Burnett Foundation Aotearoa

17 August 2023

Tēnā koe PHARMAC,

We are writing on behalf of the National HIV and AIDS Forum, in relation to the current dispensing of antiretroviral treatments for people living with HIV.

The National HIV and AIDS Forum is a collective of parties working in HIV prevention, care, policy, and research in Aotearoa New Zealand. The objective of the Forum is to serve as a multi-disciplinary national HIV and AIDS body that provides leadership and enables cross-sector collaboration. We do this by identifying and debating key issues, providing guidance to relevant government Ministries and agencies, and supporting the coordination of HIV-related service delivery by public sector and civil society organisations.

We are writing in relation to the current default dispensing of antiretroviral treatments (ARTs) in Aotearoa New Zealand being 'monthly dispensing' of 30 days, instead of 'STAT' dispensing' (of 90 days). We believe this policy is not fit for purpose and it currently poses a barrier to effective treatment for some people living with HIV. We urge PHARMAC to nationally apply STAT dispensing to antiretroviral treatments (ARTs) as soon as possible, as this will enable people living with HIV to have access to three months of ARTs at a time, enabling smoother pathways to care.

We understand that PHARMAC proposed expanding the 'STAT' medicines list in 2020 (PHARMAC, 2020). The rationale behind the proposal was PHARMAC's desire to enable patient access to medication for adequate periods of time and in line with their needs (PHARMAC, 2020). PHARMAC argued that this initiative was aligned with the 'people-powered' theme of the 2016 New Zealand Health Strategy and World Health Organization (WHO) definition of the rational use of medicines, where patients receive medications for adequate periods of time at the lowest cost to them and their community (PHARMAC, 2020). In line with this approach of people-centred policies for medication access, we strongly encourage PHARMAC to apply STAT dispensing to ART.

We outline our arguments for this change in this letter, which in summary include:

- HIV is a life-long condition with no cure and severe risk of poor health outcomes when there are barriers to adherence, including monthly ART dispensing. Poor adherence can have a flow-on effect on the person's health, as well as their ability to maintain an undetectable viral load and therefore prevent further transmission.
- People living with HIV face unique difficulties in accessing medication, relating to experiences of stigma and discrimination in healthcare, alongside internalised and intersectional stigma. As a specialist medication, ART is not routinely stocked by all pharmacies, creating delays in dispensing.
- The current policy exacerbates inequities for marginalised subgroups of people living with HIV, including through imposing an increased financial burden through indirect travel costs and greater time commitment. This is particularly true for Māori who experience significant inequities in access to healthcare, lower rates of pharmaceutical dispensings, and general worse health outcomes.
- Arguments for monthly dispensing related to wastage are not relevant as people living with HIV have demonstrated adherence levels to their treatment with high rates of people reporting undetectable viral loads.
- The WHO, UNAIDS, and a growing literature base support multi-month dispensing.

Poor access to ART is major barrier to adherence

HIV is a life-threatening condition that demands daily adherence to ART. HIV has no cure and requires a life-long commitment to treatment for people to remain healthy. Long term issues with adherence are dangerous, as it can lead to insufficiently supressed viral load, the development of HIV drug resistance, treatment failure, HIV disease progression, AIDS, and even death. While one missed dose is unlikely to result in HIV drug resistance, repeat instances of treatment interruption are an opportunity for mutation. The development of drug resistance would be a particular issue in Aotearoa New Zealand, given the limited range of funded ART medications available in this country.

With an ageing population of people living with HIV and the increased burden of polypharmacy and co-morbidities, there is a need to reduce the dependence on clinical and pharmacy visits. According to the WHO, frequent ART pick-ups and clinic visits can be burdensome for people living with HIV and is likely associated with poor adherence and poor retention to care (World Health Organization, 2021), in turn leading to worse outcomes for those people living with HIV. At the recent British HIV Association Conference, disengagement from care was presented as an increasingly pertinent challenge for the wider HIV response, with the estimated number of people living with HIV who had disengaged from care comprising over three times the estimated number of people who were undiagnosed (Cairns, 2023). Given this context, monthly dispensing of ART is inappropriate and not beneficial to people living with HIV.

