Co-Chairs: Professor Edwina Wright and Associate Professor Vincent Cornelisse



TIME	PROGRAM OUTLINE	FACILITATOR
9:30 – 9:45	Welcome <ul style="list-style-type: none">Acknowledgement of CountryOverview of workshop objectives	Co-Chairs
9:45 – 10:00	HIV sero-conversion rates in PrEP users and non-PrEP users in Australia	Dr. Nick Medland, The Kirby Institute
10:00 – 10:15	Overview of the PBAC listing of CAB-LA for PrEP	Clin Prof. Louise Owen, Sydney Sexual Health
10:15 – 11:00	Long-Acting PrEP <ul style="list-style-type: none">Profile and summaryASHM Injectable PrEP Guidelines	A/Prof. Vincent Cornelisse
11:00 – 11:15	Morning Tea	
11:15 – 12:00	Round Table Panel: Pathways and challenges to bringing novel HIV treatment and prevention therapeutics to PBS listing	Prof. Edwina Wright
12:00 – 12:45	Identifying potential users of CAB-LA in diverse healthcare settings. Optimal models of injectable PrEP care delivery to different populations in diverse healthcare settings: <ul style="list-style-type: none">GB MSMYoung MSMPPL with medical contraindications	Dr. Melanie Bissessor, MSHC and Alfred Hospital
12:45 – 1:30	Lunch	



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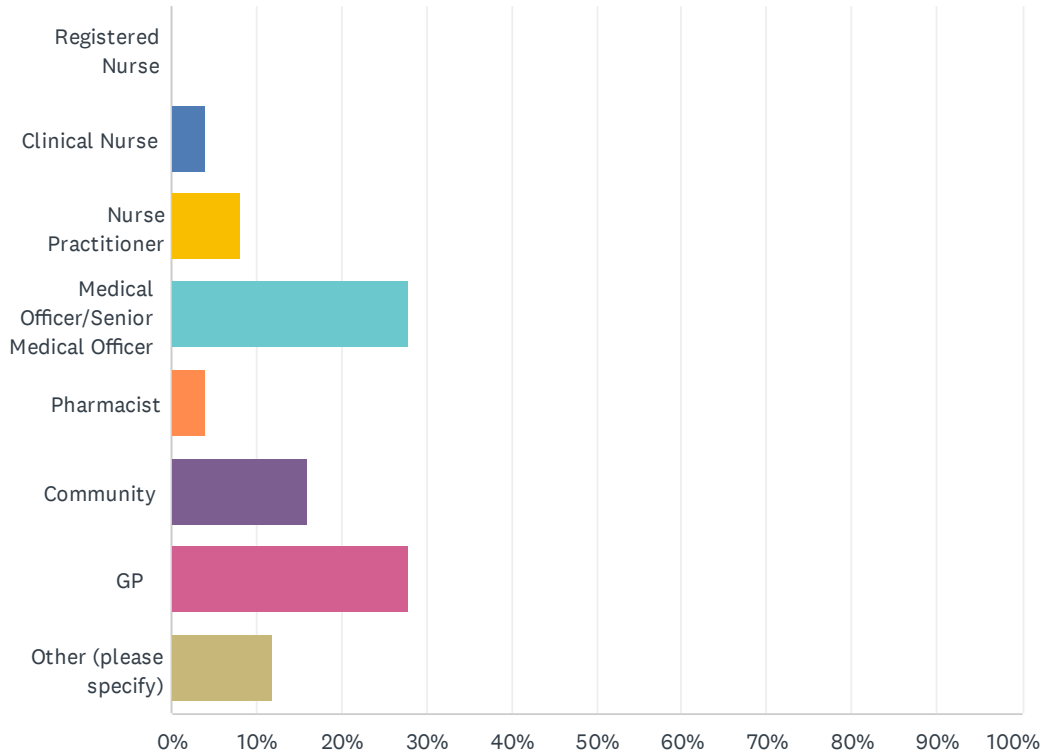
Co-Chairs: Professor Edwina Wright and Associate Professor Vincent Cornelisse



