

# **PrEPared Against HIV: 2.0**

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Master of Arts in Political Science

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*“This is going straight to the pool room” – Darryl Kerrigan, The Castle*

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## Abstract

In 2016, there were 244 new HIV infections in New Zealand; this is the fifth consecutive year of rising infection rates, and the largest number of new diagnoses reported since records began in 1985. In New Zealand, men who have sex with men (MSM) can account for up to 80% of new HIV diagnoses yearly. Until now, HIV prevention has focused on behavioural methods, such as condom use, abstinence, and serosorting. However, recent trials show that a new biomedical method, pre-exposure prophylaxis (PrEP), is more than 90% effective at preventing HIV acquisition among HIV-negative, at-risk individuals when taken daily. Unfortunately, PrEP is not a silver bullet for HIV, as cited complexities associated with PrEP include potential antiretroviral resistance, side effects, cost, stigmatisation, and risk compensation. Therefore, this research aimed to answer the following questions: Do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties regarding implementation faced overseas? Following Carol H. Weiss's problem-solving model, this thesis uses a multiple, mixed-methods approach to reduce uncertainty regarding HIV prevention and treatment attitudes (specifically regarding PrEP) among a particular cohort (MSM) and thus, informs more effective future policies. The methods used are a survey, interviews, and document analysis.

The first research question was answered using an anonymous, online, Likert scale survey. Participants were recruited using non-probability purposive sampling. 42 MSM from the Canterbury region were surveyed to measure their attitudes towards HIV, PrEP and condom use. 100% of participants agreed that taking PrEP is a good way to reduce their chances of HIV infection, 100% of participants agreed that PrEP is a worthwhile prevention method for MSM, and 97.5% believed that PrEP should be subsidised for MSM.

Building upon the preliminary data, I propose PrEPared Against HIV: 2.0 as a solution to the second research question that follows Weiss's problem-solving model. This policy is designed specifically to fit within New Zealand's public health system and is informed by the grassroots input and empirical evidence collected through interviews with HIV experts, survey data, and document analysis. PrEPared Against HIV: 2.0 pays specific attention to 'PrEP problem areas' such as developing adequate clinical guidelines, ensuring PrEP providers receive adequate support, encouraging adherence, and reducing stigmatisation linked to PrEP use. This research shows there is a need for greater investment in HIV prevention rather than costly HIV treatment. PrEP can reduce future HIV infections and there is obvious support from both HIV experts and MSM for a PrEP policy in New Zealand. However, PrEP needs to be one plank in a multi-faceted policy for wider HIV prevention to ensure that it can have a positive impact on the HIV epidemic in New Zealand.

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## Abbreviations

ADHB	Auckland District Health Board
AIDS	Acquired Immune Deficiency
ART	Antiretroviral therapy
ASHA	Australasian Sexual Health Alliance
ASHM	Australasian Society for HIV Medicine
BIA	Budget-impact analysis
CBA	Cost-benefit analysis
CDC	Centers for Disease Control and Prevention
CUA	Cost-utility analysis
DHBs	District Health Boards
DTCA	Direct-to-consumer advertising
FDA	Food Drug Administration
FTC	Emtricitabine
GAPSS	Gay Auckland Periodic Sex Survey
GOSS	Gay men's Online Sex Survey
GRID	Gay-Related Immune Deficiency
HAART	Highly active antiretroviral therapy
HBV	Hepatitis B
HEC	University of Canterbury Human Ethics Committee
HIV	Human Immunodeficiency Virus
HLRB	Homosexual Law Reform Bill 1986
HPA	Health Protection Agency
HTLV-III	Human T Lymphotropic virus III
IDUs	Injecting drug users
LGBTI	Lesbian, Gay, Bisexual, Transgender, Intersex
LYC	Love Your Condom
MDG	Millennium Development Goals
Medsafe	New Zealand Medicines and Medical Devices Safety Authority
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MOH	Ministry of Health
MSM	Men who have sex with men
NYSDOH AI	New York State Department of Health AIDS Institute
NZAF	New Zealand AIDS Foundation
NZSHS	New Zealand Sexual Health Society Inc.
PEP	Post-exposure prophylaxis
PHARMAC	New Zealand Pharmaceutical Management Agency
PrEP	Pre-exposure prophylaxis
RCT	Randomised controlled trial(s)
ROI	Return on investment
SDG	Sustainable Development Goals

STIs	Sexually transmitted infections
TDF	Tenofovir disoproxil fumarate
TGM	Transgender men
TGW	Transgender women
WHO	World Health Organization
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
U=U	Undetectable = uninfected
YMSM	Young men who have sex with men



## Chapter 1: Setting the Scene – an Introduction to HIV and PrEP

“While a vaccine or a cure may one day end the HIV epidemic, PrEP is a powerful tool that has the potential to alter the course of the... HIV epidemic today.” – Jonathan Mermin, Center for Disease Control and Prevention.<sup>1</sup>

2016 saw record levels of new HIV infections in New Zealand since epidemiologists began tracking the virus in 1985. New Zealand’s current and past HIV prevention strategy has relied solely on behavioural methods, however, recent scientific trials have shown that pre-exposure prophylaxis (PrEP) is effective at preventing the transmission of HIV. The World Health Organization (WHO) has recommended that PrEP is made available for all those who are at-risk of HIV. However, PrEP is a complicated drug and has faced difficulties when being implemented in the real world beyond the structure of clinical trials. This research follows Carol H. Weiss’s problem-solving model to use research to reduce uncertainty regarding a problem and inform a policy solution. Multiple, mixed-methods were used to gain an understanding of attitudes towards PrEP, and explore whether the medication could be implemented effectively while managing the complications that have occurred overseas.

Chapter 1 surveys the known science on HIV and discusses a brief political history of the epidemic, in order to provide a framework for the analysis of PrEP to follow. The chapter concludes by setting out the major sections and approach for this thesis.

### HIV and AIDS

Human Immunodeficiency Virus, commonly known as HIV, is a retrovirus that attacks cells in the body’s immune system. Once an individual is infected with HIV, they will remain infected for the rest of their life. HIV specifically attacks the CD4 lymphocyte T cells (also known as T-helper cells, CD4 cells or T4 cells), which the immune system uses to fight off infections.<sup>2</sup> HIV uses ribonucleic acid, RNA, as genetic material to overcome the CD4 cells. A simplified definition of the early stages of HIV states:

CD4 T cells are pivotal to generating effective immunity against invading pathogens, and HIV specifically targets this population of T cells, infecting and destroying an estimated 1-2 billion of them daily, and in doing so producing up to 100 billion new viruses. If untreated... the destruction of the CD4 T cells eventually outstrips the body’s ability to generate them.<sup>3</sup>

This transition signals that HIV has turned into AIDS, Acquired Immune Deficiency Syndrome. AIDS is a disorder that impacts the immune system rendering the body

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<sup>1</sup> Centers for Disease Control and Prevention, ‘HIV PrEP Guidelines: Press Release’, *Centers for Disease Control and Prevention*, 14 May 2014, <http://www.cdc.gov/nchhstp/newsroom/2014/PrEP-Guidelines-Press-Release.html>.

<sup>2</sup> AIDS.gov, ‘What Is HIV/AIDS?’, *AIDS.gov*, 31 December 2015, <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/what-is-hiv-aids/>.

<sup>3</sup> Dorothy H. Crawford, *Virus Hunt: The Search for the Origin of HIV/AIDs* (Oxford: Oxford University Press, 2013), 22.

unable to fight “normally manageable infections, cancers, and other diseases.”<sup>4</sup> This transition can occur in two ways: when an individual’s CD4 cell count falls below 200 cells per cubic millilitre of blood (<200 CD4 cells/ml<sup>3</sup>), or if an HIV-positive individual is diagnosed with one or more opportunistic infections (see Appendix 1 for a list).<sup>5, 6, 7</sup> The period between HIV infection and the progression to AIDS differs from a few months to more than twenty years.<sup>8</sup>

There are two strains of HIV: HIV-1, which is present all around the world, and HIV-2, which is generally found in West Africa.<sup>9</sup> Within HIV-1 there are three strands or groups (M, N, and O); there are eleven subtypes of the virus (A-K, and U (unclassified)) in group M of HIV-1.<sup>10</sup> There are eight groups of HIV-2 (A-H).<sup>11</sup> All of the subtypes of the HIV-1 virus can share genetic information with one another, thus resulting in a continually increasing number of HIV-1 combinations.<sup>12, 13</sup> Therefore, HIV is considered much more complex than other common viruses that infect the human body. Furthermore, HIV is more lethal because according to Crawford,

It works by stealth, silently entering the body and wiping out the very immune defences that have specifically evolved to fight such invaders. Without modern drug treatments it eventually kills virtually everyone it infects, but only after a period of ten years or so. At first it shows no outward signs of its presence and this is the key to its success. Those living with HIV, unaware of the virus within, get on with their daily lives and in so doing unwittingly spread the virus to others.<sup>14</sup>

HIV is spread person-to-person through blood, pre-seminal fluid, semen, vaginal fluid, rectal fluid, and breast milk.<sup>15, 16, 17</sup> However, for transmission to occur these body fluids must come into contact with a mucous membrane or damaged tissue, or be injected straight into the bloodstream.<sup>18</sup> Mucous membranes line multiple orifices to the body and surround internal organs for protection, and can be found in

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<sup>4</sup> Raymond A. Smith, *Encyclopedia of AIDS: A Social, Political, Cultural and Scientific Record of the HIV Epidemic* (Chicago, Ill.: Fitzroy Dearborn Publishers, 1998), 2.

<sup>5</sup> Jay A. Levy, *HIV and the Pathogenesis of AIDS*, 3rd ed (Washington, D.C: ASM Press, 2007), 26, <http://site.ebrary.com/lib/uofcanterbury/Top?id=10346896>.

<sup>6</sup> Crawford, *Virus Hunt*, 22.

<sup>7</sup> AIDS.gov, ‘What Is HIV/AIDS?’

<sup>8</sup> Ministry of Health, ‘HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy’ (Wellington: Ministry of Health, 2003), 2.

<sup>9</sup> Theodore H. Tulchinsky and Elena Varavikova, ‘HIV/AIDS’, in *The New Public Health*, Third edition (San Diego: Academic Press, 2014), 222.

<sup>10</sup> Tony Hughes, ‘The HIV/AIDS Epidemic in New Zealand: Environmental Scan’ (Auckland: New Zealand AIDS Foundation, August 2003), 4.

<sup>11</sup> Crawford, *Virus Hunt*, 40.

<sup>12</sup> Hughes, ‘The HIV/AIDS Epidemic in New Zealand: Environmental Scan’, 4.

<sup>13</sup> Anthony J. Hughes and Peter J. Saxton, ‘Thirty Years of Condom-Based HIV Prevention by Gay Men in New Zealand’, *The New Zealand Medical Journal (Online)* 128, no. 1426 (4 December 2015): 19–20.

<sup>14</sup> Crawford, *Virus Hunt*, 24.

<sup>15</sup> Michael W. Adler et al., eds., *ABC of HIV and AIDS*, Sixth, vol. 40, ABC Series (John Wiley & Sons, 2012), 2, <http://site.ebrary.com/lib/uofcanterbury/detail.action?docID=10575564>.

<sup>16</sup> Tulchinsky and Varavikova, ‘HIV/AIDS’, 222.

<sup>17</sup> AIDS.gov, ‘How Do You Get HIV or AIDS?’, *AIDS.gov*, 12 December 2015, <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/>.

<sup>18</sup> Ibid.

the nose, mouth, genital areas and anus. The most common method of HIV transmission is through vaginal or anal sexual intercourse, and the chances of infection increases with unprotected sexual intercourse. Sharing or reusing needles used to inject drugs and needle-stick injuries can also spread HIV. Due to the numerous methods of transmission, HIV/AIDS can affect multiple groups in society. Those who have a higher risk of contracting HIV/AIDS are: gay and bisexual men/men who have sex with men (MSM), sex workers, members of serodiscordant couples (where one partner is HIV-positive and one partner is HIV-negative), refugees and migrants from countries where HIV/AIDS is prevalent, prisoners, and injecting drug users (IDUs).<sup>19</sup>

There are three stages of the HIV infection: acute HIV infection, clinical latency, and AIDS. Acute HIV infection occurs upon the initial infection and symptoms tend to appear within two to four weeks. The symptoms of HIV tend to imitate the influenza virus. During this period, the virus is produced in large quantities within the body, which causes the CD4 cell count to drop dramatically.<sup>20</sup> HIV-positive individuals are most infectious during the acute HIV infection. Once these symptoms disappear, the infection has progressed to the clinical latency stage. HIV-positive individuals may feel and look healthy for many years without symptoms or realising their HIV-positive status.<sup>21, 22, 23</sup> The virus still replicates within the body but at much lower levels. HIV can remain at this stage with antiretroviral therapy (ARTs), which keeps HIV-positive individuals healthy and lowers their chances of spreading the virus to others.<sup>24</sup> Furthermore, an HIV diagnosis is no longer a death sentence, as an HIV-positive individual has a high chance of living just as long as HIV-negative individuals when following the correct ART schedule.<sup>25</sup> As a result, there has been an increase of HIV infections worldwide but a decrease in the number of AIDS-related deaths.<sup>26, 27</sup> The final stage of HIV is AIDS, where the CD4 cells are significantly lowered or the individual has one or more opportunistic infections or cancers.

Due to HIV's ability to continually mutate the possibility of an effective vaccine is slim. In 2003, the New Zealand AIDS Foundation (NZAF) Research Director, Tony Hughes, argued that, "almost every known obstacle to vaccine development seems to occur with HIV."<sup>28</sup> Crawford states that,

Within one HIV-1 subtype, variation at the amino acid level reaches up to 30 per cent, while for measles virus, where a single vaccine is effective, this figure is

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<sup>19</sup> Ministry of Health, 'HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy', 11.

<sup>20</sup> AIDS.gov, 'Stages of HIV Infection', *AIDS.gov*, 27 August 2015, <https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/hiv-in-your-body/stages-of-hiv/>.

<sup>21</sup> Ministry of Health, 'HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy', 4.

<sup>22</sup> Tulchinsky and Varavikova, 'HIV/AIDS', 222.

<sup>23</sup> AIDS.gov, 'Stages of HIV Infection'.

<sup>24</sup> AIDS.gov, 'What Is HIV/AIDS?'

<sup>25</sup> Ibid.

<sup>26</sup> Heather Worth, *Gay Men, Sex and HIV in New Zealand* (Palmerston North, N.Z: Dunmore Press, 2003), 15.

<sup>27</sup> Adler et al., *ABC of HIV and AIDS*, 40:1.