Furthermore, PHARMAC recently applied STAT dispensing to PrEP, facilitating ease of access to this important biomedical tool for HIV prevention. While we commend PHARMAC for this decision, as a collective of organisations involving people living with HIV, we have heard frustration that the rules currently allow someone to receive 3 months' supply of PrEP, but people living with HIV cannot get 3 months' supply of ART, even though they need to take these medications daily for their survival. There is also similar frustration that those living with chronic conditions other than HIV have their medication dispensed every 3 months. We urge PHARMAC to consider the serious and unique risk of access barriers to people living with HIV's health and move urgently to STAT dispensing.

HIV stigma poses a unique barrier to ART access

People living with HIV face unique inequities to accessing medication due to the persistence of HIV stigma, particularly in the healthcare setting. While we encourage pharmacy staff to upskill in understanding HIV and tackling stigma and discrimination, people living with HIV should not be subject to increased chances of discrimination.

The Aotearoa New Zealand People living with HIV Stigma Index Report showed that fear of others finding out about one's HIV status, fear of mistreatment by healthcare workers, and previous poor experiences with health workers all led to people living with HIV delaying or hesitating in getting HIV treatment or care (The Aotearoa New Zealand People Living with HIV Stigma Index, 2020). Previous experiences of discrimination and stigma in healthcare interactions were prominent among Stigma Index participants, with 12% reporting experiences of avoidance of physical contact in HIV-related healthcare (15% in non-HIV related healthcare) (The Aotearoa New Zealand People Living with HIV Stigma Index, 2020). Almost a quarter of Māori participants of the Stigma Index had experienced discriminatory behaviour from healthcare staff for non-HIV related care (Te Whāriki Takapou, 2021). These findings were mirrored in the experiences shared by some of our staff, one of whom argued that they "hate picking up [their] HIV medication from the chemist. My pharmacist once questioned me in front of other customers. It was really embarrassing".

HIV stigma can impact healthcare access through less direct pathways as well. Internalised stigma measures showed 13% of all stigma index participants had chosen not to seek health care in the last 12 months (The Aotearoa New Zealand People Living with HIV Stigma Index, 2020). People living with HIV must take time away from work for HIV-related care, like appointments, bloodwork, and medicine pick-ups, which is difficult if they have not disclosed their status at work for fear of subsequent discrimination or due to internalised stigma. These situations can create tension with employers, and limit people living with HIV's ability to engage in their HIV care and treatment.

A person's physical and mental condition can influence the ease with which they can physically access their local pharmacy (PHARMAC, 2019). Poor mental health makes the administrative burden of accessing healthcare more prominent as a barrier to access (Carswell et al., 2018). 43% of all participants in the Stigma Index survey experienced mental health conditions such as anxiety, depression, or insomnia in the past 12 months, indicating a disproportionate burden of these mental health problems among people living with HIV and presenting a barrier to accessing ART at pharmacies (The Aotearoa New Zealand People Living with HIV Stigma Index, 2020). Compared to non-Māori participants, Māori living with HIV in the Stigma Index were more likely to report experiences of undiagnosed mental health conditions and were less likely to receive support for those conditions (Te Whāriki Takapou, 2021). The burden of monthly coordination of medication pickups, which includes the monthly expenditure of financial and time resources, and the need to navigate HIV-related stigma can impact a patient's mental health negatively, creating a vicious cycle that impedes access to ART.