TIME	PROGRAM OUTLINE	FACILITATOR
1:30 – 2:15	Identifying potential users of CAB-LA in diverse healthcare settings. Optimal models of injectable PrEP care delivery to different populations in diverse healthcare settings: <ul style="list-style-type: none">• Aboriginal and Torres Strait Islanders• Overseas-born population	A/Prof. Darren Russell, James Cook University Prof. Chris Lemoh, Western Health
2:15 – 3:00	Identifying potential users of CAB-LA in diverse healthcare settings. Optimal models of injectable PrEP care delivery to different populations in diverse healthcare settings: <ul style="list-style-type: none">• Women• Heterosexuals• FIFO• Travel clinics	Dr. Fergus McCabe, View St Medical, Perth A/Prof. Mina John, Royal Perth Hospital
3:00 – 3:30	Afternoon Tea	
3:30 – 4:00	Identifying educational needs for healthcare providers	Cherie Bennett, ASHM
4:00 - 4:15	Wrap Up & Close	Co-Chairs

Q1 Which of the following best describes your main role?

Answered: 25 Skipped: 0



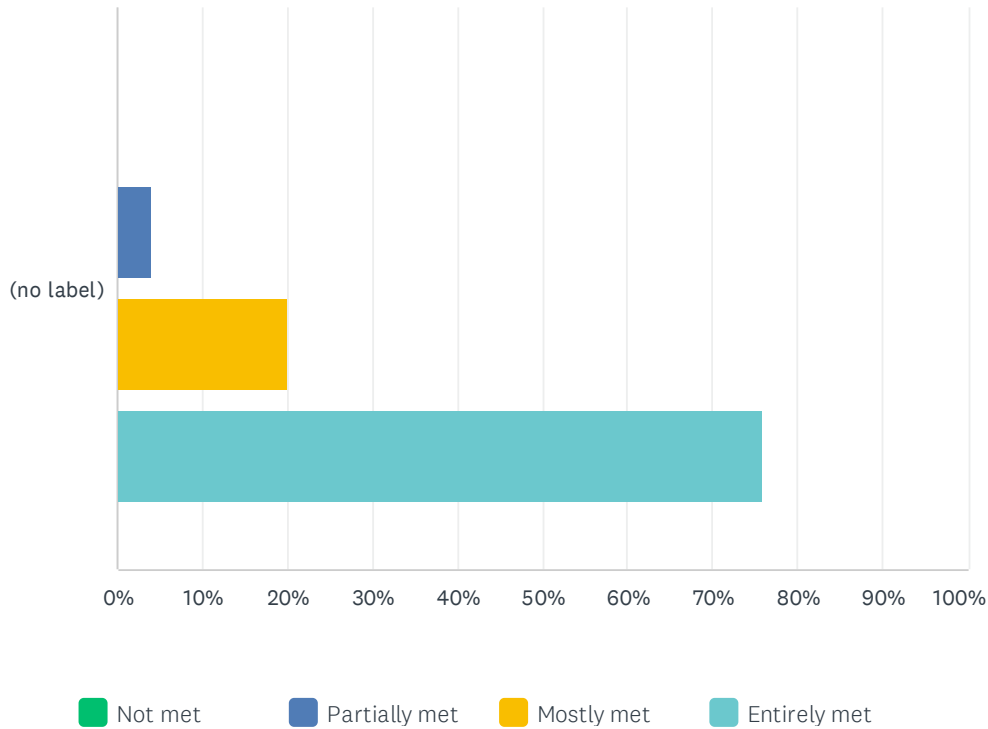
ANSWER CHOICES	RESPONSES
Registered Nurse	0.00% 0
Clinical Nurse	4.00% 1
Nurse Practitioner	8.00% 2
Medical Officer/Senior Medical Officer	28.00% 7
Pharmacist	4.00% 1
Community	16.00% 4
GP	28.00% 7
Other (please specify)	12.00% 3
TOTAL	25

#	OTHER (PLEASE SPECIFY)	DATE
1	Research	4/9/2024 9:18 AM
2	Admin	4/6/2024 3:06 PM
3	Research	4/6/2024 3:06 PM

Q2 There were four objectives of the workshop. The following questions will explore to what extent where these met. Objective one of the

workshop was: Provide a comprehensive understanding of ASHM's CAB-LA for PrEP guidelines. To what extent was this objective met?

