

# HIV prevention today: with coordinated action, we can end transmission

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**N**ew Zealand has an enviable international record in HIV prevention, with diagnosis rates for most-at-risk groups being among the lowest in the world.<sup>1</sup> HIV infection is now treatable, affected communities have established cultures of risk reduction,<sup>2,3</sup> and laws and policies have mostly been aligned to support prevention.<sup>3</sup>

Successes so far cannot be allowed to engender complacency. HIV transmission is preventable, but not declining; an HIV diagnosis is still life changing, and HIV medication is expensive. Government funding for antiretroviral therapy (ART) alone has risen from \$14.5 million in mid-2010 to \$26.4 million by mid-2014 (prior to PHARMAC discounts) for a relatively small number of patients.<sup>4</sup>

Warning signs of a reversal in control in New Zealand are becoming apparent. Last year 117 gay and bisexual men (GBM) were newly diagnosed with HIV infection—including 86 who were infected here—the highest annual number ever recorded.<sup>1</sup> The proportion of GBM engaging in unprotected casual sex, although low by international standards, increased in 2014.<sup>2</sup> Infectious syphilis cases among GBM reported by sexual health clinics doubled in 2014 in some regions including Auckland, and the number of rectal gonorrhoea cases reported in males rose from 31 in 2010, to 121 in 2014;<sup>5</sup> both are proxies for changes in risky sexual behaviour. The small number of HIV infections acquired heterosexually in New Zealand is incrementally rising.<sup>1</sup> In many countries, we are watching HIV prevention in GBM unravelling, spurring an urgency to adapt our own responses now, before the achievements of the past 30 years are squandered.

If we do adapt quickly we can virtually eliminate HIV transmission in New Zealand,

and be the first country to do so. This will take revived political will and adequate resourcing. While 2014 brought harbingers of a worsening epidemic phase, scientific breakthroughs this year, 2015, gave us the tools to constrict transmission through multi-pronged interventions if we respond boldly. We call this approach ‘comprehensive prevention’, and five locally relevant action points are summarised in Table 1.

First, condom-based HIV prevention for GBM, who remain most at risk in this country, must continue and become even more sophisticated. This is because barrier protection responds so well to qualities of HIV transmission during sexual behaviour, because it is cheap, and because it is easily scaleable.<sup>3</sup> Second and third, we must deploy the full repertoire of treatment-based prevention interventions, particularly immediate ART on diagnosis to minimise HIV transmission risks from those infected, and pre-exposure prophylaxis (PrEP) to minimise HIV acquisition risks for the subset of uninfected individuals at highest risk of exposure. Fourth, HIV testing access and frequency must be improved to provide timely pathways into these twin treatment-based prevention levers. Fifth, vaccination against sexually transmitted infections (STI) such as HPV, HAV and HBV needs to be expanded to all at risk groups, and screening and treatment practices must be enhanced, because of the synergies between STI and HIV control.

Together, these action points synchronise condom-based and treatment-based HIV prevention strategies to reduce the reproductive rate of HIV below replacement. The possibilities of this approach were recently modelled in Australia, where a 44% reduction in HIV diagnoses nationally was estimated in the first year if condoms, ART and PrEP were mobilised in tandem

**Table 1:** Five actions to eliminate HIV transmission in New Zealand

Action	Goal
(1) Increasingly sophisticated promotion of condoms for protection against HIV and STIs during anal and vaginal intercourse	To interrupt HIV and STI transmission
(2) Immediate access to HIV antiretroviral treatment post diagnosis	To minimise infectiousness and maximise personal wellbeing of individuals with confirmed HIV infection
(3) A Government-funded programme of voluntary pre-exposure prophylaxis (PrEP) and quarterly STI screening for the minority of high risk individuals who are unable to sustain consistent and correct condom use during anal and vaginal intercourse	To target the most at risk individuals who play a disproportionate role in fuelling the HIV epidemic
(4) Prompt HIV testing following intercourse without a condom by rapid testing and potentially home HIV testing or home HIV sampling	To reduce the number with undiagnosed HIV infection
(5) Improved access to comprehensive STI screening, treatment and vaccination	To control resurgent STI epidemics that synergise with HIV control

at sufficient scale among GBM.<sup>6</sup> There is government enthusiasm to achieve this across the Tasman; New Zealand cannot afford to merely watch and wait.