Moreover, some people living with HIV experience intersecting forms of stigma and discrimination in relation to things like their gender, sexual orientation, and ethnicity that compound upon HIV-related stigma (The Aotearoa New Zealand People Living with HIV Stigma Index, 2020). This intersecting stigma can create further reluctance to engage in health services, like accessing pharmacies, which can further amplify inequities between people living with HIV. People who inject drugs (PWID) remain a vulnerable population due to the stigma they are exposed to. This is very much the case where PWID live rurally and are required to travel to receive their medications. Additionally, the difficult lives that some PWID lead increase this vulnerability, where scarce resources further impact on poor health and disinclination to accessing mainstream health services due to distrust and negative experiences. For these reasons, clear and streamlined pathways to treatment, including STAT dispensing of ART, are of paramount importance to supporting all groups of people living with HIV.

Specialist medications like ART involve additional access barriers

Geographic availability of pharmacies can pose a barrier to accessing medication depending on where a person lives or works (Carswell et al., 2018). Local research shows that more than 13% of New Zealanders live more than 5km away from a pharmacy, and 1-2% live more than 25km away from a pharmacy (Norris et al., 2014). The most readily accessible pharmacy geographically may also have inconvenient opening hours that clash with patients' working hours (Carswell et al., 2018). While these issues affect all people accessing pharmacies, an additional issue for people living with HIV is that ART is a specialist medication. ART is therefore not stocked at all pharmacies. This means that there are already limited pharmacies from which people living with HIV can access their medication, especially in rural settings. Consequently, patients may have to wait for the pharmacy to order their medication in, resulting in multiple pharmacy visits, or else travel to pharmacies further away. As a collective of organisations working with people living with HIV, we understand that one of the many time-consuming parts of many people living with HIV's healthcare is having to pick up refills on their medication. For transient or mobile populations, these barriers may be particularly challenging to navigate. Under the current rules, people living with HIV must navigate these access issues every month to access their life-saving medication. Moving to STAT dispensing would limit the number of visits to pharmacies, reducing the burden of these access barriers to treatment for people living with HIV.

Monthly dispensing could be exacerbating inequities

Any medicine requiring monthly collection can impose additional time and financial pressure for individuals to access the pharmacy. However, these pressures are not equitably distributed.

People with low incomes face significant constraints on their choices about how to spend money, given the need to prioritise basic living costs like food and housing (Carswell et al., 2018). We welcome news that the \$5 co-payment fee has been removed as a barrier to accessing medication in Aotearoa. However, indirect financial costs can also impact people living with HIV's access to medication. Pharmacies may not be allowed to charge directly for repeats, but there have been reports of other costs per dispensing, including fees for faxed prescriptions, delivery fees, and after-hours fees. There are cost barriers associated with public transport, as well as car ownership, petrol, and parking (Carswell et al., 2018). Costs related to transport and mobile phone usage (to organise appointments and answer voicemails) and organising time off work disproportionately affect the access of people with lower incomes (Carswell et al., 2018). Lack of availability of transport is also major factor in inequities in unmet primary healthcare needs for people living in the most deprived neighbourhoods of Aotearoa New Zealand (as compared to least deprived neighbourhoods) (Carswell et al., 2018). Switching to STAT dispensing will reduce the amount of indirect costs that add to the overall financial burden of accessing healthcare for people with low incomes.

Māori also experience inequities in relation to access to medications. In 2012/2013, Māori had 41% lower pharmaceutical dispensings than non-Māori (Metcalfe et al., 2018). Annual health statistics showed Māori are 2.45 times more likely than non-Māori to defer GP visits due to transport unavailability, which is an issue that we can infer likely extends to accessing pharmacies (Ministry of Health, 2022). Despite high levels of education, almost half of Māori participants living with HIV in the Stigma Index survey reported being unable to meet basic food, shelter, and clothing needs some or most of the time in the previous 12 months (Te Whāriki Takapou, 2021). This indicates racism intersects with HIV stigma in ways that restrict Māori living with HIV from securing stable incomes. It also means Māori living with HIV have inequitable access to financial resources needed to access medication. For Māori, previous bad experiences of healthcare including implicit bias, unsafe cultural practices, and racism all lead to mistrust and reluctance to engage in further care (Carswell et al., 2018).