Answered: 25 Skipped: 0

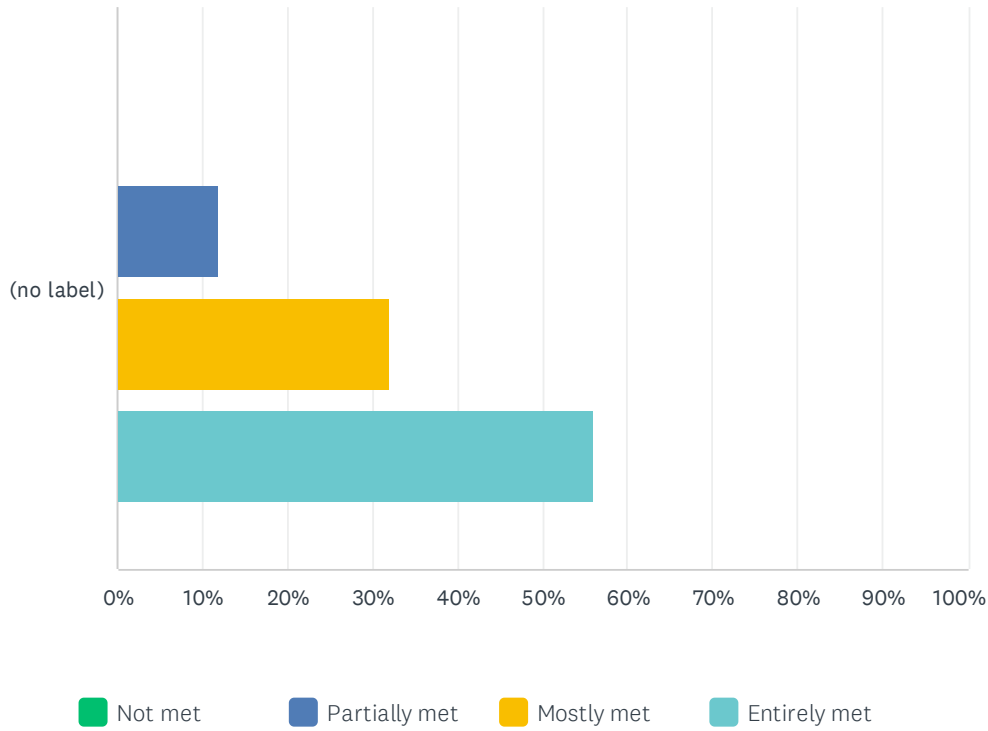


	NOT MET	PARTIALLY MET	MOSTLY MET	ENTIRELY MET	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	4.00% 1	20.00% 5	76.00% 19	25	3.72

Q3 Objective two of the workshop was: Optimise the identification process of patients suitable for CAB-LA across a range of healthcare settings. To what extent was this objective met?