<sup>28</sup> Hughes, 'The HIV/AIDS Epidemic in New Zealand: Environmental Scan', 16.

around 4 per cent. Thus in reality a single vaccine is unlikely to prevent infection with all HIV-1 subtypes and variants.<sup>29</sup>

Until more advanced medical treatments are developed to eradicate HIV/AIDS, education and prevention campaigns remain the best approaches of reducing this pandemic.

### HIV/AIDS and MSM

MSM is one of the most common terms used in HIV/AIDS literature since the early 1990s.<sup>30</sup> While labels such as homosexual, gay, bisexual, queer, and transgender can carry a stigma in the broader society, MSM attempts to cover a range of individuals by only categorising their sexual behaviour.<sup>31, 32</sup> For example, 'gay/homosexual and bisexual men' does not include men who are not open about their sexuality or have to hide it, men married to women but who have sex with men, or transgender men (TGM). There are critiques of the term MSM,<sup>33, 34</sup> but it is currently used more often in HIV literature than other labels. Due to the all-encompassing nature of the term MSM, it will be used throughout this thesis.

HIV infection transmission is not equal, as some behaviour is more likely to pass on the virus than others. In every area where HIV statistics are available, MSM are overrepresented compared to the rest of the population.<sup>35</sup> For example, studies of sexual health clinics have shown that MSM are 40 times more likely to have HIV than heterosexual men and women in New Zealand.<sup>36</sup> MSM accounted for 80% of HIV diagnoses in 2014, despite making up only 2.5% of New Zealand's population.<sup>37</sup> The incidence of HIV infections in MSM is "not an accident of history, but a real phenomenon" and there are multiple reasons for this higher prevalence of HIV.<sup>38</sup> Firstly, individuals are 18 times more likely to contract HIV through unprotected receptive anal sex than unprotected vaginal sex. This is because the cells in the anus are more vulnerable to the HIV virus, and semen and "rectal mucosa... carry more HIV than vaginal fluid." Secondly, there are fewer MSM so the number of potential partners to choose from is much smaller than for heterosexuals. As a result, HIV and sexually

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<sup>29</sup> Crawford, *Virus Hunt*, 126.

<sup>30</sup> Chris Beyrer et al., 'HIV in Men Who Have Sex with Men 1: Global Epidemiology of HIV Infection in Men Who Have Sex with Men', *The Lancet* 380, no. 9839 (28 August 2012): 368.

<sup>31</sup> Worth, *Gay Men, Sex and HIV in New Zealand*, 14.

<sup>32</sup> Beyrer et al., 'HIV in Men Who Have Sex with Men 1', 368.

<sup>33</sup> Rebecca M. Young and Ilan H. Meyer, 'The Trouble With "MSM" and "WSW": Erasure of the Sexual-Minority Person in Public Health Discourse', *American Journal of Public Health* 95, no. 7 (July 2005): 1144–49.

<sup>34</sup> Shivananda Khan and Omar A. Khan, 'The Trouble with MSM', *American Journal of Public Health* 96, no. 5 (May 2006): 765–66.

<sup>35</sup> Anthony J. Hughes and Peter J. Saxton, 'Thirty Years of Condom-Based HIV Prevention by Gay Men in New Zealand', *The New Zealand Medical Journal* 128, no. 1426 (4 December 2015): 20.

<sup>36</sup> S. M. McAllister et al., 'Unlinked Anonymous HIV Prevalence among New Zealand Sexual Health Clinic Attenders: 2005-2006', *International Journal of STD and AIDS* 19, no. 11 (November 2008): 754.

<sup>37</sup> New Zealand AIDS Foundation, 'HIV in New Zealand', *New Zealand AIDS Foundation*, n.d., <https://www.nzaf.org.nz/hiv-aids-stis/hiv-aids/hiv-in-new-zealand/>.

<sup>38</sup> Hughes and Saxton, 'Thirty Years of Condom-Based HIV Prevention by Gay Men in New Zealand', 4 December 2015, 21.

transmitted infections (STIs) are likely to spread faster than among heterosexuals.<sup>39</sup> Thirdly, male homosexual relationships allow both men to partake in receptive and insertive sexual intercourse. In the 2002-2006 Gay Auckland Periodic Sex Surveys (GAPSS), more than 50% of males reported both insertive and receptive anal intercourse with a regular partner or casual partner in the past six months.<sup>40</sup> Thus, the flexible nature of anal sexual intercourse between men increases the chances of becoming infected and subsequently passing HIV onto other sexual partners.<sup>41</sup> Finally, MSM continue to report high numbers of casual sexual partners.<sup>42, 43, 44, 45</sup> While reports of more than 10 sexual partners in six months are generally decreasing, the 2002-2014 GAPSS shows that more than one in five men have at least 11 sexual partners in six months.<sup>46</sup> It is argued that if the unprotected anal intercourse between men happened in long-term relationships instead of casual partnerships, HIV infections could be reduced by 29-51%.<sup>47</sup>

### International history and prevention of HIV/AIDS

The discovery and subsequent understanding of HIV was, and continues to be, greatly impacted by the complexity of the retrovirus. Initially, it was not understood that there was a link between HIV and AIDS because of the long period between the initial infection and when the virus manages to deplete the body of enough CD4 cells or cause an opportunistic infection. As a result, the history of HIV is complicated. The following section will briefly discuss the highlights from the history of HIV/AIDS around the world.

#### **Early 1980s: The early pandemic years**

The first cases of AIDS (although it had no name then) were discovered in early 1981 in Los Angeles, USA, where doctors reported patients that had severely weakened immune systems and died from basic infections or typically benign cancers. It became apparent that these cases were not unique to Los Angeles, as they were also reported in New York and San Francisco. The USA's Centers for Disease Control and Prevention (CDC) reported the disease in the *Morbidity and Mortality Weekly Report (MMWR)*, an

<sup>39</sup> New Zealand AIDS Foundation, 'Three Reasons Gay Guys Are More Likely to Get HIV', *New Zealand AIDS Foundation*, n.d., <https://www.nzaf.org.nz/getting-tested/testing-month/hiv-risk-for-gay-men/>.

<sup>40</sup> Peter Saxton, Nigel Dickson, and Tony Hughes, *GAPSS 2008: Findings from the Gay Auckland Periodic Sex Survey: Te Rangahau Tāne Ai Tāne* (Auckland, N.Z: New Zealand Aids Foundation, 2010), 57, 69.

<sup>41</sup> Hughes and Saxton, 'Thirty Years of Condom-Based HIV Prevention by Gay Men in New Zealand', 4 December 2015, 21-22.

<sup>42</sup> Peter Saxton, Nigel Dickson, and Tony Hughes, *GAPSS 2004: Findings from the Gay Auckland Periodic Sex Survey* (Auckland, N.Z: New Zealand Aids Foundation, 2004), 31.

<sup>43</sup> Saxton, Dickson, and Hughes, *GAPSS 2008*, 34.

<sup>44</sup> Beyrer et al., 'HIV in Men Who Have Sex with Men 1', 369.

<sup>45</sup> Peter Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) / Te Rangahau Tāne Ai Tāne: Basic Frequency Tables 2002-2014' (Auckland, N.Z: The University of Auckland, 2014), 17, <http://www.nzaf.org.nz/resources-research/publications/gapss-goss-2002-2014/>.

<sup>46</sup> Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay Men's Online Sex Survey (GOSS) / Te Rangahau Tāne Ai Tāne: Basic Frequency Tables 2002-2014'.

<sup>47</sup> Beyrer et al., 'HIV in Men Who Have Sex with Men 1', 368.

epidemiological publication for health professionals around the USA.<sup>48</sup> At this stage, AIDS was only present in homosexual men and it was called the 'gay plague,' 'gay pneumonia,' or 'gay flu.'<sup>49</sup> It seemed that the majority of the homosexual men who had AIDS were frequent visitors of gay bathhouses, nightclubs and sex clubs, which were synonymous with promiscuity and 'poppers' (a popular inhalant drug used before sex and in night clubs).<sup>50</sup> It was also initially thought to be a sexually transmitted virus among homosexual men.<sup>51</sup>

It was not until doctors in Africa, London, Paris, Copenhagen and other European nations found patients with similar symptoms that the extent of the AIDS disease became known. It became clear that AIDS was a "new, inexplicable epidemic."<sup>52</sup> As with the Spanish flu, poliomyelitis virus, and severe acute respiratory syndrome (SARS), the spread of HIV/AIDS was greatly facilitated by access to air travel.<sup>53, 54</sup> Gaëtan Dugas, also known as Patient Zero, a Canadian air steward, was originally linked to the initial spread of HIV around America after reporting an estimated 2,500 sexual partners in ten years.<sup>55</sup> In March 2016, researchers from the University of Arizona argued that Dugas was not the "index patient" of AIDS in America based on the sequences of HIV that were around at that time.<sup>56</sup> However, it is highly likely that Dugas would have helped spread HIV/AIDS given the number of sexual contacts and his occupation.

By January 1982, multiple names emerged for AIDS, including Gay-Related Immune Deficiency (GRID).<sup>57</sup> AIDS was then associated with the '4-H club,' which was the infection of "homosexuals, haemophiliacs, heroin addicts, and Haitians."<sup>58</sup> However, it was not until September 1982 that the CDC named AIDS officially. By late-1982, reports emerged of AIDS in a child who had numerous blood transfusions as a baby, and women who had sex with bisexual men. Within a week of this announcement, the CDC reported 22 cases of "unexplained cellular immunodeficiency and opportunistic infections" in the weekly *MMWR*.<sup>59</sup>

By 1983, it was established that AIDS was caused by a retrovirus. French scientists Luc Montagnier and Françoise Barré-Sinoussi discovered the HIV virus in an

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<sup>48</sup> Centers for Disease Control and Prevention, 'World AIDS Day- December 1, 2015', Morbidity and Mortality Weekly Report (Centers for Disease Control and Prevention, 27 November 2015), [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s\\_cid=mm6446a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s_cid=mm6446a5_w).

<sup>49</sup> Crawford, *Virus Hunt*, 14.

<sup>50</sup> Ibid.

<sup>51</sup> Levy, *HIV and the Pathogenesis of AIDS*, 40.

<sup>52</sup> Crawford, *Virus Hunt*, 14.

<sup>53</sup> Randy Shilts, *And the Band Played on: Politics, People, and the Aids Epidemic*, 20th anniversary ed (New York: St Martin's Griffin, 2007), 156–57.

<sup>54</sup> Crawford, *Virus Hunt*, 124.

<sup>55</sup> Ibid., 14.

<sup>56</sup> Jon Cohen, "'Patient Zero' No More", *Science* 351, no. 6277 (4 March 2016): 1013.

<sup>57</sup> Shilts, *And the Band Played on*, 121.

<sup>58</sup> Crawford, *Virus Hunt*, 15.

<sup>59</sup> Centers for Disease Control and Prevention, 'Unexplained Immunodeficiency and Opportunistic Infections in Infants -- New York, New Jersey, California', Morbidity and Mortality Weekly Report (USA: Centers for Disease Control and Prevention, 17 December 1982), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001208.htm>.

AIDS patient, which they called Lymphadenopathy-Associated Virus (LAC). Further crucial discoveries were made, including reports that AIDS was present in heterosexual women and the CDC established that AIDS could be spread via sexual activity or blood.<sup>60</sup> In April 1984, the American National Cancer Institute claimed to have found a virus that morphs into AIDS, which was named HTLV-III, Human T Lymphotropic virus III. By 1984, an estimated 10,000 American haemophiliacs were HIV-positive after being given infected blood transfusions.<sup>61</sup>

### **Late 1980s: The politicisation of AIDS**

By 1986, the International Committee on Taxonomy of Viruses acknowledged that the virus that causes AIDS was to be called Human Immunodeficiency Virus and abbreviated to HIV. HIV replaced LAV, HTLV-III, AIDS-associated virus (ARV), and immunodeficiency-associated virus (IDAV).<sup>62</sup> By the end of the 1980s celebrities like Rock Hudson had died of AIDS, a teenager from Indiana was excluded from school due to his AIDS infection, and AIDS had been reported in every region in the world.<sup>63</sup> HIV/AIDS was stigmatised and those who tested positive often faced discrimination. The pandemic also impacted the friends and family of those diagnosed with the virus; it was estimated that by 1988, a homosexual American man would have already lost an average of 6 people close to him due to AIDS.<sup>64</sup>

However, medical advances were being made slowly. The USA's Food Drug Administration (FDA) approved the first ART for HIV and the Western Blot blood test to diagnose HIV. The WHO and the United Nations (UN) both created action plans to help raise awareness and prevention methods to stop the spread of HIV. Despite this progress, there had been 100,000 reported cases of AIDS in America by July 1989.<sup>65</sup>

### **1990s: International developments and antiretroviral therapy**

The 1990s brought a number of exciting developments for HIV treatment despite the severity of the pandemic. In 1992, AIDS became the number one cause of death for American men aged 25-44 years.<sup>66</sup> The US FDA also released a HIV-1 test that could

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<sup>60</sup> AIDS.gov, 'A Timeline of HIV/AIDS', *AIDS.gov*, n.d., <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/>.

<sup>61</sup> Richard Colvin, 'Hemophilia, People with', ed. Raymond A. Smith, *Encyclopedia of AIDS: A Social, Political, Cultural, and Scientific Record of the HIV Epidemic* (Chicago: Fitzroy Dearborn, 1998), 247.

<sup>62</sup> Kathleen Case, 'Nomenclature: Human Immunodeficiency Virus', *Annals of Internal Medicine* 105, no. 1 (July 1986): 133.

<sup>63</sup> AIDS.gov, 'A Timeline of HIV/AIDS'.

<sup>64</sup> Jacquelyn Summers, 'Bereavement', ed. Raymond A. Smith, *Encyclopedia of AIDS: A Social, Political, Cultural, and Scientific Record of the HIV Epidemic* (Chicago: Fitzroy Dearborn, 1998), 100.

<sup>65</sup> Centers for Disease Control and Prevention, 'Current Trends First 100,000 Cases of Acquired Immunodeficiency Syndrome -- United States', *Morbidity and Mortality Weekly Report* (USA: Centers for Disease Control and Prevention, 18 August 1989), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001442.htm>.