For minority ethnic groups in general, issues such as racism and Eurocentric care create negative experiences of healthcare and lead to reluctance to access healthcare in the future (Carswell et al., 2018). Refugees and migrants with limited proficiency in English face language and communication barriers (Carswell et al., 2018). Local research showed that Indian and Chinese migrants faced difficulty accessing pharmacies on account of language barriers, with some participants choosing to travel longer distances to visit pharmacists that speak their native language (Babar et al., 2013). The participants in this study also expressed confusion related to repeat prescription processes and having to return monthly to collect repeats, stating that pharmacies had failed to explain this process to them (Babar et al., 2013). In the context of these socioeconomic, cultural and communication barriers, keeping the process as streamlined as possible through mechanisms like STAT dispensing would facilitate greater access to medication like ART and address inequities for people living with HIV who also belong to minority ethnic groups.

There are also increased inequities for young people living with HIV. Young people often experience limited financial autonomy and freedom of movement (e.g. lack of car ownership or financial resources for public transport), which poses barriers to accessing medication (Kim et al., 2014). STAT dispensing will help reduce the impact of these barriers on young people's ability to access ART. Young people also tend to have highly unstructured lifestyles (i.e. balancing school, work, social outings, and periods of increased substance use) which can make adherence to ART difficult (Fields et al., 2017; MacDonell et al., 2016). Taking responsibility for daily medication adherence can be particularly challenging in terms of the degree of self-management, planning and responsibility it requires, as young people navigate the challenges of transitioning into adulthood and issues of identity and new social relationships (Fields et al., 2017). Navigating HIV stigma in the context of these precarious, new formed social relationships in young adulthood is an additional challenge for ART adherence (Fields et al., 2017). As such, rather than requiring monthly pharmacy visits, young people living with HIV should have access to a stable supply of medication via STAT dispensing to ensure adherence.

Facilitating access to ART is crucial to supporting combination prevention of HIV transmission

Another reason it is so important to ensure access to ART is that it is crucial for the protection of public health. ART is vital to ensuring people living with HIV maintain an undetectable viral load, which both ensures their own health, while also protecting others from further HIV transmission as people with undetectable viral loads are not able to transmit (undetectable = untransmissable, or U=U). U=U is one of the most important components of combination prevention of HIV. Ensuring people living with HIV have prompt and sustained access to antiretroviral treatment and thus maintain an undetectable viral load helps eliminate the risk of forward transmission. In addition, UNAIDS (2015) set out a target of virtual elimination of HIV by 2030, which involves a 95% reduction in the number of new HIV infections compared to the 2010 baseline. If Aotearoa is to meet the UNAIDS targets we have committed to and end local HIV transmission by 2030, it is imperative that we support people living with HIV to continue to maintain suppressed viral loads. This requires prioritisation of initiatives that facilitate convenient access to ART through mechanisms like STAT dispensing.

There is minimal risk of wastage for ART

One of the main concerns related to increasing medications with STAT dispensing is the risk of wastage. However, there will be no need for pharmacies to claim wastage for ART, as it is dispensed in packs of 30 and patients take these medicines ongoing. In addition, given that ART is needed for survival, there is limited risk of wastage. We know that the vast majority of people living with HIV in Aotearoa New Zealand are on effective treatment with a suppressed viral load (McAllister et al., 2021). Furthermore, local research showed that the most commonly reported reasons for not using medication were that it passed the expiry date, treatment was changed, or the condition resolved (Braund et al., 2009). None of these reasons are likely to apply to a person living with HIV who is successfully established on ART. Braund & Yuen (2007) state that while wastage is a risk of STAT dispensing, it is likely beneficial for patients on stable, long-term medication regimes, like ART.