Answered: 25 Skipped: 0

Long Acting PrEP Workshop 2024: Post-Workshop Survey

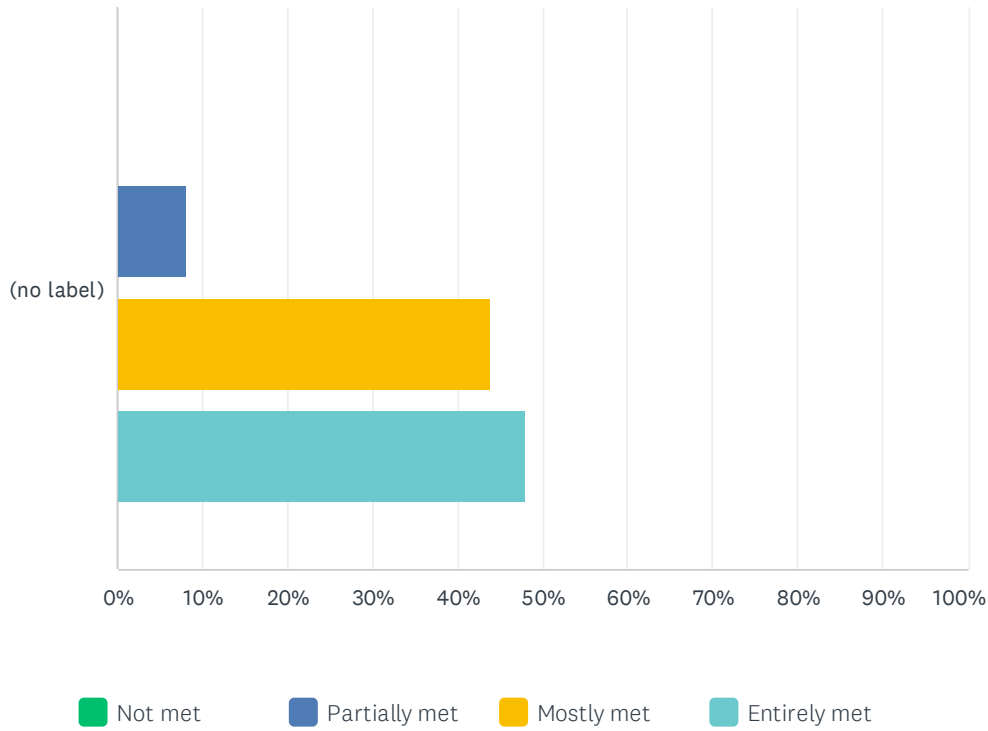


	NOT MET	PARTIALLY MET	MOSTLY MET	ENTIRELY MET	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	12.00% 3	32.00% 8	56.00% 14	25	3.44

Q4 Objective three of the workshop was: Explore implementation considerations and models of care for specific populations, examining their delivery within diverse healthcare settings. To what extent was this objective met?

Answered: 25 Skipped: 0

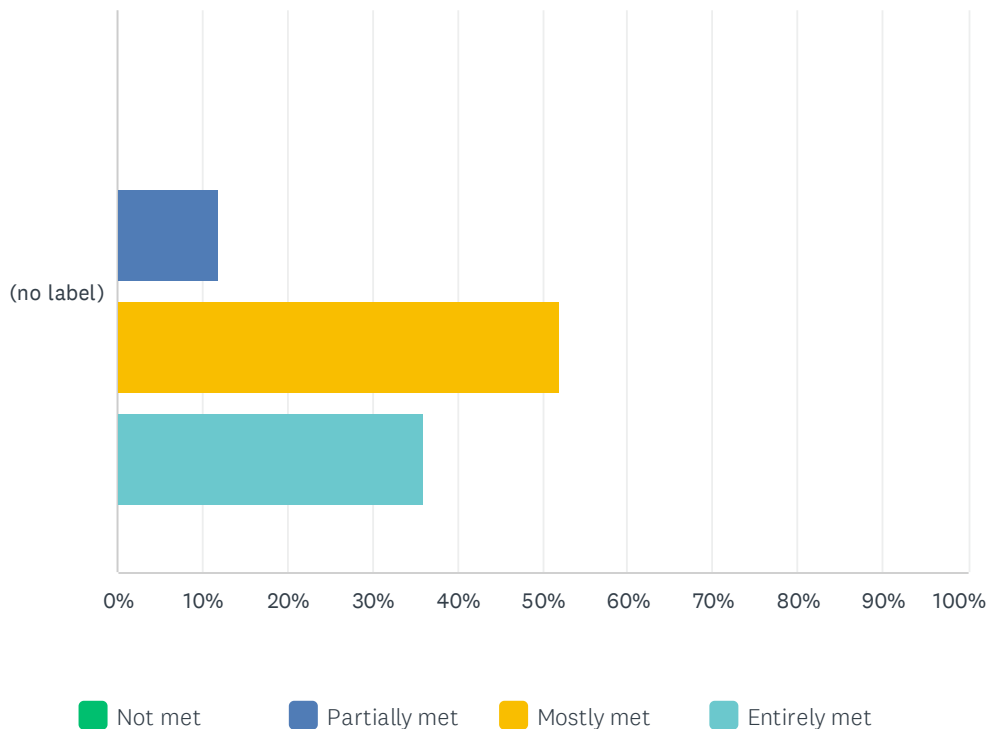
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	NOT MET	PARTIALLY MET	MOSTLY MET	ENTIRELY MET	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	8.00% 2	44.00% 11	48.00% 12	25	3.40

Q5 Objective four of the workshop was: Identify and explore educational needs and models that will support providers over the next 12 months. To what extent was this objective met?