Fortunately, New Zealand has an excellent platform to launch a new phase in our epidemic response, being a low HIV prevalence country with a committed HIV workforce and enjoying the small scale that enables coordinated action. But, we will also need more allies. Regulatory change is urgently needed to remove PHARMAC's CD4 prescribing obstacle for ART for individuals with confirmed HIV infection, and bring it into line with new WHO guidelines.<sup>7</sup> Protocols for prescribing targeted PrEP to uninfected high-risk individuals need to be accelerated.<sup>8</sup> Funding for NGOs at the frontline should match the increased capacity needed to add testing and PrEP and STI screening promotion onto condom promotion. Research, surveillance and evaluation of the HIV sector's performance must be resourced on a sustainable basis. Inadequate responsiveness to health issues affecting GBM must be corrected, and greater inclusivity of sexual orientation minorities fostered.<sup>9</sup> And the ongoing stigma surrounding people living with HIV must be stridently challenged—while not diminishing the threat that HIV poses—if we are to motivate individuals to engage with enhanced HIV screening and care options.

Adding 'test and treat' approaches to condoms and behaviour change can dramatically alter the trajectory of the HIV epidemic in New Zealand; we discuss some opportunities and challenges.

## Opportunities

### Treatment for confirmed HIV infection

In July 2015, two studies confirmed that early treatment of HIV infection is critical for optimising long term health.<sup>10,11</sup> Notably, the START study reported that the risk of developing serious illness or death was 57% lower among those treated early when CD4+ counts were above 500 cells/mm<sup>3</sup>, compared to those in the deferred group treated when their CD4+ counts declined below 350 cells/mm<sup>3</sup>.<sup>10</sup> Early ART initiation also showed minimal or no increase in adverse events.<sup>12</sup> The WHO<sup>13</sup> and other international bodies<sup>14</sup> now recommend access to ART for all individuals with confirmed HIV infection regardless of CD4+ count, and New Zealand must urgently follow suit.

In 2015, the prevention benefits of ART were also confirmed. In final results from a large trial of HIV discordant, mostly heterosexual couples, ART conferred a 93% protective effect on transmission.<sup>15</sup> Interim analyses of two further cohort

studies in 2014 and 2015 found no HIV transmissions between HIV discordant gay male couples where the HIV infected partner had an undetectable viral load.<sup>16,17</sup> Although a low rate of transmission cannot be ruled out, ART undoubtedly offers a strong preventive effect at the individual level with full adherence.

### HIV pre-exposure prophylaxis (PrEP)

PrEP is the daily use of HIV antiretroviral drugs, such as Truvada, by confirmed HIV negative individuals to reduce the likelihood of HIV acquisition.<sup>13</sup> PrEP should be taken 5–7 days prior to anal intercourse to achieve optimum protective concentrations and adherence is key for lasting impact. In the iPrEx trial among GBM, PrEP was 44% protective overall, with an adherence-adjusted protection of 92%.<sup>18</sup> Taking tablets 4 or more days a week appears to achieve full protection.<sup>19</sup> Interim results of two subsequent clinic-based studies in 2015 (PROUD<sup>20</sup> and Ipergay<sup>21</sup>) both reported an overall 86% protective effect.

WHO has now recommended PrEP in populations where HIV incidence exceeds 3 per 100py,<sup>13</sup> and Australia has several demonstration projects underway among high risk GBM. This includes individuals reporting any of the following in the last 3 months and who are likely to continue this behaviour in the next 3 months: i) an HIV positive partner with whom condoms were not used; ii) receptive anal intercourse with a casual male partner of HIV positive or unknown status; iii) a bacterial rectal STI; iv) methamphetamine use.<sup>6</sup> Participants in most projects internationally represent a high-risk subset of GBM with low rates of condom use, multiple partners, and high baseline and incident STIs.<sup>22</sup> Preliminary data suggest that in a high HIV incidence setting, such as the UK, temporary and targeted PrEP to high-risk individuals can be cost effective, or even cost saving, when compared to the cost of lifelong HIV treatment of people whose infection could have been averted, although this depended heavily on assumptions about uptake and future drug discounts.<sup>23,24</sup> New Zealand needs local data describing anticipated PrEP uptake so that the same cost/benefit calculations and eligibility can be assessed.

### HIV testing

HIV testing has to improve to fully realise the public health benefits of HIV treatments at the population level, as neither ART nor PrEP can be offered in absence of confirmed HIV status. Of paramount importance is reducing the number of individuals with undiagnosed infection, estimated to be around 600 in New Zealand,<sup>1</sup> based on a 2011 study that found 1 in 5 HIV positive GBM were unaware they were infected.<sup>25</sup> Currently, 42% of GBM report having tested in the last year.<sup>26</sup> A 2015 preliminary study modelled that the estimated 10.3% of Australia's HIV infected population who remain undiagnosed contributes 44.9% of onward HIV transmissions.<sup>27</sup> Shifting undiagnosed individuals into clinical management and reducing their viral load through ART as soon as possible is consequently a high priority for HIV control as well as for their own care. Testing access, testing uptake, testing frequency and exploration of new testing technologies, such as home testing or home sampling, therefore need to be key targets in the new HIV prevention era.