<sup>66</sup> Centers for Disease Control and Prevention, 'Update: Mortality Attributable to HIV Infection Among Persons Aged 25-44 Years -- United States, 1991 and 1992', *Morbidity and Mortality Weekly Report* (USA: Centers for Disease Control and Prevention, 19 November 1993), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00022174.htm>.

produce a result in 10 minutes.<sup>67</sup> In 1996, the UN established UNAIDS, the Joint United Nations Programme on HIV/AIDS to combine global efforts to fight against the HIV/AIDS epidemic. By this stage, “over four million people had died from AIDS, several million were living with HIV and future predictions were dire.”<sup>68</sup>

At the end of the 20th century, multiple highly active antiretroviral therapy (HAART) drugs had been approved, the first HIV vaccines were explored, and the first significant decline in AIDS-related deaths occurred.<sup>69</sup> Furthermore, compensation was given to haemophiliacs who were infected with HIV between 1982 and 1987 by the America’s Blood Centers as instructed by the *Ricky Ray Hemophilia Relief Act of 1998*.<sup>70</sup>

### **2000s: The end in sight?**

In September 2000, the UN included a target to reduce HIV/AIDS in the Millennium Development Goals (MDG 6).<sup>71</sup> By 2001, a number of large pharmaceutical companies that produced generic HAART drugs offered their products to developing nations for lower prices after pressure from UNAIDS.<sup>72</sup> A “rapid HIV test” was developed and approved in the USA, which produced a result within 20 minutes with 99.6% accuracy.<sup>73</sup> In 2003, the WHO promoted their ‘3 by 5’ policy to ensure that HIV treatment was given to 3 million people worldwide by 2005. By 2007, more than 565,000 Americans had died of AIDS in just over 25 years.<sup>74</sup> By 2009, there were 100 ART drugs available for the treatment of HIV.<sup>75</sup>

Between 2010 and now, there has been a focus on reducing the numbers of HIV infections worldwide, providing greater access to HAART, and promoting new prevention methods. By 2013, “AIDS-related deaths” had decreased by nearly one-third since the peak of the pandemic in 2005, but there were still an estimated 35 million people living with HIV around the world.<sup>76</sup> In 2014, UNAIDS introduced two important programmes: Fast Track, and 90-90-90. Fast Track focuses on ending the AIDS epidemic by 2030, so “that the spread of HIV has been controlled or contained and that the impact of the virus on societies and on people’s lives has been

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<sup>67</sup> U.S. Food and Drug Administration, ‘Rapid AIDS Test Licensed’, FDA Talk Paper (USA: U.S. Food and Drug Administration, 27 May 1992), 1,

<http://quod.lib.umich.edu/c/cohen/aids/5571095.0235.013/1?page=root;size=100;view=image>.

<sup>68</sup> Lindsay Knight, ‘UNAIDS: The First 10 Years, 1996-2006’ (UNAIDS, 2008), 5.

<sup>69</sup> AIDS.gov, ‘A Timeline of HIV/AIDS’.

<sup>70</sup> ‘Ricky Ray Hemophilia Relief Act of 1998’, Pub. L. No. 105-369, 112 STAT. 3368 (1998), § 102 (a) (1-3).

<sup>71</sup> United Nations, ‘United Nations Millennium Development Goals’, *End Poverty: Millennium Development Goals and Beyond 2015*, n.d., <http://www.un.org/millenniumgoals/aids.shtml>.

<sup>72</sup> AVERT, ‘History of HIV and AIDS Overview | AVERT’, *AVERT: AVERING HIV and AIDS*, 26 January 2016, <http://www.avert.org/professionals/history-hiv-aids/overview>.

<sup>73</sup> AIDS.gov, ‘A Timeline of HIV/AIDS’.

<sup>74</sup> Ibid.

<sup>75</sup> U.S. Food and Drug Administration, ‘FDA Marks 100th HIV/AIDS Drug Authorized for Purchase Under PEPFAR’ (Press Release, USA, 6 October 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm185416.htm>.

<sup>76</sup> UNAIDS, ‘Global Report: UNAIDS Report on the Global AIDS Epidemic 2013’ (Geneva, Switzerland: UNAIDS, 2013), 4.



marginalized and lessened.”<sup>77</sup> Fast Track relies on the 90-90-90 policy, which calls for the following:

By 2020, 90% of all people living with HIV will know their HIV status... 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy... [and] 90% of all people receiving antiretroviral therapy will have durable viral suppression.<sup>78</sup>

After much hard work over nearly 30 years, UNAIDS announced that the MDG 6A had been achieved six months earlier than the deadline, with HAART given to 15 million people. The UN’s Sustainable Development Goals (SDGs) now focus on HIV action plans and prevention policies. The SDG 3 fosters “healthy lives and promote[s] well-being for all at all ages,” which includes eliminating the AIDS epidemic. Within this goal, the UNAIDS has a target for “fewer than 500,000 new HIV infections,” “fewer than 500,000 AIDS-related deaths,” and the “elimination of HIV-related discrimination” by 2021.<sup>79</sup>

### New Zealand history and prevention of HIV/AIDS

#### ***Early 1980s: The epidemic years***

The first cases of HIV did not occur in New Zealand until late 1983, when Bruce Burnett and Ray Taylor returned home after contracting the virus overseas. Until then, AIDS was seen to be a distant threat localised in bigger cities or “something manufactured by people who opposed the gay community.”<sup>80</sup> However, in 1984, New Plymouth became the first city with a case of transmitted AIDS and an AIDS-related death of a homosexual man in New Zealand.<sup>81</sup> A small group of New Zealanders concerned about HIV created the AIDS Support Network in June 1984. As more cases of HIV/AIDS emerged it became clear that intervention was necessary to stop potential hysteria, so condoms were promoted to prevent HIV transmission. By the end of 1984, HIV tests were available, gay and bisexual men were dissuaded from giving blood donations, and there were Gay Task Force groups in the main centres around the country.<sup>82</sup>

#### ***Late 1980s: The politicisation of AIDS***

In 1985, the fight against HIV/AIDS became linked to the Homosexual Law Reform Bill (HLRB) 1986. At this time, homosexual behaviour between two or more men was

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<sup>77</sup> UNAIDS, ‘Fast Track: Ending the AIDS Epidemic by 2030’ (Brochure, Geneva, Switzerland, 2014), 2, [http://www.unaids.org/en/resources/documents/2014/fast\\_track](http://www.unaids.org/en/resources/documents/2014/fast_track).

<sup>78</sup> UNAIDS, ‘Ambitious Treatment Targets: Writing the Final Chapter of the AIDS Epidemic’ (Discussion paper, Geneva, Switzerland, 2014), 1, [www.unaids.org/sites/default/files/media\\_asset/JC2670\\_UNAIDS\\_Treatment\\_Targets\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/JC2670_UNAIDS_Treatment_Targets_en.pdf).

<sup>79</sup> UNAIDS, ‘On the Fast-Track to End AIDS’ (Geneva, Switzerland: UNAIDS, 2016), 8–9, [http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/october/20151030\\_PR\\_PCB37](http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/october/20151030_PR_PCB37).

<sup>80</sup> *Beginnings: The New Zealand AIDS Foundation, 1983-1986*, DVD, Documentary (Roll Tape Productions, 2008).

<sup>81</sup> Worth, *Gay Men, Sex and HIV in New Zealand*, 11, 26.

<sup>82</sup> *Beginnings*.

illegal and could result in a maximum prison sentence of 14 years.<sup>83</sup> The NZAF (formerly AIDS Support Network and AIDS Support Network Trust) realised that without decriminalising homosexual activity, “we couldn’t tell gay men to use condoms because they weren’t supposed to be” having sex.<sup>84</sup> The HLRB aimed to legalise homosexual behaviour between two or more consenting men and remove discrimination based on sexuality.<sup>85, 86</sup> The opposition for the HLRB was strong, and included National MP Norman Jones, the Coalition of Concerned Citizens and fundamentalist churches like the Salvation Army. However, public support for the HLRB was partly due to the gay community’s positive and proactive response to HIV.<sup>87</sup> In April 1986, the anti-discrimination section of the HLRB was defeated, but the Bill passed its final reading in Parliament on the 9<sup>th</sup> of July 1986, 49 votes to 44 votes. New Zealand became the only country in the world to decriminalise homosexuality “in the absolute peak of the HIV crisis which people increasingly realised was driven among gay men by anal sex.”<sup>88</sup>

After this law reform the work of the NZAF was imperative. The gay and lesbian community was supported by the Ottawa Charter: a worldwide agreement to improve healthcare and remove stigmatisations against certain groups.<sup>89, 90, 91, 92, 93, 94</sup> Since it became clear that the unprotected anal intercourse was one of the main methods of transmission, particularly between two men, New Zealand’s main HIV prevention method was consistent condom use.<sup>95</sup>

### **1990s: National developments and antiretroviral therapy**

*The New Zealand Strategy on HIV/AIDS 1990* was one of the first national programmes established for HIV prevention and education, and incorporated HIV/AIDS into wider national health policy.<sup>96</sup> The key policy recommendations included: ensuring that HIV-positive individuals did not face discrimination, additional funding for drug clinics to provide HIV prevention methods, more appropriate counselling, and free HIV tests.<sup>97</sup>

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<sup>83</sup> William C. Hodge, ‘Homosexual Law Reform: Questions and Answers Concerning the Legality of Male Homosexual Conduct in New Zealand’ (Discussion paper, Auckland, N.Z., 1985).

<sup>84</sup> *Beginnings*.

<sup>85</sup> Chris Brickell, *Mates & Lovers: A History of Gay New Zealand* (Auckland, N.Z.: Godwit, 2008), 349.

<sup>86</sup> Ministry for Culture and Heritage, ‘Homosexual Law Reform in New Zealand’, *New Zealand History*, 1 July 2014, <http://www.nzhistory.net.nz/culture/homosexual-law-reform/reforming-the-law>.

<sup>87</sup> *Beginnings*.

<sup>88</sup> *Ibid*.

<sup>89</sup> Hughes, ‘The HIV/AIDS Epidemic in New Zealand: Environmental Scan’, 6.

<sup>90</sup> Ministry of Health, ‘HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy’, 18.

<sup>91</sup> Worth, *Gay Men, Sex and HIV in New Zealand*, 30.

<sup>92</sup> *Beginnings*.

<sup>93</sup> Hughes and Saxton, ‘Thirty Years of Condom-Based HIV Prevention by Gay Men in New Zealand’, 4 December 2015, 24.

<sup>94</sup> World Health Organization, ‘The Ottawa Charter for Health Promotion’, *World Health Organization*, 2016, <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>.

<sup>95</sup> Hughes, ‘The HIV/AIDS Epidemic in New Zealand: Environmental Scan’, 6.

<sup>96</sup> National Council on AIDS, ‘The New Zealand Strategy on HIV/AIDS 1990’, n.d., 2.

<sup>97</sup> *Ibid*, 4–5.

By 1996, there were 1077 HIV diagnoses, just over 500 New Zealanders living with AIDS, and 429 AIDS-related deaths.<sup>98</sup>

However, New Zealand was among the first countries worldwide to “experience a decline in AIDS incidence... and the major factors for this are likely to have been the reduction in HIV infection[s]” through successful health policies.<sup>99</sup> In 1997 HIV diagnoses were at an all time low since they were first recorded in 1985 (see Figure 1). The success of HIV prevention can be attributed to the gay community’s quick acceptance of prevention campaigns, which led to success limiting the transmission of HIV in the 1990s.<sup>100, 101</sup>

### **2000s: The end is in sight?**

In 2003, the Ministry of Health (MOH) developed the *HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy* to concentrate on those groups who have the highest risk of contracting HIV based on statistical profiles. The 2003 *Strategy*’s goals included improved social attitudes towards HIV/AIDS, increasing prevention education, establishing specialist services and policies around the country, and creating a database to track the epidemiology of the virus.<sup>102</sup>

More recent HIV campaigns included the use of social media to promote condom use. The NZAF’s Love Your Condom (LYC) brand had a large social media presence targeted to young MSM in New Zealand. LYC was a frank, explicit website that encouraged people to feel comfortable talking about condom use and safe sex, particularly those at-risk of HIV.<sup>103</sup> Through a combination of mass, social, and guerrilla marketing, and community engagement methods, LYC was able to reach a large audience.<sup>104, 105</sup> The LYC brand was discontinued in January 2017 to make way for a new campaign, Ending HIV.

However, national HIV infections have begun to rise again. In 2017, there are around 3200 people living with HIV in New Zealand.<sup>106</sup> Figure 1 depicts the number of people diagnosed with HIV infections yearly from 1985-2016. Figure 1 shows that 2016 was the fifth consecutive year that HIV diagnoses have increased overall. Initially it was too early to interpret whether the rise in infections was significant, however in

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<sup>98</sup> Nick Crofts and John Ballard, ‘Australia and New Zealand’, ed. Raymond A. Smith, *Encyclopedia of AIDS: A Social, Political, Cultural, and Scientific Record of the HIV Epidemic* (Chicago: Fitzroy Dearborn, 1998), 89.

<sup>99</sup> Sharples et al. 1996, cited in Saxton, Dickson, and Hughes, *GAPSS 2008*, 13.

<sup>100</sup> Worth, *Gay Men, Sex and HIV in New Zealand*, 7.

<sup>101</sup> *Beginnings*.

<sup>102</sup> Ministry of Health, ‘HIV/AIDS Action Plan: Sexual and Reproductive Health Strategy’, 23, 27, 32, 38.

<sup>103</sup> New Zealand AIDS Foundation, ‘Love Your Condom’, *New Zealand AIDS Foundation*, n.d., <http://www.nzaf.org.nz/services-programmes/hiv-prevention-programmes/get-it-on/>.

<sup>104</sup> Blake Crayton-Brown, ‘AIDS Foundation Finds Explicit Content Effective in Promoting Condoms’, *Stuff.co.nz*, 17 May 2015, <http://www.stuff.co.nz/national/health/68811622/aids-foundation-finds-explicit-content-effective-in-promoting-condoms>.

<sup>105</sup> New Zealand AIDS Foundation, ‘Love Your Condom’.

<sup>106</sup> New Zealand AIDS Foundation, ‘NZAF Welcomes Medsafe’s Milestone Decision to Approve Truvada for Pre-Exposure Prophylaxis (PrEP)’, *New Zealand AIDS Foundation*, 9 February 2017, <https://www.nzaf.org.nz/news-and-media/news/nzaf-welcomes-medsafes-milestone-decision-to-approve-truvada-for-pre-exposu/>.

2017 it was confirmed “the persisting increase in diagnosis of recent infections, along with the increase in total diagnoses suggests a true rise in incidence in recent years.”<sup>107</sup> The NZAF also notes that the large increases in HIV infections seen in Figure 1 between 2002-2004 is linked to more refugees and immigrants moving to New Zealand before HIV tests were compulsory prior to arrival.<sup>108</sup>

Figure 2 shows the number of MSM diagnosed with HIV between 1984 and 2016 in New Zealand. Yearly MSM HIV infections between 1984-1990 were not available. These graphs show that 53% of the 4,438 HIV infections between 1984 and 2016 occurred between MSM in New Zealand.<sup>109</sup> Figure 2 also shows how HIV infection rates for MSM have fluctuated between 1990 and 2016 in New Zealand. The AIDS Epidemiology Group originally argued that despite the clear increase in HIV infections between 2001 and 2005, infection rates from 2006 until 2015 show no specific trend of increasing or decreasing.<sup>110</sup> However, 2016 saw the highest number of HIV infections of MSM recorded in New Zealand. It appears that this trend is not unique to New Zealand; reports have shown that in many developed nations there are “re-emergent epidemics” of HIV between MSM despite greater overall access to ARTs.<sup>111</sup>

The AIDS Epidemiology Group Leader Sue McAllister granted the researcher permission to republish this data seen in Figures 1 and 2, as it is publicly available. Figures 1 and 2 are on the following page.