Answered: 25 Skipped: 0



Long Acting PrEP Workshop 2024: Post-Workshop Survey

	NOT MET	PARTIALLY MET	MOSTLY MET	ENTIRELY MET	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	12.00% 3	52.00% 13	36.00% 9	25	3.24

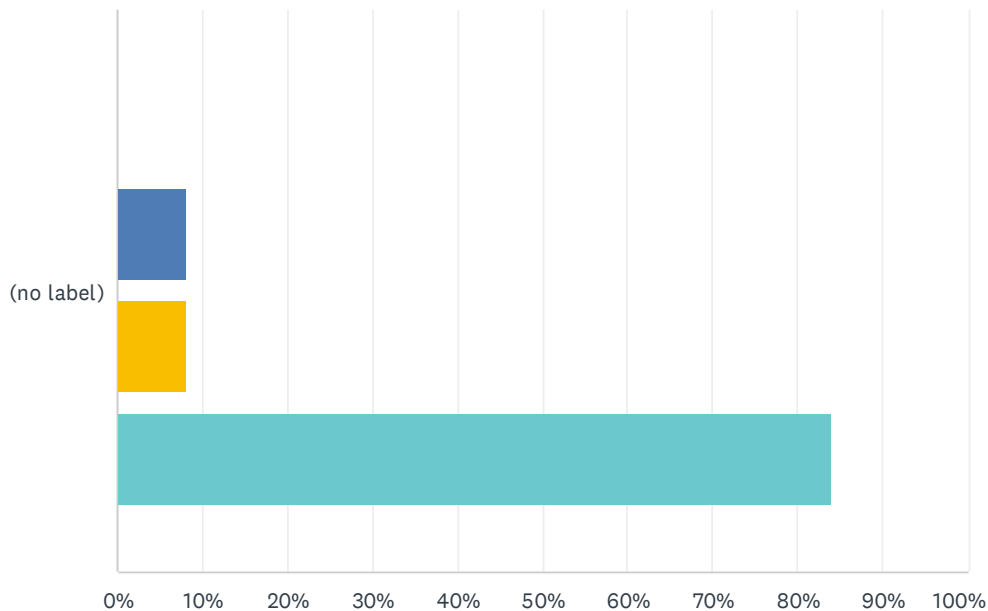
Q6 For what reason(s) were the workshop learning objectives not met?

Answered: 6 Skipped: 19

#	RESPONSES	DATE
1	It's not that they were "not" met, it is just that the discussions, while extremely insightful and useful, were a bit of a conversation starter rather than actually figuring much out. There is a huge amount of work yet to do on all four of these objectives. But the workshop was a great start.	4/9/2024 9:23 AM
2	It necessary to look at resource limited and remote settings too. It is quite difficult to make medications available to remote primary health services.	4/9/2024 8:28 AM
3	Early phase of discussion Lots of moving parts	4/6/2024 3:09 PM
4	Could have spent more time on implementation details	4/6/2024 3:08 PM
5	Nil	4/6/2024 3:08 PM
6	N/A	3/28/2024 3:35 PM

Q7 To what extent was this activity relevant to your role?

Answered: 25 Skipped: 0



■ Not relevant
 ■ Somewhat ...
 ■ Mostly rele...
 ■ Entirely rel...