## Challenges

### ART: Matching promise with practice

Against the undisputed prevention promise of treating HIV positive individuals, 'test and treat' approaches have to overcome several hurdles. HIV testing is essential to identify those infected, and increases both in coverage and frequency can reduce HIV incidence.<sup>28</sup> However, even more frequent testing of all GBM may not intervene soon enough to halt the epidemic, because a small proportion of individuals typically drive clusters of transmission,<sup>29</sup> the gap length between sexual partners for these men can be very brief, and a large fraction of transmissions therefore occur in the highly infectious period following HIV infection, but prior to testing.<sup>30</sup> Even in societies with high rates of HIV testing, such as GBM in Australia,<sup>31</sup> the median time from infection to diagnosis is estimated to be 1.4 years,<sup>32</sup> implying that those who test often are not always those most at risk. In New Zealand, over a third of GBM newly diagnosed are diagnosed late,<sup>1</sup> and around half of GBM

engaging in risky sex in the last six months had not tested since that episode.<sup>26</sup> Increased HIV testing promotion and newer HIV testing technologies should be responsive to the needs of these individuals first.

Then a number of milestones need to be met, such as linking and retaining those diagnosed into specialist care, ensuring treatment access and adherence to medication, and sustaining undetectable viral load. Attrition occurs at each step in this “HIV-care cascade”,<sup>33</sup> and no country to date has achieved the UNAIDS target of 73% of HIV infected individuals having undetectable viral load,<sup>34</sup> although cities such as Stockholm provide a model to emulate.<sup>35</sup> Maintaining access to a range of affordable, effective and tolerable HIV medication as trade agreements are negotiated will also be an important government goal in order to meet the needs of all HIV patients.

Modelling from the UK in 2015 helps us visualise possible targets.<sup>36</sup> Achieving 90% of all HIV infected GBM diagnosed, treated and undetectable within one year of infection would require a more than trebling in the annual number of HIV tests conducted (to 65% of all GBM tested annually), ART being initiated on diagnosis, and retention in care and treatment adherence remaining high and not declining. This would reduce HIV incidence by 79% by 2030, push the epidemic below replacement long term, and be cost effective. Each additional 10% of HIV-infected GBM virally suppressed from the current situation of 58% equated to 37% fewer HIV infections per year.

These potential epidemiological gains from ‘test and treat’ can be counteracted if condom use deteriorates. If the optimistic rhetoric surrounding HIV treatments reduces condom use by a mere 10%, and yet HIV testing levels and ART initiation do not improve, HIV incidence is predicted to double in 15 years.<sup>36</sup> Increases in condomless anal sex can trigger resurgent STI epidemics that are serious in their own right and heighten HIV transmission and acquisition risks. Moreover, a singular focus on HIV testing as the entry point into HIV prevention is also arguably unethical, as it will have delayed intervention until after infection has already happened, neglecting opportunities for earlier condom-based

primary prevention. Undoubtedly, the best outcomes will be achieved when condom-based and treatment-based HIV prevention are mutually reinforcing and do not undermine each other. For all these reasons, increased promotion of HIV testing and early treatment must not erode condom advocacy.

### PrEP: uptake, targeting and equity

Likewise, we need to motivate the most at risk individuals to attend medical clinics if we are to fully capitalise on PrEP. PrEP is a programme, not simply a prescription, involving a high level of clinical monitoring, including regular HIV and STI screening, drug adherence and adverse events, and ongoing safe-sex counselling. Cost-effectiveness will vary by setting and eligibility criteria, being influenced by background HIV incidence and local healthcare costs.<sup>23,24</sup> It is unclear whether PrEP is a temporary or long-term option for some individuals, and under what circumstances it will be ceased. Affordability is a pressing issue, as Truvada is currently an expensive on-patent medication. Targeting will be necessary to minimise PrEP uptake among low-risk individuals, conserve drug stocks, and avoid drug resistance developing.

There are also concerns about reductions in community-wide condom use, and increases in STIs, resulting from perceptions that the combination of PrEP and ‘test and treat’ have already eliminated HIV acquisition risks, regardless of the actual level of population scale up. Scant consideration has so far been given to equity, despite evidence of uneven access to HIV services within GBM communities particularly by ethnicity,<sup>33</sup> and low rates of sexual orientation disclosure,<sup>9</sup> both of which are required before PrEP can be offered. Unlike a condom, PrEP is a pill that has to be taken for several days prior to sex in order to build up protective levels, making it an unverifiable intervention for casual sex partners. This raises important issues of power asymmetry during sexual encounters, as it relies on people communicating honestly and without coercion in the heat of the moment. Nevertheless, if tightly targeted to the most at risk and motivated individuals, PrEP has considerable potential to improve HIV control by interrupting chains of transmission in the most vulnerable subsets of the community.