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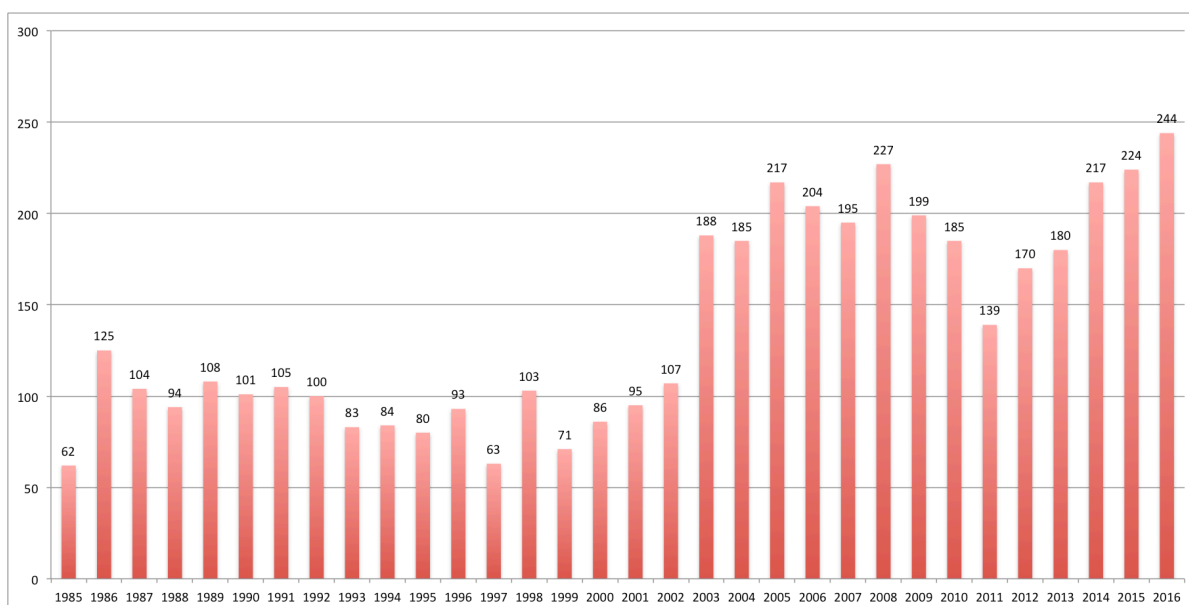
<sup>107</sup> AIDS Epidemiology Group, ‘AIDS - New Zealand’, Newsletter (Dunedin, New Zealand: AIDS Epidemiology Group, Dunedin School of Medicine, University of Otago, May 2017), 2, <http://dnmeds.otago.ac.nz/departments/psm/research/aids/newsletters.html>.

<sup>108</sup> New Zealand AIDS Foundation, ‘HIV in New Zealand’.

<sup>109</sup> AIDS Epidemiology Group, ‘AIDS-NZ Newsletters from the AIDS Epidemiology Group’, *AIDS Epidemiology Group, Dunedin School of Medicine*, June 2014, <http://dnmeds.otago.ac.nz/departments/psm/research/aids/newsletters.html>.

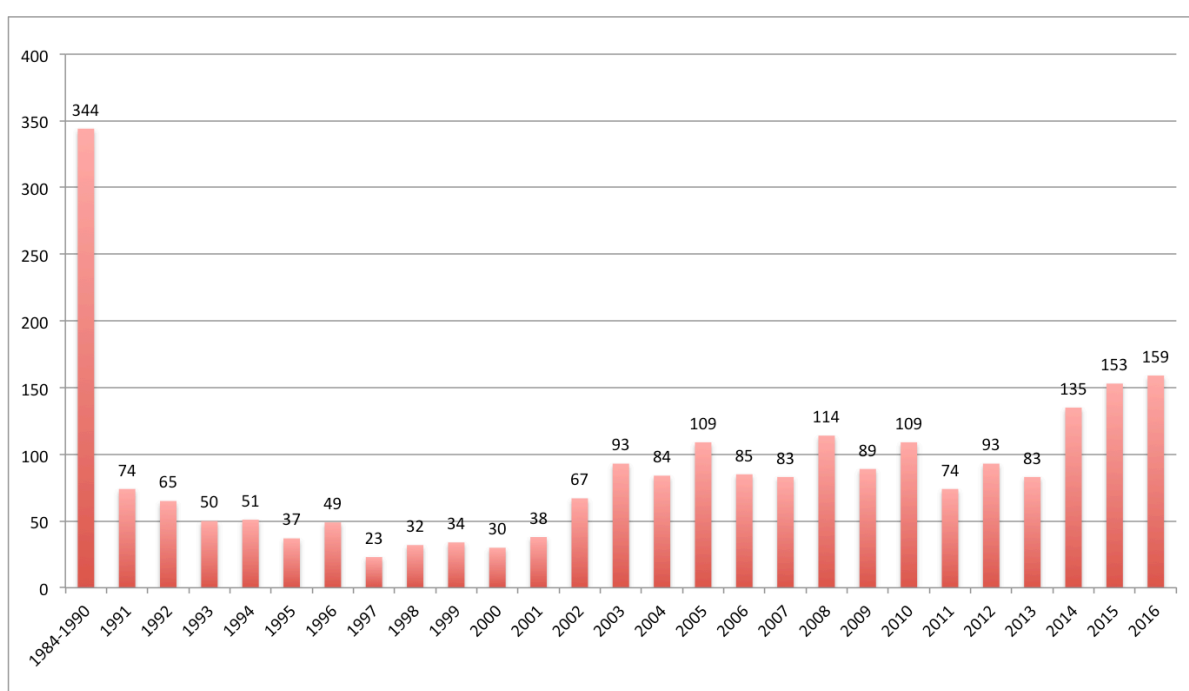
<sup>110</sup> Matthew Sothorn, ‘HIV + Bodyspace: AIDS and the Queer Politics of Future Negation in Aotearoa/New Zealand’, in *Geographies of Sexualities: Theory, Practices and Politics*, by Gavin Brown, Jason Lim, and Kath Browne (Aldershot, Hampshire; Burlington, VT: Ashgate, 2007), 279.

<sup>111</sup> Beyrer et al., ‘HIV in Men Who Have Sex with Men 1’, 367.



**Figure 1: Number of people diagnosed with HIV in New Zealand, 1985-2016**

Source: New Zealand AIDS Epidemiology Group and Associate Professor Nigel Dickson, University of Otago, New Zealand<sup>112</sup>



**Figure 2: Number of MSM diagnosed with HIV in New Zealand, 1984-2016**

Source: New Zealand AIDS Epidemiology Group and Associate Professor Nigel Dickson, University of Otago, New Zealand<sup>113</sup>

<sup>112</sup> Nigel Dickson to Alice Hartley, 'RE: Statistics for MA', 2 May 2016.

<sup>113</sup> Ibid.

## Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis, commonly known as PrEP, is a prophylactic medicine taken by individuals who are not infected by HIV but have a high risk of contracting the virus.<sup>114, 115, 116, 117, 118, 119, 120, 121</sup> A prophylactic drug is designed to “prevent or control” an infection or disease.<sup>122</sup> Therefore, if an individual engages in risky behaviour that is linked to HIV transmission, PrEP minimises the likelihood of the virus creating a permanent infection in the body.<sup>123</sup> PrEP is the first successful biomedical HIV prevention method, which signals a new era of HIV prevention and policy.

PrEP is an oral, once-daily pill. The antiretroviral drug currently comes in two forms: tenofovir disoproxil fumarate (TDF), or a tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) combination called Truvada.<sup>124, 125, 126, 127</sup> Truvada is made by Gilead Sciences, Incorporated. PrEP reached the market in 2012 when the United State’s FDA approved Truvada for prophylactic prevention of HIV. However, Truvada was originally developed as a HAART for HIV-1. When combined with other HIV-1 treatment drugs, Truvada

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<sup>114</sup> U.S. Food and Drug Administration, ‘Consumer Updates: FDA Approves First Medication to Reduce HIV Risk’, *U.S. Food and Drug Administration*, 16 July 2012, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm311821.htm>.

<sup>115</sup> Centers for Disease Control and Prevention, ‘CDC Features - PrEP for HIV Prevention’, *Centers for Disease Control and Prevention*, 14 May 2014, <http://www.cdc.gov/Features/stop-hiv-prep/>.

<sup>116</sup> Jill Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’, *AIDS and Behaviour* 19, no. 5 (2015): 803.

<sup>117</sup> Sarah K. Calabrese and Kristen Underhill, ‘How Stigma Surrounding the Use of HIV Pre-Exposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize “Truvada Whores”’, *American Journal of Public Health* 105, no. 10 (October 2015): 1960.

<sup>118</sup> Centers for Disease Control and Prevention and Start Talking. Stop HIV., ‘Are You Ready for PrEP?’ (Centers for Disease Control and Prevention, 25 June 2015), 3, [http://www.cdc.gov/actagainstaids/pdf/campaigns/starttalking/stsh\\_prep-ig\\_englishbrochure\\_508.pdf](http://www.cdc.gov/actagainstaids/pdf/campaigns/starttalking/stsh_prep-ig_englishbrochure_508.pdf).

<sup>119</sup> Centers for Disease Control and Prevention, ‘Prevention Research - HIV/AIDS: Pre-Exposure Prophylaxis (PrEP)’, *Centers for Disease Control and Prevention*, 7 October 2015, <http://www.cdc.gov/hiv/prevention/research/prep/>.

<sup>120</sup> Natasha Mack et al., ‘Human Resource Challenges to Integrating HIV Pre-Exposure Prophylaxis (PrEP) into the Public Health System in Kenya: A Qualitative Study’, *African Journal of Reproductive Health* 19, no. 1 (2015): 54.

<sup>121</sup> UNAIDS, ‘Oral Pre-Exposure Prophylaxis: Putting a New Choice in Context’ (Geneva, Switzerland: UNAIDS, 2015b), 3, <http://www.avac.org/resource/oral-pre-exposure-prophylaxis-%E2%80%93-putting-new-choice-context>.

<sup>122</sup> Centers for Disease Control and Prevention and Start Talking. Stop HIV., ‘Are You Ready for PrEP?’, 3.

<sup>123</sup> Centers for Disease Control and Prevention, ‘Prevention Research - HIV/AIDS: Pre-Exposure Prophylaxis (PrEP)’.

<sup>124</sup> David N. Burns et al., ‘Role of Oral Pre-Exposure Prophylaxis (PrEP) in Current and Future HIV Prevention Strategies’, *Current HIV/AIDS Reports* 11, no. 4 (2014): 394.

<sup>125</sup> Centers for Disease Control and Prevention, ‘HIV/AIDS: HIV Basics: PrEP’, *Centers for Disease Control and Prevention*, 25 June 2015, <http://www.cdc.gov/hiv/basics/prep.html>.

<sup>126</sup> Mack et al., ‘Human Resource Challenges to Integrating HIV Pre-Exposure Prophylaxis (PrEP) into the Public Health System in Kenya: A Qualitative Study’, 54.

<sup>127</sup> Tanya L. K. Mullins et al., ‘Clinician Attitudes toward CDC Interim Pre-Exposure Prophylaxis (PrEP) Guidance and Operationalizing PrEP for Adolescents’, *AIDS Patient Care and STDs* 29, no. 4 (2015): 193.

Helps make it harder for HIV-1 to multiply by blocking an enzyme in your body...  
Helps lower the viral load, which means decreasing the amount of HIV in the blood... [and] increase the number of CD4 cells.<sup>128</sup>

When PrEP is taken consistently, the risk of contracting HIV is more than 90% lower than participants who do not use prophylactic drugs.<sup>129, 130, 131</sup> PrEP is more effective when combined with additional HIV prevention methods such as condoms and regular HIV testing. However, if PrEP is not taken consistently the chances of efficacy decrease dramatically. The first-generation randomised clinical trials (RCTs) of PrEP found the efficacy ranged between 0-75%, which was later explained by participants missing pills or not taking them at all.<sup>132</sup> These results are explained in detail in Chapter 2.

The CDC recommends that PrEP be prescribed to the following individuals who are at the highest risk of contracting HIV:

- Sexually-active adult men who have sexual intercourse with other men (MSM);
- Sexually-active adult men and women who engage in risky heterosexual sexual intercourse;
- Serodiscordant couples, where one partner is infected with HIV and the other is not; and
- Adult injection drug users (IDUs).<sup>133, 134</sup>

PrEP is only for individuals who are regularly at-risk of HIV, as those who are only at-risk of HIV on a single occasion can use post-exposure prophylaxis (PEP) within 72 hours of the event.<sup>135</sup> In 2014, the WHO recommended that PrEP was made accessible to all MSM to reduce global HIV infections. In November 2015, the WHO extended this recommendation to all groups around the world that are at a significant risk of HIV infection.<sup>136</sup> In February 2017, New Zealand's Medicines and Medical Devices Safety Authority, Medsafe, approved Truvada for the prevention of HIV. In June 2017, the

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<sup>128</sup> Gilead Sciences, Inc., 'About TRUVADA', *Truvada*, 2014, <http://www.truvada.com/treatment-for-hiv>.

<sup>129</sup> James Wilton, 'Moving PrEP into Practice: An Update on Research and Implementation', *CATIE: Canada's Source for HIV and Hepatitis C Information*, 2014, <http://www.catie.ca/en/pif/spring-2014/moving-prep-practice-update-research-and-implementation>.

<sup>130</sup> Centers for Disease Control and Prevention, 'HIV/AIDS: HIV Basics: PrEP'.

<sup>131</sup> Dawn K. Smith et al., 'Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition - United States, 2015', *Morbidity and Mortality Weekly Report (USA: Centers for Disease Control and Prevention, 27 November 2015)*, 1291, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s\\_cid=mm6446a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s_cid=mm6446a5_w).

<sup>132</sup> Wilton, 'Moving PrEP into Practice: An Update on Research and Implementation'.

<sup>133</sup> Centers for Disease Control and Prevention, 'Act Against AIDS: HIV Treatment Works - Protect Others', Centers for Disease Control and Prevention, *HIV Treatment Works*, (12 January 2016), <http://www.cdc.gov/actagainstaids/campaigns/hivtreatmentworks/getincare/index.html>.

<sup>134</sup> Centers for Disease Control and Prevention, 'HIV/AIDS: HIV Basics: PrEP'.

<sup>135</sup> Ibid.