	NOT RELEVANT	SOMEWHAT RELEVANT	MOSTLY RELEVANT	ENTIRELY RELEVANT	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	8.00% 2	8.00% 2	84.00% 21	25	3.76

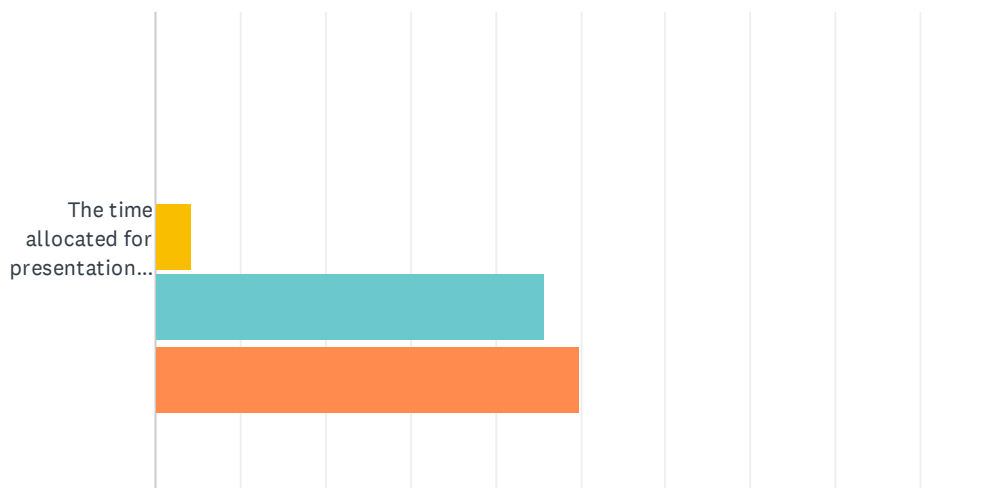
Q8 What was your highlight of the day?