## Accommodating both public health and clinical medicine

The championing of pharmaceuticals for HIV prevention, as well as for HIV care, has shifted the momentum internationally towards clinic-based HIV control. This emerged after 1996 with the effectiveness of the first triple combination ART and hastened following the influential clinical trial results from the HPTN 052,<sup>15</sup> iPrex<sup>18</sup> and PARTNER<sup>16</sup> studies in the last 5 years. However, some public health practitioners have challenged the privileging of such trials as the gold standard for scientific decision making about interventions in real-world communities. Shelton, for example, has argued that the issue is not only whether an intervention (such as HIV treatment) is efficacious in an RCT, but if it can be made to work practicably at scale, be additive rather than zero-sum against other interventions, and be sustained over long periods given available resources and capacity.<sup>37,3</sup> Situational variability means that successful interventions may not translate faithfully elsewhere. In this view, ‘what works’ is deducing the optimal combination of interventions for local conditions.<sup>37</sup> Research on New Zealand-based experiences would sharpen implementation and help avoid unintended effects.

## Avoiding disinvestment in community-based HIV prevention

Disinvestment in behaviour-based HIV prevention programmes has correspondingly become a concerning trend internationally. In the mid-1990s, a contraction in high-level investment and coordination in several Australian jurisdictions, but not in New South Wales, preceded an increase in HIV notifications.<sup>38</sup> In England, GBP 2.9 million was spent on national HIV prevention programmes in 2011/12 and reducing, less than half a percent of the GBP 762 million spent on treatment and care and rising.<sup>39</sup> Since 2011, government funding for the New Zealand AIDS Foundation (NZAF) has been static (around \$4.2 million),<sup>40</sup> while HIV treatment expenditure here has risen 57% to \$26.4 million.<sup>4</sup> The reallocation of HIV funding portfolios towards clinical services overseas has typically been justified by claims of condom-based ‘prevention failure’, because HIV diagnosis rates have not declined.

Community-based advocates in response have pointed to the gradual erosion of an already imbalanced funding quota and the inevitably diminished population-level impact of their work. Economic analysis commissioned by NZAF suggests that investment in HIV risk behaviour change is cost effective,<sup>41</sup> but primary prevention will only succeed if delivered at sufficient intensity. And while the substantial investment in HIV clinical medicine has transformed life expectancy for people living with HIV, and treatment has high individual-level prevention efficacy, public health researchers have noted that pharmaceuticals have not so far been a panacea for controlling HIV at the population level.<sup>42</sup> Given finite resources, analyses remind us that investment in community-based education is still more cost-effective than ART, and ART is more cost-effective than PrEP.<sup>43</sup>

## Medicalisation of HIV prevention

These shifts have heralded a growing medicalisation of HIV prevention. Some social researchers have argued that clinic-based prevention models privatise HIV and remove it as a subject of public discussion, debate and action—the latter being foundations of the early, effective, community-based HIV response.<sup>42</sup> Medicalisation also tends to position GBM as patients and consumers of diagnostic technologies and pharmaceuticals. Those may be easier identities for the health system to engage with, but it can bypass the topic of sex and sexuality, and sterilises discussions of HIV prevention. In doing so, medicalisation de-emphasises the agency of gay men and other groups to safeguard their own sexual health, and avoids the need to address vulnerabilities driven by social marginalisation.

Furthermore, difficulties achieving the necessary scale, clinical linkage and retention, medication affordability, access and adherence have to date limited the full public impact of pharmaceutical-based prevention interventions.<sup>31</sup> These are the same criticisms often levelled against behaviour-based programmes: both require repeated actions to be effective (testing and taking medications regularly; using condoms consistently). Unsurprisingly, some individuals are reluctant to have their sexual lives revolve around clinic appoint-

ments and medication, in much the same way that some men discontinue regular condom use.

## Conclusion

HIV infection is avoidable and unnecessary. Today's prevention tools offer the possibility of virtually eliminating HIV transmission if we can re-activate the spirit of cooperation that defined New Zealand's early successes. This task now calls for a partnership for prevention: a strategic cooperation between community-based primary prevention (condom promotion), clinic-based primary prevention (PrEP)<sup>44</sup>, and clinic-based secondary prevention

('test and treat'). We must deliver this in a way that maximises, not compromises, the effectiveness of each of these approaches. This recognises that effective clinic-based prevention is dependent on vigorous community-based promotion of testing; similarly, effective community-based condom promotion must be supported by advocacy for continued condom use in the clinic setting. Once such a programme is established, the most challenging task will then be to maintain it over long periods of time, galvanising ongoing political commitment and community engagement, until a sterilising vaccine or cure eventually becomes available.

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### Competing interests:

Peter Saxton is the current New Zealand AIDS Foundation Fellow at the Faculty of Medicine, University of Auckland. Tony Hughes is Scientific Director at the New Zealand AIDS Foundation. Massimo Giola serves on the Board of Trustees of the New Zealand AIDS Foundation.

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