<sup>136</sup> World Health Organization, 'Treat All People Living with HIV, Offer Antiretrovirals as Additional Prevention Choice for People At "substantial" risk' (Press Release, Geneva, Switzerland, 30 September 2015), 1, <http://www.who.int/entity/mediacentre/news/releases/2015/hiv-treat-all-recommendation/en/>.

WHO added PrEP to its list of essential medicines, which consists of medicines for “the most important public health needs.”<sup>137</sup>

Scientists are not certain about how long PrEP takes to become effective because it can depend on the user’s high-risk behaviour. If PrEP is taken everyday, it is estimated that it takes 5-7 days in rectal tissue, 20 days in vaginal tissue, and 20 days in blood to reach its maximum level of protection.<sup>138, 139, 140</sup>

Short-term side effects of PrEP appear to be mild and mainly seem to occur in the first month of treatment. These include loss of appetite, headaches, nausea, and weight loss.<sup>141, 142, 143</sup> These side effects occurred in less than 10% of clinical trial participants.<sup>144</sup> Due to the recent development of PrEP as a prophylactic, the long-term effects are unknown at this stage. However, more serious side effects reported include lactic acidosis,<sup>145</sup> worsening of hepatitis B (HBV) if present, and bone density, liver and kidney problems.<sup>146</sup> More information about side effects is in Chapter 2.

There have been six studies in the “first generation PrEP RCTs.”<sup>147</sup> These six trials were iPrEx, Partners PrEP, TDF2, VOICE, FEM-PrEP, and the Bangkok Tenofovir Study. All six RCTs studied PrEP’s efficacy at preventing HIV infection for the following high-risk statistical profiles: MSM, IDUs, serodiscordant couples, and/or heterosexual men and women. Greater detail about the trials of PrEP is in Chapter 2. PROUD and IPERGAY are the last trials for PrEP that will occur, as any “future RCTs would be unethical.”<sup>148</sup> Regardless, the combined results from iPrEx, IPERGAY, and PROUD show the drug is 86-92% effective at preventing HIV infection. A number of countries have

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<sup>137</sup> World Health Organization, ‘WHO Updates Essential Medicines List with New Advice on Use of Antibiotics, and Adds Medicines for Hepatitis C, HIV, Tuberculosis and Cancer’ (Press Release, Geneva, Switzerland, 6 June 2017), <http://www.who.int/mediacentre/news/releases/2017/essential-medicines-list/en/>.

<sup>138</sup> GayNZ.com, ‘New Zealand Daily News: New Zealand PrEP Trial Gets Green Light’, *GayNZ.com*, 11 June 2015, Online edition, sec. New Zealand Daily News, [http://www.gaynz.com/articles/publish/2/article\\_16946.php](http://www.gaynz.com/articles/publish/2/article_16946.php).

<sup>139</sup> Massimo Giola, ‘News from ASHM Conference, Brisbane Focus on PrEP: From the World to Australian to New Zealand’ (ASHM Conference, Brisbane, 2015), 23.

<sup>140</sup> UNAIDS, ‘Oral Pre-Exposure Prophylaxis: Questions and Answers’ (Geneva, Switzerland: UNAIDS, 2015a), 4, <http://www.avac.org/resource/oral-pre-exposure-prophylaxis-%E2%80%93-questions-and-answers>.

<sup>141</sup> Wilton, ‘Moving PrEP into Practice: An Update on Research and Implementation’.

<sup>142</sup> UNAIDS, ‘Oral Pre-Exposure Prophylaxis: Questions and Answers’, 7.

<sup>143</sup> AIDS.gov, ‘Pre-Exposure Prophylaxis (PrEP)’, *AIDS.gov*, 29 January 2016, <https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/>.

<sup>144</sup> Wilton, ‘Moving PrEP into Practice: An Update on Research and Implementation’.

<sup>145</sup> Linda J. Vorvick, ‘Lactic Acidosis: MedlinePlus Medical Encyclopedia’, *U.S. National Library of Medicine*, 2 November 2014, <https://www.nlm.nih.gov/medlineplus/ency/article/000391.htm>.

<sup>146</sup> Gilead Sciences, Inc., ‘TRUVADA® Side Effects’, *Truvada*, February 2014, <http://www.truvada.com/truvada-side-effects>.

<sup>147</sup> Giola, ‘News from ASHM Conference, Brisbane Focus on PrEP: From the World to Australian to New Zealand’, 1.

<sup>148</sup> *Ibid.*, 22.



approved demonstration projects and pilot studies for PrEP, including New Zealand, Australia, South Africa, and America.<sup>149</sup>

### Challenges and controversies of PrEP

Despite the success of PrEP's clinical trials and the promising nature of the drug, there have been mixed reactions from medical practitioners and users. The following section will explore various challenges that are associated with PrEP, which includes medical environments, labels and stigmatisation, adherence issues, potential risky behaviour while using PrEP, ensuring regular HIV and STI tests, and the cost of PrEP. These challenges associated with PrEP are discussed in further detail in Chapter 2, however, it is important to mention these themes to provide a sufficient introduction to this subject.

#### **Medical environments**

Sexual behaviour is a private, intimate topic that can be uncomfortable to discuss, which is why it is often dismissed by patients and doctors.<sup>150</sup> However, if patients and clinicians are unable to discuss sexual behaviour together, the clinician cannot provide the necessary medical care. In the 2014 GAPSS and Gay men's Online Sex Survey (GOSS), one third of participants said their doctor did not know their sexuality.<sup>151, 152</sup> Results also show that respondents who identify as bisexual, were younger, were of "Asian or other non-European/Māori/Pacific ethnicity," or had a small number of same-sex relationships believed their doctor was less likely to know of their sexuality.<sup>153</sup> Without adequate and relevant healthcare, nearly half of HIV infections of MSM between 2010 and 2015 in New Zealand were diagnosed later than the usual point that ART begins.<sup>154</sup> It is imperative that patients and doctors take a collaborative approach to their sexual healthcare; patients must feel comfortable enough to discuss their sexuality and doctors must provide non-judgmental healthcare.

#### **Labels and stigmatisation**

Despite claims that PrEP may reduce fear of HIV,<sup>155</sup> a number of studies have cited stigmatisation as a deterrent to using PrEP. This negative reaction towards PrEP is not surprising given the stigma associated with HIV since its outbreak. Further

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<sup>149</sup> AVAC, 'Ongoing and Planned PrEP Demonstration and Implementation Studies, as of April 2017' (AVAC, April 2017), <http://www.avac.org/resource/ongoing-and-planned-prep-demonstration-and-implementation-studies>.

<sup>150</sup> Centers for Disease Control and Prevention, 'US Public Health Service - Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Practice Guideline' (Department of Health & Human Services, USA, 2014), 26, [www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf](http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf).

<sup>151</sup> Adrian H. Ludlam et al., 'General Practitioner Awareness of Sexual Orientation among a Community and Internet Sample of Gay and Bisexual Men in New Zealand', *Journal of Primary Health Care* 7, no. 3 (September 2015): 207.

<sup>152</sup> New Zealand AIDS Foundation, 'Half of GPs Unaware of Gay and Bisexual Men's Sexuality', *New Zealand AIDS Foundation*, 2 October 2015, <https://www.nzaf.org.nz/news-and-media/news/half-of-gps-unaware-of-gay-and-bisexual-mens-sexuality/>.

<sup>153</sup> Ibid.

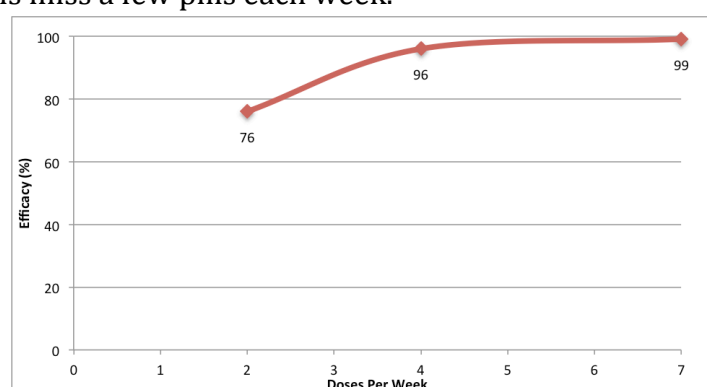
<sup>154</sup> Ibid.

<sup>155</sup> UNAIDS, 'Oral Pre-Exposure Prophylaxis: Putting a New Choice in Context', 13.

stigmatisation includes negative attitudes towards “homosexuality, so-called ‘promiscuity’, sex work, and injecting drug use.”<sup>156</sup> PrEP-users have also been called ‘Truvada whores’ for taking the drug so they can engage in risky behaviour by the American AIDS Healthcare Foundation President Michael Weinstein.<sup>157, 158</sup> If the stigmatisations and labels linked to PrEP cannot be overcome, it is unlikely that potential PrEP-users will want to use the drug.

### **Adherence issues**

The Fem-PrEP and VOICE studies found no significant results to prove that PrEP could effectively prevent HIV infections, leading to disagreements about whether PrEP works.<sup>159</sup> However, adherence-adjusted results of the first generation RCTs found that the low efficacy of the Fem-PrEP and VOICE studies was due to “poor adherence” of the participants.<sup>160</sup> Thus, PrEP’s efficacy at preventing HIV transmission is directly linked to taking the drug everyday. If PrEP is not taken consistently there is not enough of the drug in the individual’s bloodstream to stop the HIV virus.<sup>161, 162</sup> Figure 3 shows results from the iPrEx trial, where as the number of PrEP pills taken weekly decreases, so does the drug’s efficacy.<sup>163</sup> Although it is recommended the PrEP is taken everyday to ensure the highest possible protection against HIV, it is clear that PrEP is still effective even if individuals miss a few pills each week.



**Figure 3: Efficacy of PrEP against doses per week**

Source: Grant et al. 2010,<sup>164</sup> USA FDA 2012<sup>165</sup>

<sup>156</sup> Bridget G Haire, ‘Preexposure Prophylaxis-Related Stigma: Strategies to Improve Uptake and Adherence – a Narrative Review’, *HIV/AIDS (Auckland, N.Z.)* 7 (13 October 2015): 242.

<sup>157</sup> Calabrese and Underhill, ‘How Stigma Surrounding the Use of HIV Pre-Exposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize “Truvada Whores”’, 1961.

<sup>158</sup> Haire, ‘Preexposure Prophylaxis-Related Stigma’, 243.

<sup>159</sup> Ibid., 242.

<sup>160</sup> Ibid.

<sup>161</sup> Centers for Disease Control and Prevention, ‘HIV/AIDS: HIV Basics: PrEP’.

<sup>162</sup> New Zealand AIDS Foundation, ‘Pre-Exposure Prophylaxis (PrEP)’, *New Zealand AIDS Foundation*, n.d., <https://www.nzaf.org.nz/hiv-aids-stis/hiv-prevention/prep/>.

<sup>163</sup> Ibid.

<sup>164</sup> Robert M. Grant et al., ‘Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men’, *The New England Journal of Medicine* 363, no. 27 (30 December 2010): 2587–99.

<sup>165</sup> U.S. Food and Drug Administration, ‘Consumer Updates: FDA Approves First Medication to Reduce HIV Risk’.

The researcher made this graph herself based on results from the trial, so no permission was needed for reprinting or copyright.

### ***Minimising risk compensation***

Opponents of PrEP have argued that the drug minimises the importance of other HIV prevention methods, such as condoms. The NZAF originally resisted promoting PrEP because the drug is not as cheap as condoms and cannot prevent STIs.<sup>166</sup> With biomedical HIV prevention methods, condoms can be seen as out-dated, which has the potential to “undercut programmes to keep [HIV] negative people negative that are based on behaviour change.”<sup>167</sup> Research shows inconsistent results of the impact that PrEP may have on condom use. There was no increase in STIs in the PROUD study, which suggests that condom use did not change,<sup>168</sup> whereas 30% of PrEP-users were diagnosed with one or more STIs and “self-reported” condom use decreased by 41% in a study in San Francisco.<sup>169</sup> A focus group of African-American young adults in Atlanta, Georgia had mixed responses about the potential impact of PrEP on condom use, and concluded that participants were likely to continuing using condoms if they used them prior to taking PrEP.<sup>170</sup> Educational campaigns and support systems that encourage a combined approach of condoms and PrEP are necessary to ensure that patients have the highest levels of protection against HIV transmission.

### ***Ensuring regular HIV and STI tests***

One of the biggest challenges associated with PrEP is that individuals must be vigilant about regular HIV and STI tests. If individuals become HIV-positive and continue to take PrEP, they risk becoming resistant to the active components of PrEP.<sup>171, 172, 173, 174</sup> Antiretroviral resistance occurs because HIV-positive individuals are treated with a combination of two or three antiretroviral drugs (polypharmacy) that limit different phases of the virus’s replication because the virus mutates too fast for monotherapy. Therefore, if an individual becomes HIV-positive and continues to use PrEP, the monotherapy components in PrEP will not provide enough protection against HIV and there is a high risk of antiretroviral resistance. As a result, it is imperative that PrEP-users complete an HIV test prior to starting the medication and regular HIV and STI

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<sup>166</sup> GayNZ.com, ‘New Zealand Daily News: New Zealand PrEP Trial Gets Green Light’.

<sup>167</sup> Hughes, ‘The HIV/AIDS Epidemic in New Zealand: Environmental Scan’, 6.

<sup>168</sup> UNAIDS, ‘Oral Pre-Exposure Prophylaxis: Questions and Answers’, 6.

<sup>169</sup> Jonathan E. Volk et al., ‘No New HIV Infections With Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting’, *Clinical Infectious Diseases* 61, no. 10 (15 November 2015): 1602, 1603.

<sup>170</sup> Dawn K. Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’, *AIDS Education and Prevention* 24, no. 5 (2012): 417.

<sup>171</sup> S. Nadery and S. E. Geerlings, ‘Pre-Exposure Prophylaxis (PrEP) in HIV-Uninfected Individuals with High-Risk Behaviour’, *Netherlands Journal of Medicine* 71, no. 6 (August 2013): 296, 298.

<sup>172</sup> Wilton, ‘Moving PrEP into Practice: An Update on Research and Implementation’.

<sup>173</sup> GayNZ.com, ‘GayNZ.com PrEP a “Reasonable Option” for Some NZ Men’, *GayNZ.com*, 25 September 2015, Online edition, sec. New Zealand Daily News, [http://www.gaynz.com/articles/publish/2/article\\_17343.php](http://www.gaynz.com/articles/publish/2/article_17343.php).

<sup>174</sup> PrEPWatch, ‘About PrEP’, *PrEPWatch*, n.d., <http://www.prepwatch.org/about-prep/>.

tests while using the drug. If patients are unable to commit to regular tests, it is unlikely that PrEP will be a worthwhile prevention method for them.