Answered: 19 Skipped: 6

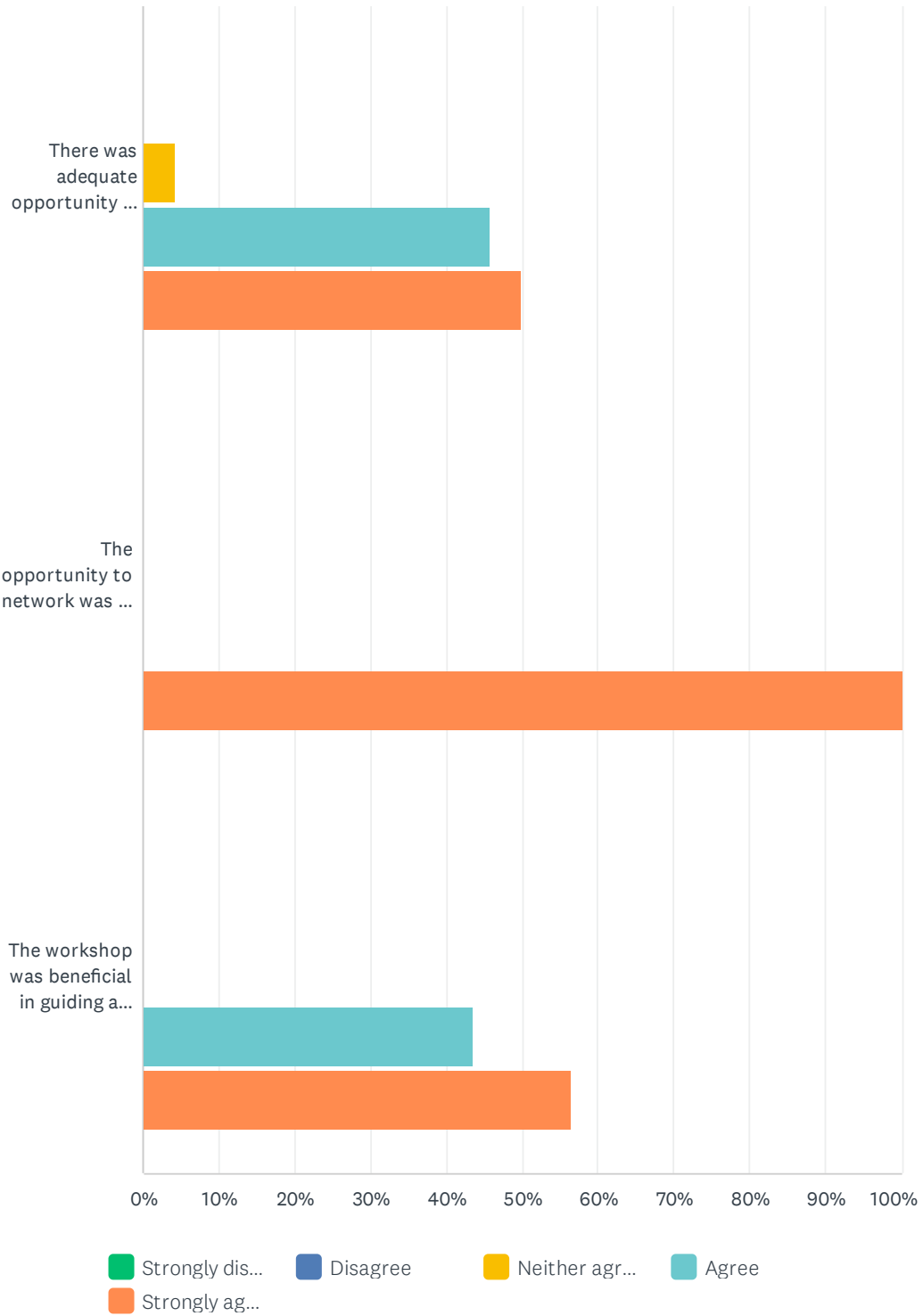
#	RESPONSES	DATE
1	Being in a room with a great variety of clinical experts from across Australia! And seeing the broad array of complex case presentations, which is useful for contextualising education messaging to community.	4/17/2024 3:17 PM
2	Hearing from the chair of PBAC was very useful. An entire session could have been devoted to this topic as opposed to it being part of the panel! Really helpful.	4/9/2024 9:23 AM
3	Having the opportunity to participate & question key leaders in sexual health. Sharing developments and what's working in some clinical areas	4/9/2024 9:21 AM
4	Inclusion of all states and territories in Australia	4/9/2024 8:28 AM
5	Finding out there is a YMCA on an oil rig! honestly-the whole day was excellent	4/6/2024 6:11 PM
6	Broad based discussions	4/6/2024 3:09 PM
7	Great to be with esteemed. Colleagues and community Thanks for bringing us together	4/6/2024 3:09 PM
8	Group photo 📸	4/6/2024 3:08 PM
9	Everything	4/6/2024 3:08 PM
10	Fun educational day with lovely colleagues 😊	4/6/2024 3:08 PM
11	Interaction and side discussions	4/6/2024 3:08 PM
12	Case discussions were excellent!	4/6/2024 3:08 PM
13	Case studies	4/6/2024 3:08 PM
14	Logistics of LA AB use	4/6/2024 3:08 PM
15	Hearing everyone else's great ideas.	4/6/2024 3:07 PM
16	The case studies and PBAC person	4/6/2024 3:07 PM
17	Case studies	4/6/2024 3:07 PM
18	All good!	4/6/2024 3:07 PM
19	the Projector worked beautifully and CourtENAY was very helpful	3/28/2024 3:35 PM

Q9 To what extent do you agree with the following statements?

Answered: 24 Skipped: 1



Long Acting PrEP Workshop 2024: Post-Workshop Survey



Long Acting PrEP Workshop 2024: Post-Workshop Survey

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
The time allocated for presentations/sessions was about right.	0.00% 0	0.00% 0	4.17% 1	45.83% 11	50.00% 12	24	4.46
There was adequate opportunity for discussion and participation.	0.00% 0	0.00% 0	4.17% 1	45.83% 11	50.00% 12	24	4.46
The opportunity to network was a key benefit to attending the workshop	0.00% 0	0.00% 0	0.00% 0	0.00% 0	100.00% 1	1	5.00
The workshop was beneficial in guiding and planning the implementation of CAB-LA in my setting.	0.00% 0	0.00% 0	0.00% 0	43.48% 10	56.52% 13	23	4.57

Q10 Considering the ongoing rollout of CAB-LA in your clinical practice, what additional activities or resources do you believe are necessary for health practitioners? For example, further training sessions, updated educational materials, or access to specialised resources.