WHO and UNAIDS endorse multi-month dispensing

Internationally, multi-month dispensing of ART has been recognised as a measure to support adherence and good health of people living with HIV in various contexts (Traub et al., 2020a; Traub et al., 2020b). It has also been endorsed by the WHO and UNAIDS.

Multi-month dispensing is part of the overall differentiated care delivery model championed by the WHO, which involves person-centred approaches to HIV services that are responsive and tailored to the needs of people living with HIV and reduces unnecessary burdens on the health system (World Health Organization, 2021). The WHO's consolidated guidelines on HIV prevention, testing, treatment, service delivery, and monitoring recommends providing ART refills lasting between 3-6 months for people living with HIV who are established on ART (World Health Organization, 2021). This recommendation has been in place since 2016 (World Health Organization, 2021), however the 2021 guidelines specify that six months dispensing is preferable where feasible (World Health Organization, 2021).

UNAIDS also reports on the proportion of people living with HIV on ART receiving multimonth dispensing of ART as an indicator for the Global AIDS Monitoring of progress on the 2021 Political Declaration on HIV and AIDS (UNAIDS, 2022). This is because of the potential of multi-month dispensing to improve health outcomes, support long term treatment adherence (and efforts to achieve and maintain the 95-95-95 cascade targets), and contribute to health system efficiency (UNAIDS, 2015). Given this overwhelming support internationally for multi-month dispensing, Aotearoa New Zealand should seriously consider rapid implementation of multi-month dispensing.

Research supports STAT dispensing

There is growing literature that shows multi-month dispensing of ART supports treatment continuity, successful viral load suppression, and improved health outcomes as compared to monthly schedules (Bailey et al., 2021; Traub et al., 2020a; World Health Organization, 2021). For example, a systematic review of international literature found reduced frequency of ART pick-ups show a trend towards better retention, and therefore may improve clinical outcomes (Mutasa-Apollo et al., 2017). In addition, multi-month dispensing is likely to produce reasonable cost savings to people living with HIV, as it reduces the cost of travel, time spent at pharmacies, and the amount of work missed (Nichols et al., 2021; Prust et al., 2017). International research has also indicated that people living with HIV prefer to collect ART less frequently than one monthly (Eshun-Wilson et al., 2020). PHARMAC have also stated that dispensing larger quantities of medicine through STAT dispensing also increases the supply chain's resilience to unexpected increases in demand, emergencies, and other issues that affect manufacturing and supply (PHARMAC, 2020). The importance of supply chain resiliency has been demonstrated through the COVID-19 context.

National HIV and AIDS Forum Recommendation: Apply STAT dispensing to all ARTs

We understand that there are already some forms of multi-month dispensing available to individual patients, including the "Long Term Conditions (LTC)" programme through which people can have medication dispensed as frequently as pharmacist deems appropriate to meet their medicine support needs. However, as discussed, many people living with HIV are well established on their ART regimen and could be well managed with STAT dispensing. Furthermore, the persistence of HIV stigma poses a barrier to engagement with this kind of programme for many people living with HIV.

Where people living with HIV could benefit from being enrolled in the LTC programme, we are highly supportive. However, we believe a three-monthly default for ART dispensing is more suitable for all people living with HIV. While many issues affecting treatment access are out of PHARMAC's control, PHARMAC's ability to determine mechanisms of medicine distribution (such as less frequent dispensing) can help facilitate patient access to medicine (PHARMAC, 2019). We strongly recommend that PHARMAC apply STAT dispensing to ART as soon as possible.

Thank you for considering our recommendation. Please do not hesitate to contact the Burnett Foundation Aotearoa Policy and Science Manager Brooke Hollingshead at <u>brooke.hollingshead@burnettfoundation.org.nz</u> should you require clarification on any of the points made.

Ngā mihi

Burnett Foundation Aotearoa, on behalf of the National HIV and AIDS Forum

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