### ***Cost of PrEP***

Information regarding the cost of PrEP differs; regardless, branded PrEP is expensive compared to generic PrEP. Truvada costs NZ \$900-1,200 per month<sup>175, 176, 177</sup> and generic PrEP costs between \$60-100 per month. The cost of branded PrEP is out of most people's budgets, which is why individuals would need to rely on subsidisation from PHARMAC, the government agency in charge of subsidising medicines in New Zealand. The New Zealand health budget is finite but citizens' needs are infinite, which forces PHARMAC to make decisions as to which medicines are subsidised and which are not. PHARMAC uses multiple economic methods to determine all potential positive and negative impacts that a medical investment like PrEP can have. PHARMAC's use of economic analysis aims "to bring greater rationality to often complex decisions, and shed light on the logic behind choices."<sup>178</sup> The cost of PrEP is a clear barrier to PrEP use and will be discussed further in Chapter 2.

These challenges of PrEP mentioned above simply skim the surface. A more detailed analysis of the complexities of PrEP is provided in the literature review in Chapter 2.

### **Thesis structure**

The aim of this thesis is to inform a health policy for the New Zealand government for the implementation of PrEP for MSM. Email correspondence with the MOH has indicated that as at March 2017, the MOH was developing a policy framework for PrEP. The researcher also acknowledges the occurrence of a PrEP demonstration project led by the Auckland Sexual Health Service and Auckland District Health Board (ADHB), and partnered by the NZAF, Body Positive, and the University of Auckland. As at August 2016, there were over 250 people who had registered their interest in the project, but current funding was only available for 150 individuals.<sup>179</sup> As mentioned throughout this chapter, there are four recommended groups that can benefit from PrEP based on statistical profiles. However, due to numerous constraints this thesis will only focus on the use of PrEP for MSM in New Zealand. This thesis seeks to inform a policy design for the implementation of PrEP via the research's focus on MSM, which occurs through the use of a survey, interviews and document analysis.

The thesis is divided into six chapters, the first being this chapter, Setting the Scene. This chapter provided a necessary overview of HIV/AIDS and PrEP to set the

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<sup>175</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic, interview by Alice Hartley, Face-to-face, 23 September 2016.

<sup>176</sup> New Zealand AIDS Foundation, 'Pre-Exposure Prophylaxis (PrEP) Factsheet' (New Zealand Aids Foundation, n.d.), 1.

<sup>177</sup> Shriya Chitale, 'Cost of PrEP and HIV Treatment', 9 March 2017.

<sup>178</sup> PHARMAC, 'Prescription for Pharmacoeconomic Analysis: Methods for Cost-Utility Analysis' (New Zealand: PHARMAC, 2012), 9.

<sup>179</sup> Joe Rich, 'Updates about PrEP in New Zealand', 22 August 2016.

reader up with enough knowledge to follow and understand the subsequent chapters. Chapter 2, Understanding the Complexities of PrEP, is a literature review of the relevant scholarly information on PrEP. Chapter 2 is split into three key review sections: the first-generation RCTs of PrEP, clinicians' opinions of PrEP, and the attitudes that MSM have towards PrEP. Many of the challenges of PrEP that were briefly discussed in this chapter are explored in greater depth in Chapter 2. Chapter 3, Methodology, discusses and justifies the methods used for this thesis. The thesis follows Carol H. Weiss's problem-solving model that uses research methods to help reduce uncertainty regarding a problem and inform a policy recommendation. This research uses a multiple, mixed-methods approach for primary research. These methods are an attitude scaling survey, interviews, and document analysis. Chapter 4, Canterbury MSM and their attitudes towards PrEP, presents the results from the online, anonymous, attitude scaling survey of MSM that took place in March and April 2017. Chapter 5, PrEPared Against HIV: 2.0, is the champion of the thesis; this chapter presents the health policy for the implementation of PrEP for MSM in New Zealand. The policy also follows Weiss's problem-solving model and includes insights from the survey, interviews, and document analysis. Chapter 6, The Beginning of a New Era, is the conclusion of the thesis. This chapter looks at the impact this research could have on academia and the future.

## Chapter 2: Understanding the Complexities of PrEP

*A literature review of first-generation randomised controlled trials, providers, and MSM patients.*

This chapter presents a comprehensive literature review of PrEP in three major categories: the six first-generation randomised controlled trials; the opinions that clinicians have of PrEP; and the attitudes that MSM have towards PrEP for preventing HIV. The chapter concludes by highlighting the gap in the literature where this thesis gains its legitimacy for research.

### Introduction to the literature of PrEP

PrEP is a recent HIV prevention technology that has shown a high level of promise in the fight against HIV. However, since the approval of Truvada in July 2012, PrEP has not been received in the way that many of its supporters imagined. For example, a 2013 survey of infectious disease specialists in America and Canada found that one-third of practitioners did not think PrEP was “relevant to their practice.”<sup>180</sup> Furthermore, while three out of four doctors surveyed said they supported the use of PrEP for high-risk individuals, only 9% had prescribed PrEP.<sup>181</sup> Similarly, there have been mixed reviews from high-risk patients. Two surveys found that only 12.8% of MSM in Canada,<sup>182</sup> and 28% of MSM in Australia<sup>183</sup> were willing to use PrEP.

There has been an increase in positive responses to PrEP as a worthwhile HIV prevention method since it has become better known. For example, a recent American survey of pharmaceutical prescriptions<sup>184</sup> found that nearly 80,000 individuals used

Truvada for PrEP between early 2012 and the end of 2015. The numbers rose from just 1671 prescriptions in the last quarter of 2012 to 14,000 in late 2015 – a 738% increase.<sup>185</sup>

However, ‘An Open Letter to the CDC on PrEP’ (Centers for Disease Control and Prevention) from the US AIDS Healthcare Foundation states that Truvada “manufacturer Gilead Sciences gives the impression that PrEP is very popular even

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<sup>180</sup> Maile Y. Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)? Provider Opinions on the Real-World Use of PrEP in the United States and Canada’, *Clinical Infectious Diseases* 58, no. 5 (1 March 2014): 705.

<sup>181</sup> Ibid.

<sup>182</sup> Kain, Fowler, Grennan, Hart, Maxwell, Wilson et al. 2013, cited in David N. Burns et al., ‘Role of Oral Pre-Exposure Prophylaxis (PrEP) in Current and Future HIV Prevention Strategies’, *Current HIV/AIDS Reports* 11, no. 4 (2014): 394, 395.

<sup>183</sup> Martin Holt et al., ‘Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men’, *Sexually Transmitted Infections* 88, no. 4 (June 2012): 258–63.

<sup>184</sup> R Mera et al., ‘Truvada (TVD) for HIV Pre-Exposure Prophylaxis (PrEP) Utilization in the United States (2013-2015)’ (AIDS 2016, Durban, South Africa, 2016), <http://programme.aids2016.org/Abstract/Abstract/10159>.

<sup>185</sup> Liz Highleyman, ‘PrEP Use Exceeds 79,000 in US Pharmacy Survey, but Some Groups Lagging behind’, *NAM AidsMap*, 19 July 2016, <http://www.aidsmap.com/prep-use-exceeds-79000-in-us-pharmacy-survey-but-some-groups-lagging-behind/page/3072084>.

though the raw numbers tell another story.” The AIDS Healthcare Foundation estimates that as at June 2016, less than 0.04% of American MSM were using PrEP.<sup>186</sup>

It is clear that while PrEP may be a good option for HIV prevention, its entry into the HIV circuit has been complicated. The purpose of this literature review is to explore the various issues surrounding PrEP. This literature review will cover three crucial topics: first-generation randomised control trials (RCTs), provider opinions of PrEP, and potential patient reactions to PrEP. These three themes have all been purposefully picked. The first-generation RCTs are essential because these six studies proved the efficacy of PrEP to prevent HIV. Without the results from these trials, PrEP would not be available for HIV prevention. The second and third topics for this literature review are necessary because they move PrEP away from the controlled environment of a clinical trial and into the ‘real world,’ where daily life has an impact on the drug. Provider opinions of PrEP are crucial to understand because without doctors, the target populations of PrEP would not have access to the drug. And finally, the third section focuses on the responses MSM have toward PrEP. The uptake of PrEP ultimately relies on whether patients see PrEP as a worthwhile HIV prevention technology. The literature review will conclude by placing this thesis in the broader scope of research that has already been undertaken regarding PrEP.

### First-generation randomised control trials of PrEP

There are six first-generation PrEP trials: iPrEx, Partners PrEP, TDF2, VOICE, FEM-PrEP, and the Bangkok Tenofovir Study. These six trials all aimed to determine whether PrEP stops the transmission of HIV infection among high-risk groups. The results from these RCTs were deemed to provide sufficient evidence in favour of using PrEP as an HIV prevention method.

There were a total of 18,019 participants in the six RCTs, although all of the trials lost participants. iPrEx<sup>187</sup> had 2,499 MSM and transgender women (TGW) from Brazil, United States, Thailand, Ecuador, Peru, and South Africa. FEM-PrEP<sup>188</sup> had 2,120 HIV-negative women from Kenya, South Africa, and Tanzania. VOICE<sup>189</sup> had 5,029 HIV-negative female participants from South Africa, Uganda, and Zimbabwe. The TDF2<sup>190</sup> trial used 1,200 high-risk heterosexual men and women in Botswana aged between 18-39 years old. 45.7% of the participants in TDF2 were women. Partners

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<sup>186</sup> AIDS Healthcare Foundation, ‘An Open Letter to the CDC on PrEP’, Open letter, (20 July 2016), <http://www.businesswire.com/news/home/20160721005613/en/PrEP-Update-Facts-Speak-Notes-AHF>.

<sup>187</sup> Robert M. Grant et al., ‘Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men’, *The New England Journal of Medicine* 363, no. 27 (30 December 2010): 2587–99.

<sup>188</sup> Lut Van Damme et al., ‘Preexposure Prophylaxis for HIV Infection among African Women’, *The New England Journal of Medicine* 367, no. 5 (2 August 2012): 411–22.

<sup>189</sup> Jeanne M. Marrazzo et al., ‘Tenofovir-Based Preexposure Prophylaxis for HIV Infection among African Women’, *New England Journal of Medicine* 372, no. 6 (5 February 2015): 509–18.

<sup>190</sup> Michael C. Thigpen et al., ‘Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana’, *The New England Journal of Medicine* 367, no. 5 (2 August 2012): 423–34.



PrEP<sup>191</sup> had 4,758 serodiscordant couples from Kenya and Uganda. The Bangkok Tenofovir Study<sup>192</sup> used 2,413 injecting drug users (IDUs) from Bangkok, Thailand. All of the trials had one or more placebos. iPrEx, FEM-PrEP, TDF2 and the Bangkok Tenofovir Study had two arms with a 50% chance of a placebo drug. Partners PrEP had three arms with a 33% chance of placebo, and VOICE had five arms with a 20% chance of an oral PrEP placebo (VOICE also used a vaginal 1% gel and placebo gel). All six RCTs used a mixture of TDF and TDF+FTC for PrEP. iPrEx, TDF2 and FEM-PrEP used TDF+FTC, the Bangkok Tenofovir Study used TDF, and Partners PrEP and VOICE used both TDF and TDF+FTC.

## Results of RCTs

### ***Efficacy of PrEP***

The levels of efficacy of PrEP differed dramatically between the RCTs from -49.0% to 75.0%. Unadjusted efficacy levels of TDF preventing HIV infections were -49.0% in VOICE, 48.9% in the Bangkok Tenofovir Study, and 67.0% in Partners PrEP. Unadjusted efficacy levels of TDF+FTC preventing HIV infections were -4.4% in VOICE, 6.0% in the FEM-PrEP trial, 44.0% in iPrEx, 62.2% in TDF2, and 75.0% in Partners PrEP. These results determine that iPrEx, Partners PrEP, TDF2, and the Bangkok Tenofovir Study RCTs all prove that PrEP (in either form) can effectively prevent HIV infection among high-risk groups. As a contrast, the FEM-PrEP and VOICE results showed that PrEP did not prevent HIV infections. The varying levels of PrEP's efficacy and overall results of PrEP's ability to limit HIV infections have been linked to adherence levels (discussed below).

The number of participants who underwent seroconversion (changing from HIV-negative to HIV-positive) during the RCTs was significantly small compared to the total number of trial subjects. Ranked smallest to largest, the proportion of HIV infections out of the total trial participants were 0.017% in Partners PrEP, 0.021% in the Bangkok Tenofovir Study, 0.03% in TDF2, 0.032% in FEM-PrEP, 0.04% in iPrEx and 0.057% in VOICE (excluding vaginal 1% gels).

### ***Adherence claims and results***

The difference between the four successful RCTs (iPrEx, Partners PrEP, TDF2, and the Bangkok Tenofovir Study) and two unsuccessful RCTs (FEM-PrEP and VOICE) has been linked to the rates of adherence of trial subjects. These trials measured adherence in multiple ways due to discrepancies between self-reported and actual adherence levels. These methods include self-reported adherence claims, numbers of returned bottles and tablets, and pill counts. iPrEx had a 44% efficacy rate but the drug was found in only 51% of a sample of participants. As a result, the iPrEx results were

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<sup>191</sup> Jared M. Baeten et al., 'Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women', *The New England Journal of Medicine* 367, no. 5 (2 August 2012): 399–410.

<sup>192</sup> Kachit Choopanya et al., 'Antiretroviral Prophylaxis for HIV Infection in Injecting Drug Users in Bangkok, Thailand (the Bangkok Tenofovir Study): A Randomised, Double-Blind, Placebo-Controlled Phase 3 Trial', *The Lancet* 381, no. 9883 (15 June 2013): 2083–90.



adjusted to 73% when participants claimed to take the drug 90% of the time, and 92% among subjects with detectable levels of PrEP in their bloodstream. The Bangkok Tenofovir Study reported similar levels of adherence; 83.8% of the pills provided to the TDF arm were taken, but only 66% of participants in a random sample of this arm had detectable levels of TDF. As a result, the Bangkok Tenofovir Study states that PrEP was 70% effective at preventing HIV infections. Similarly, TDF2 found TDF+FTC was 62.2% effective at preventing HIV but the adherence-adjusted result shows that it was 77.9% effective among those who had taken PrEP in the last thirty days. Partners PrEP did not need adherence-adjusted levels of efficacy, as adherence levels were so high. By contrast, VOICE and FEM-PrEP found no evidence of PrEP's efficacy. In the VOICE RCT there were detected drug levels in only 30% and 29% of participants of the TDF and TDF+FTC arms, respectively. Similarly, the FEM-PrEP tests showed that less than 40% of participants had active components of TDF+FTC in their bloodstream. These results show how obvious the link between adherence and efficacy for PrEP is.