Answered: 12 Skipped: 13

#	RESPONSES	DATE
1	ASHM's patient letter as an advocacy tool for patients to inform their GP about PrEP and where to seek clinical educational resources.	4/17/2024 3:19 PM
2	I am not in clinical practice but here is what I think anyway: - tools/processes to aid in identifying appropriate patients - decision aids and resources to aid patients and practitioners in deciding whether CAB-LA is suitable for them - clear and easy to use appointment scheduling and follow-up procedures - injection training sessions (this is not a simple injection to do - even experienced people are going to need specific training) - CAB-LA guidelines summary and training sessions - Sessions with pharmacies are going to be needed - will many pharmacies even stock this drug? So many of them still don't even stock oral PrEP. Hopefully the CAB-LA implementation science trial will become a reality and we will explore and develop a lot of these through that process, in partnership with all the stakeholders.	4/9/2024 9:28 AM
3	Educational & practical resources eg templates for clinical records etc	4/9/2024 9:23 AM
4	ashm online training module and an intake forms.	4/9/2024 8:30 AM
5	Updated educational resources including patient directed educational resources	4/6/2024 6:13 PM
6	Training and education and exploration of systems	4/6/2024 3:37 PM
7	System implementation tips	4/6/2024 3:29 PM
8	Patient consent form, 2 page ASHM summary	4/6/2024 3:10 PM
9	Training and handouts. Consent form	4/6/2024 3:09 PM
10	Guidelines/protocols for CAB LA	4/6/2024 3:09 PM
11	Another workshop	4/6/2024 3:08 PM
12	Webinars and tool kit	4/6/2024 3:08 PM

Q11 Additionally, do you think a similar workshop conducted 12 months into the rollout of CAB-LA would be beneficial, or do you have other suggestions for supporting health practitioners in this process?"

Answered: 16 Skipped: 9

#	RESPONSES	DATE
1	Yes - to identify and aim to resolve pain points in the rollout and establish patterns of uptake thus far.	4/17/2024 3:19 PM
2	Yes, it is likely to be beneficial but I would be aiming to try to include more clinicians who are not specialists in HIV. The HIV and SH specialists are going to be the early adopters of CAB-LA in clinics. It is very unclear at this point whether other clinicians will be interested in it and want to implement it.	4/9/2024 9:28 AM
3	Yes - what worked, hiccups noted, barriers to equitable access Australia wide.	4/9/2024 9:23 AM
4	Yes	4/9/2024 8:30 AM
5	Yes	4/6/2024 6:13 PM
6	Not sure	4/6/2024 3:37 PM
7	Yes	4/6/2024 3:29 PM
8	Yes	4/6/2024 3:10 PM
9	Yes	4/6/2024 3:09 PM
10	Train the trainer sounds good.	4/6/2024 3:09 PM
11	Would be useful	4/6/2024 3:09 PM
12	Could be helpful	4/6/2024 3:09 PM
13	Absolutely	4/6/2024 3:08 PM
14	Yes	4/6/2024 3:08 PM
15	Yes	4/6/2024 3:08 PM
16	Yes	4/6/2024 3:08 PM

Q12 Do you have any additional comments?

Answered: 10 Skipped: 15

#	RESPONSES	DATE
1	Well organised, perhaps slightly longer may have stimulated deeper exploration.	4/9/2024 9:23 AM
2	Thank you	4/9/2024 8:30 AM
3	Really excellent thought provoking session - thank you	4/6/2024 6:13 PM
4	Useful to have national data collection during first 12 months. Not onerous. Just timing of clinic visits, lost to follow-up and HIV test results. Also interviews with different clinics to see what systems were implemented	4/6/2024 3:37 PM
5	Great day excellent brain storming	4/6/2024 3:29 PM
6	No	4/6/2024 3:10 PM
7	No	4/6/2024 3:09 PM
8	All wonderful	4/6/2024 3:08 PM

Long Acting PrEP Workshop 2024: Post-Workshop Survey

9	Excellent opportunity for me this meeting . Thank you	4/6/2024 3:08 PM
10	thank you	3/28/2024 3:36 PM