### ***Antiretroviral resistance***

A major concern with PrEP is that individuals can contract a virus that becomes resistant to the active components in PrEP if it is still taken after seroconversion. There were only 10 cases of resistance to PrEP active drug components out of a total of 509 HIV infections from the six RCTs oral PrEP arms. There was 1 instance of TDF resistance in the TDF arm and 1 instance of FTC resistance in the TDF+FTC arm of Partners PrEP. There was 1 case of FTC resistance in the TDF+FTC arm of the VOICE RCT. There were 5 and 2 confirmed cases of PrEP resistance in the FEM-PrEP and TDF2 trials, respectively, but the results did not reveal what component of PrEP the participants became resistant to.

### ***Side effects***

The degree to which side effects of PrEP were reported varied between the six RCTs and the drug that was taken (TDF or TDF+FTC). TDF side effects include grade 1-4 neutropenia, nausea and/or vomiting, and liver issues. The nausea and vomiting decreased over time whereas the liver issues did not. TDF+FTC side effects include nausea, vomiting, unintentional weight loss, gastrointestinal side effects, fatigue, and dizziness. The major side effects reported were liver damage and decreased bone density.

### ***Other modes of prevention***

In order for PrEP to be as successful as possible, all of the six RCTs provided additional modes of HIV prevention. The RCTs offered participants HIV tests, risk-reduction counselling and condoms. Partners PrEP, iPrEx, and TDF2 also offered STI tests and treatment. Bangkok Tenofovir Study, VOICE, and FEM-PrEP provided adherence counselling. These additional modes of prevention can improve PrEP's efficacy when it is taken out of the controlled environment of the RCT to the 'real world,' which is also known as the 'efficacy-effectiveness gap.' This will be discussed later in the chapter.

The next section of the literature review will explore the second of the three themes: providers and PrEP. These providers include general practitioners, HIV specialists, and infectious disease specialists.

### **Providers and PrEP**

A portion of PrEP's success or failure as a new HIV prevention method is linked greatly to providers. The majority of the literature reviewed in this section focuses on clinicians and their opinions and attitudes towards PrEP. Overall, this literature explored the factors that would persuade or dissuade a doctor to offer their patients PrEP. It is crucial to look at these factors because without the support of clinicians, potential PrEP-users will struggle to gain access to this HIV prevention method.

The literature on physicians' opinions regarding PrEP had a combined total of 2,678 participants, which took place between 2006 and 2015. The studies were conducted in the United States, Canada, Italy and Peru. The sampling methods used include snowball sampling, convenience sampling, and purposive sampling. The studies used surveys, pilot surveys, focus groups, and interviews.

#### **Knowledge, support, and previous prescription patterns of PrEP before the studies**

Knowledge of, support for, and previous prescription patterns of PrEP varied across the literature, although this seems logical depending on when the research was conducted. Knowledge of PrEP is measured simply by whether the physicians knew what PrEP was prior to the research. Overall, 83.6% of Canadian clinicians,<sup>193</sup> and 89% of Boston HIV physicians<sup>194</sup> self-reported knowledge about PrEP.

Support for PrEP varied greatly between the different studies, but the majority found that physicians were generally supportive. Two of the earlier studies, published in 2012 and 2013, found physicians were 97%<sup>195</sup> and 95%<sup>196</sup> supportive of PrEP under the condition that more research was conducted into the drug's efficacy. Results for physician support of PrEP were 45.4%,<sup>197</sup> 64%,<sup>198</sup> 69.5%,<sup>199</sup> 74%,<sup>200</sup> 74%,<sup>201</sup> and

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<sup>193</sup> Malika Sharma et al., 'Preparing for PrEP: Perceptions and Readiness of Canadian Physicians for the Implementation of HIV Pre-Exposure Prophylaxis: e105283', *PLoS One* 9, no. 8 (August 2014).

<sup>194</sup> Douglas Krakower et al., 'HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings: A Qualitative Study', *AIDS and Behavior* 18, no. 9 (September 2014): 1712–21, doi:10.1007/s10461-014-0839-3.

<sup>195</sup> Avnish Tripathi et al., 'Preexposure Prophylaxis for HIV Infection: Healthcare Providers' Knowledge, Perception, and Willingness to Adopt Future Implementation in the Southern US', *Southern Medical Journal* 105, no. 4 (April 2012): 199.

<sup>196</sup> Jaclyn M. White et al., 'Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention', *AIDS Patient Care and STDs* 26, no. 7 (2012): 395–405.

<sup>197</sup> Sharma et al., 'Preparing for PrEP'.

<sup>198</sup> Jill Blumenthal et al., 'Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP', *AIDS and Behaviour* 19, no. 5 (2015): 802–10.

<sup>199</sup> Vincenzo Puro et al., 'Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists', *BMC Infectious Diseases* 13 (2013): 217.

<sup>200</sup> Karris et al., 'Are We Prepped for Preexposure Prophylaxis (PrEP)?'

100%.<sup>202</sup> Some of the higher recorded support for PrEP was linked to previous knowledge or prescriptions given.<sup>203, 204</sup> By contrast, opposition towards PrEP also varied. The proportion of physicians that were unwilling to prescribe PrEP was 3.1%,<sup>205</sup> 4.7%,<sup>206</sup> 12%,<sup>207</sup> and 30%.<sup>208</sup> One study did not give a final figure, but reported that the majority of general practitioners were unwilling to prescribe PrEP.<sup>209</sup>

Prescriptions of PrEP prior to the research fluctuated over the years but generally increased over time. The proportions of doctors who had prescribed PrEP were 4%,<sup>210</sup> 9%,<sup>211</sup> 12.9%,<sup>212</sup> 19%,<sup>213</sup> 21%,<sup>214</sup> and 97%.<sup>215</sup> Only two studies recorded whether physicians had been asked about PrEP before the research was undertaken. 26.2%<sup>216</sup> and 43%<sup>217</sup> of doctors had been asked about PrEP, and 10.6% had suggested PrEP to their patients.<sup>218</sup>

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<sup>201</sup> Douglas S. Krakower et al., 'Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention: Results from a Survey of Healthcare Providers in New England: e0132398', *PLoS One* 10, no. 7 (July 2015).

<sup>202</sup> Douglas S. Krakower et al., 'Primary Care Clinicians' Experiences Prescribing HIV Pre-Exposure Prophylaxis at a Specialized Community Health Centre in Boston: Lessons from Early Adopters', *Journal of the International AIDS Society* 19, no. 1 (10 November 2016).

<sup>203</sup> Blumenthal et al., 'Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP'.

<sup>204</sup> Krakower et al., 'Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention'.

<sup>205</sup> Heather Senn et al., 'Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations', *AIDS Research and Human Retroviruses* 29, no. 9 (September 2013): 1183–89.

<sup>206</sup> Sharma et al., 'Preparing for PrEP'.

<sup>207</sup> Karris et al., 'Are We Prepped for Preexposure Prophylaxis (PrEP)?'

<sup>208</sup> Puro et al., 'Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists'.

<sup>209</sup> Eric C. Tang et al., 'Provider Attitudes Toward Oral Preexposure Prophylaxis for HIV Prevention Among High-Risk Men Who Have Sex with Men in Lima, Peru', *AIDS Research and Human Retroviruses* 30, no. 5 (May 2014): 416–24.

<sup>210</sup> Jaclyn M. White et al., 'Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention', *AIDS Patient Care & STDs* 26, no. 7 (July 2012): 395–405.

<sup>211</sup> Karris et al., 'Are We Prepped for Preexposure Prophylaxis (PrEP)?'

<sup>212</sup> Sharma et al., 'Preparing for PrEP'.

<sup>213</sup> David Tellalian et al., 'Pre-Exposure Prophylaxis (PrEP) for HIV Infection: Results of a Survey of HIV Healthcare Providers Evaluating Their Knowledge, Attitudes, and Prescribing Practices', *AIDS Patient Care & STDs* 27, no. 10 (October 2013): 553–59.

<sup>214</sup> Blumenthal et al., 'Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP'.

<sup>215</sup> Krakower et al., 'Primary Care Clinicians' Experiences Prescribing HIV Pre-Exposure Prophylaxis at a Specialized Community Health Centre in Boston'.

<sup>216</sup> Senn et al., 'Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations'.

<sup>217</sup> Tellalian et al., 'Pre-Exposure Prophylaxis (PrEP) for HIV Infection'.

<sup>218</sup> Senn et al., 'Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations'.

### Reasons why physicians support PrEP

The majority of the literature about provider opinions of PrEP focuses on concerns about PrEP so there is very little information available as to why providers support PrEP. This section will collate the two reasons cited in support of PrEP.

#### ***Efficacy***

The efficacy of PrEP was cited as the most common reason why physicians support the drug; the higher the efficacy, the more support was reported for PrEP. An average efficacy level of 71% was considered sufficient enough to prescribe to high-risk individuals.<sup>219</sup> One study reported that 94% of physicians believe that PrEP is an effective HIV prevention method.<sup>220</sup> However, another study in 2013 found only 13% thought that PrEP was the “most effective” option for HIV prevention currently available to high-risk individuals, compared to 47% of doctors who believed increased HIV testing was better.<sup>221</sup> The most recent study on physicians’ attitudes towards PrEP cited 100% of participants believed PrEP was effective at preventing HIV in 2016.<sup>222</sup>

#### ***Herd immunity***

Herd immunity provides a community with greater immunity against infectious diseases. When there are high levels of immune community members the spread of infectious diseases is much lower, which protects individuals who are not immune. Although herd immunity is not directly linked to HIV, one study of American clinicians did claim that PrEP could have a similar impact at the community level. Multiple participants in the study supported PrEP as a method for herd immunity because “if you could get enough of just that one population protected, then you could break that cycle within the community.”<sup>223</sup> As the number of high-risk individuals using PrEP increases, there is a greater chance that the transmission of HIV could decline in a particular community.

### Barriers to PrEP implementation

Despite most of the literature focusing on physicians and PrEP to uncover their attitudes and opinions towards the drug, further analysis shows that there was more emphasis placed on uncovering the reasons why doctors do not support PrEP. This section will feature two main concerns: provider concerns and social concerns.

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<sup>219</sup> White et al., ‘Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention’, July 2012.

<sup>220</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.

<sup>221</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>222</sup> Krakower et al., ‘Primary Care Clinicians’ Experiences Prescribing HIV Pre-Exposure Prophylaxis at a Specialized Community Health Centre in Boston’.

<sup>223</sup> Emily A. Arnold et al., ‘A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection’, *PLoS One* 7, no. 7 (July 2012): 6.

## **Provider concerns**

Provider concerns are defined as concerns that primarily come from the doctors themselves and are linked to their role in regards to PrEP. There are six identified provider concerns: antiretroviral resistance, adherence, biomedicalised prevention, efficacy-effectiveness gap, lack of guidelines, and time and resources.

### **Antiretroviral resistance**

The most cited issue with PrEP according to surveyed doctors and specialists is the potential for antiretroviral resistance. To reiterate, HIV is treated using polypharmacy because when only one ART is used the virus can mutate and become resistant to that particular drug. As a result, individuals can develop an HIV virus that is resistant to PrEP if they seroconvert while continuing to take PrEP. Of the studies that provided proportions, the percentage of doctors concerned about antiretroviral resistance was 32%,<sup>224</sup> 41.9%,<sup>225</sup> 77%,<sup>226</sup> 88%,<sup>227</sup> 94%,<sup>228</sup> and >40%.<sup>229</sup> Another six articles did note antiretroviral resistance as a concern but did not cite an exact figure.

### **Adherence**

As mentioned, adherence is greatly linked to the effectiveness of PrEP. Many physicians cited adherence as a barrier because if PrEP is not taken consistently, it will not prevent HIV transmission. Three studies found that 21%,<sup>230</sup> 77%,<sup>231</sup> and >40%<sup>232</sup> of doctors cited patient adherence as a concern with PrEP. There were another three studies that did not disclose the proportion of doctors that identified adherence as a barrier to PrEP implementation.<sup>233, 234, 235</sup>

### **Biomedical prevention**

Some providers did not support PrEP as it gives drugs to otherwise healthy individuals. One provider argued against Truvada for prevention of HIV because providing patients with a “potentially toxic medication” who do not “have an active

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<sup>224</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>225</sup> Senn et al., ‘Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations’.

<sup>226</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>227</sup> Tripathi et al., ‘Preexposure Prophylaxis for HIV Infection’.

<sup>228</sup> White et al., ‘Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention’, July 2012.

<sup>229</sup> Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’.

<sup>230</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>231</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>232</sup> Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’.

<sup>233</sup> Arnold et al., ‘A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection’.

<sup>234</sup> Puro et al., ‘Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists’.

<sup>235</sup> Krakower et al., ‘HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings’.

disease” is not recommended.<sup>236</sup> Three-quarters of the literature cited toxicities as a deterrent to PrEP, particularly as the long-term side effects of PrEP are currently uncertain. The reported proportions of doctors concerned with the biomedicalisation of HIV prevention and potential long-term side effects were 41%,<sup>237</sup> 53%,<sup>238</sup> 62%,<sup>239</sup> 91%,<sup>240</sup> and >40%.<sup>241</sup> Those who do not support biomedicalised HIV prevention favour behavioural methods like condoms, serosorting, and abstinence.<sup>242</sup> 74% of physicians in Italy saw non-biomedical HIV prevention techniques as more effective, and 88% reported non-biomedical approaches as safer than PrEP.<sup>243</sup>

### Efficacy-effectiveness gap

The efficacy-effectiveness gap addresses the difference between results from the RCTs and results of the drug when it is implemented in the ‘real world.’<sup>244</sup> The poor adherence-related results of the FEM-PrEP and VOICE trials show how the efficacy-effectiveness gap can occur. Physicians from Boston hypothesised that the efficacy-effectiveness gap would decrease adherence to PrEP’s once-daily regime, as it was likely to be lower in the real-world compared to the first-generation RCTs.<sup>245</sup> If this prediction is true, the widespread application of PrEP will be unsuccessful at preventing HIV infections.

### Lack of guidelines

In mid-2014, the CDC released *Clinical Practical Guidelines for PrEP* that provide advice on the necessary medical care for patients using PrEP. Prior to these national guidelines for American doctors, the lack of guidelines was cited as a concern by the surveyed physicians.<sup>246, 247</sup> However, even after the *Guidelines* were released, 58% of American doctors saw the *Guidelines* as a major or moderate barrier to effective PrEP implementation.<sup>248</sup> The lack of clinical guidelines is not an issue solely reported by

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<sup>236</sup> Ibid.

<sup>237</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.

<sup>238</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>239</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>240</sup> Tripathi et al., ‘Preexposure Prophylaxis for HIV Infection’.

<sup>241</sup> Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’.

<sup>242</sup> Senn et al., ‘Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations’.

<sup>243</sup> Puro et al., ‘Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists’.

<sup>244</sup> Amirtha Srikanthan and Eitan Amir, ‘Efficacy-Effectiveness Gap as an Obstacle to Translating Clinical Trials to Clinical Practice’, *European Journal of Cancer* 51, no. 8 (May 2015): 905.

<sup>245</sup> Krakower et al., ‘HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings’, 26 June 2014.

<sup>246</sup> Arnold et al., ‘A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection’.

<sup>247</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>248</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.

American doctors, as physicians from Peru noted that the absence of national Peruvian clinical guidelines also deterred their implementation of PrEP.<sup>249</sup>

### Time and resources

Any new policy requires additional time and resources to ensure that it is effective, and the implementation of PrEP is no different. The application of PrEP must be carefully planned to ensure that other health programmes are not disadvantaged. Time and resources were a common concern raised by almost half of the studies focused on doctors. PrEP is a complex medication so whoever prescribes PrEP (general practitioners, sexual health doctors, and/or STI and HIV clinics) must provide additional medical support for PrEP-users. Doctors stated that this extra support could negatively impact time and resources because it may require clinics to expand their capabilities,<sup>250</sup> increase monitoring of patients,<sup>251, 252</sup> and put extra pressure on laboratories and medical facilities.<sup>253</sup> Furthermore, the CDC's *Guidelines* request counselling support for patients on PrEP, which would put additional demands on the clinics.<sup>254, 255, 256</sup>

### Social concerns

There are two social concerns identified in the literature focusing on physicians' attitudes towards PrEP. These concerns are cost, and risk compensation.

### Cost

The cost of PrEP is inaccessible for almost all potential users. As at September 2017, Truvada costs around NZ \$1000 for a 30-day supply and generic PrEP costs between NZ \$60-\$100 for a one month supply when sourced overseas.<sup>257</sup> The high cost of PrEP was mentioned in all but two of the studies regarding clinician-reported barriers to PrEP. The common theme was that the high cost of Truvada would cause inequities between who can afford this prevention method.<sup>258, 259, 260</sup> The percentages of

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<sup>249</sup> Tang et al., 'Provider Attitudes Toward Oral Preexposure Prophylaxis for HIV Prevention Among High-Risk Men Who Have Sex with Men in Lima, Peru'.

<sup>250</sup> Arnold et al., 'A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection'.

<sup>251</sup> White et al., 'Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention', July 2012.

<sup>252</sup> Senn et al., 'Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations'.

<sup>253</sup> Krakower et al., 'HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings', 26 June 2014.

<sup>254</sup> White et al., 'Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention', July 2012.

<sup>255</sup> Krakower et al., 'HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings', 26 June 2014.

<sup>256</sup> Sharma et al., 'Preparing for PrEP'.

<sup>257</sup> Joe Rich, 'Updates about PrEP in New Zealand', 22 August 2016.

<sup>258</sup> Arnold et al., 'A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection'.

<sup>259</sup> Puro et al., 'Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists'.



physicians who identified cost as an obstruction to PrEP access were 12%,<sup>261</sup> 36%,<sup>262</sup> 45%,<sup>263</sup> 57%,<sup>264</sup> 91.9%<sup>265</sup> and 96%.<sup>266</sup>

A number of studies featuring American clinicians mentioned the link between cost and insurance funding of Truvada.<sup>267, 268, 269</sup> One study reported that nearly 90% of clinicians had concerns about whether insurance companies would pay for PrEP: 26% saw it as a minor barrier, 31% a moderate barrier, and 32% a major barrier.<sup>270</sup> 48% of primary care physicians in Boston also saw a lack of insurance coverage a financial barrier to obtaining PrEP. It is important to note that the concerns regarding health insurance for PrEP are most likely about the cost of branded PrEP rather than generic PrEP. The issue of cost may no longer be so prevalent among physicians once Truvada's patent ends in 2017.

### Risk compensation

Risk compensation is the theory that individuals will engage in increased risky behaviour when they believe there is a decreased perceived risk. Risk compensation is a common issue since new HIV prevention methods such as serosorting, male circumcision, and PrEP have emerged. The “protective effective” of such prevention methods are often ‘undone’ when at-risk individuals continue to engage in alternative high-risk behaviour.<sup>271</sup> The potential for risk compensation among PrEP-users is high, as it is widely argued that once high-risk individuals start taking PrEP they may refuse to use condoms. All but one study in provider-focused literature mentioned risk compensation as a strong barrier to PrEP. Of the studies that provided figures, the percentages of doctors concerned about PrEP-related risk compensation were 22%,<sup>272</sup> 22.5%,<sup>273</sup> 24%,<sup>274</sup> 32%,<sup>275</sup> and 71%.<sup>276</sup> The only study where doctors were not

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<sup>260</sup> Krakower et al., ‘HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings’, 26 June 2014.

<sup>261</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>262</sup> Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’.

<sup>263</sup> Krakower et al., ‘Primary Care Clinicians’ Experiences Prescribing HIV Pre-Exposure Prophylaxis at a Specialized Community Health Centre in Boston’.

<sup>264</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>265</sup> Sharma et al., ‘Preparing for PrEP’.

<sup>266</sup> Tripathi et al., ‘Preexposure Prophylaxis for HIV Infection’.

<sup>267</sup> Arnold et al., ‘A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection’.

<sup>268</sup> Krakower et al., ‘HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings’, 26 June 2014.

<sup>269</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.

<sup>270</sup> Ibid.

<sup>271</sup> Michael M. Cassell et al., ‘Risk Compensation: The Achilles’ Heel of Innovations in HIV Prevention?’, *British Medical Journal* 332, no. 7541 (March 2006): 605.

<sup>272</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>273</sup> Senn et al., ‘Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations’.

<sup>274</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.



concerned about risk compensation said doctors wished to remain unbiased and non-judgemental about patients' personal lives.<sup>277</sup> Interestingly, the study that tracked physicians' attitudes before and after iPrEx found that risk compensation concerns decreased after the results were released because proof of risk compensation was not clear.<sup>278</sup> Risk compensation can be minimised through a range of techniques, such as reminders about regular adherence, risk counselling, regular meetings with clinicians, and accessible condoms.

The final section of this literature review will examine the third theme: potential PrEP-users' opinions of the medication as a biomedical HIV prevention method. This section explores the awareness of PrEP, adherence, attitudes towards, willingness to use, and patterns of use (hypothetical and 'real-world').

### **MSM and PrEP**

Even once clinical trials are completed and doctors are happy to prescribe PrEP, PrEP will not be successful without interest and engagement from target user groups, such as MSM. Given the research's focus on MSM for the PrEP health policy, the literature review only explores studies with MSM. The majority of the academic literature on the subject of PrEP focuses on MSM's self-reported willingness to use PrEP, attitudes towards PrEP, and patterns of use.

The literature on MSM and their attitudes towards PrEP features 11,475 MSM and TGW participants that took place between January 2007 and July 2015. The participants were from America, Australia, Peru, South Africa, India, Canada, Britain, Thailand, Taiwan, and China. The sampling methods included respondent-driven sampling, random sampling, convenience sampling, purposive sampling, online recruitment, targeted sampling, and venue-day-time sampling. The three research methods used in the studies were focus groups, interviews and surveys.

There were also five cross-sectional studies exploring MSM and PrEP over time, with a total of 7,926 participants. The first study took place in August-November 2008 and again in August-November 2011 in Canada.<sup>279</sup> The second cross-sectional study was part of an ongoing longitudinal cohort study on young MSM (YMSM), and data was first collected in December 2009.<sup>280</sup> The third cross-sectional survey took place between September and October 2010, and one month after the iPrEx study in January

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<sup>275</sup> Blumenthal et al., 'Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP'.

<sup>276</sup> Tripathi et al., 'Preexposure Prophylaxis for HIV Infection'.

<sup>277</sup> Arnold et al., 'A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings to Prevent HIV Infection'.

<sup>278</sup> White et al., 'Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention', July 2012.

<sup>279</sup> Alia A. Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado', *AIDS and Behavior* 18, no. 3 (4 July 2013): 340–47.

<sup>280</sup> Brian Mustanski et al., 'Perceived Likelihood of Using HIV Pre-Exposure Prophylaxis Medications Among Young Men Who Have Sex with Men', *AIDS and Behavior* 17, no. 6 (July 2013): 2173–79.

2011.<sup>281</sup> The fourth cross-sectional study took data in 2011, 2012, and 2013 from MSM who reported >9 sexual partners in the last ninety days in New York City.<sup>282</sup> The final cross-sectional study took place at the 2009-2015 Seattle Gay Pride events.<sup>283</sup>

### Awareness of PrEP

Generally, the more recent studies of MSM report higher levels of awareness about PrEP. The earliest study took place in 2007 and 19% of MSM reported some level of knowledge about PrEP.<sup>284</sup> The most recent study reported 74.5% of MSM were aware of PrEP, and data was collected between April and July 2015. Other reported proportions of MSM awareness of PrEP were 11.2%,<sup>285</sup> 18.4%,<sup>286</sup> 27.2%,<sup>287</sup> 27.6%,<sup>288</sup> 29.7%,<sup>289</sup> 31.2%,<sup>290</sup> 38%,<sup>291</sup> 62.4%,<sup>292</sup> 66%,<sup>293</sup> and 77.4%.<sup>294</sup> There were three studies that reported minimal awareness of PrEP but did not disclose percentages.<sup>295, 296, 297</sup>

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<sup>281</sup> Douglas S. Krakower et al., 'Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site', *PLoS ONE* 7, no. 3 (28 March 2012).

<sup>282</sup> Christian Grov et al., 'Willingness to Take PrEP and Potential for Risk Compensation Among Highly Sexually Active Gay and Bisexual Men', *AIDS and Behavior* 19, no. 12 (4 March 2015): 2234–44.

<sup>283</sup> Julia E. Hood et al., 'Dramatic Increase in Preexposure Prophylaxis Use among MSM in Washington State', *AIDS (London, England)* 30, no. 3 (January 2016): 515–19.

<sup>284</sup> Matthew J Mimiaga et al., 'Preexposure Antiretroviral Prophylaxis Attitudes in High-Risk Boston Area Men Who Report Having Sex With Men: Limited Knowledge and Experience but Potential for Increased Utilization After Education', *J AIDS Journal of Acquired Immune Deficiency Syndromes* 50, no. 1 (January 2009): 77–83.

<sup>285</sup> Feng Zhou et al., 'Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men', *PLoS ONE* 7, no. 3 (30 March 2012).

<sup>286</sup> Nathan J. Lachowsky et al., 'Pre-Exposure Prophylaxis Awareness Among Gay and Other Men Who Have Sex with Men in Vancouver, British Columbia, Canada', *AIDS and Behavior*, 16 February 2016, 1–15.

<sup>287</sup> J. A. Bauermeister et al., 'PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men', *Current HIV Research* 11, no. 7 (October 2014): 520–27.

<sup>288</sup> Lisa A. Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event', *Sexual Health (Online)* 11, no. 3 (2014): 244–51.

<sup>289</sup> Jamie Frankis et al., 'Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?: Understanding PrEP Awareness and Acceptability amongst Men Who Have Sex with Men in the UK – A Mixed Methods Study', *PLoS ONE* 11, no. 4 (19 April 2016): e0151385.

<sup>290</sup> Ingrid Young, Jessica Li, and Lisa McDaid, 'Awareness and Willingness to Use HIV Pre-Exposure Prophylaxis amongst Gay and Bisexual Men in Scotland: Implications for Biomedical HIV Prevention', *PLoS One* 8, no. 5 (May 2013).

<sup>291</sup> Katherine B. Rucinski et al., 'Knowledge and Use of Pre-Exposure Prophylaxis Among an Online Sample of Young Men Who Have Sex with Men in New York City', *AIDS and Behavior* 17, no. 6 (July 2013): 2180–84.

<sup>292</sup> Roland C. Merchant et al., 'Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings', *Journal of Gay & Lesbian Mental Health* 20, no. 1 (7 January 2016): 21–33.

<sup>293</sup> Daniel Yang et al., 'Acceptability of Pre-Exposure Prophylaxis among Men Who Have Sex with Men and Transgender Women in Northern Thailand', *PLoS ONE* 8, no. 10 (8 October 2013).

<sup>294</sup> William C. Goedel et al., 'HIV Risk Behaviors, Perceptions, and Testing and Preexposure Prophylaxis (PrEP) Awareness/Use in Grindr-Using Men Who Have Sex With Men in Atlanta, Georgia', *Journal of the Association of Nurses in AIDS Care* 27, no. 2 (March 2016): 133–42.

<sup>295</sup> Gabriel R. Galindo et al., 'Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy: Implications for Implementation', *Implementation Science* 7 (2012): 116.

Three of the cross-sectional studies also suggest that self-perceived awareness of PrEP between MSM is increasing. The earliest study began in 2008, where 21% of subjects reported being aware of PrEP, compared to 28% in 2011.<sup>298</sup> The study focusing on PrEP awareness pre- and post-iPrEx found an increase of knowledge of PrEP from 12.5% in 2010 to 19% in 2011.<sup>299</sup> The third study reported the proportion of MSM who knew about PrEP was 53% in 2011, 62.2% in 2012, and 72.4% in 2013.<sup>300</sup>

### ***Use of PrEP linked to awareness***

Several studies also examined the proportion of MSM who were currently using PrEP. The reported percentages of MSM using PrEP were 0.004%,<sup>301</sup> 0.5%,<sup>302</sup> 1.5%,<sup>303</sup> 2.2%,<sup>304</sup> 2.7%,<sup>305</sup> 6.8%,<sup>306</sup> and 11.9%.<sup>307</sup> Two studies reported no respondents that had used PrEP for HIV prevention.<sup>308, 309</sup> One of the cross-sectional studies reported that the number of MSM who had used PrEP increased from 5% in 2012 to 21% in 2015.<sup>310</sup> The number of surveyed MSM using PrEP is low but is generally increasing over time.

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<sup>296</sup> Kristen Underhill et al., 'Could FDA Approval of Pre-Exposure Prophylaxis Make a Difference? A Qualitative Study of PrEP Acceptability and FDA Perceptions Among Men Who Have Sex with Men', *AIDS and Behavior* 18, no. 2 (15 May 2013): 241–49.

<sup>297</sup> Katrina Kubicek, Cesar Arauz-Cuadra, and Michele D. Kipke, 'Attitudes and Perceptions of Biomedical HIV Prevention Methods: Voices from Young Men Who Have Sex with Men', *Archives of Sexual Behavior* 44, no. 2 (February 2015): 487–97.

<sup>298</sup> Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado'.

<sup>299</sup> Krakower et al., 'Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site'.

<sup>300</sup> Grov et al., 'Willingness to Take PrEP and Potential for Risk Compensation Among Highly Sexually Active Gay and Bisexual Men'.

<sup>301</sup> Mimiaga et al., 'Preexposure Antiretroviral Prophylaxis Attitudes in High-Risk Boston Area Men Who Report Having Sex With Men'.

<sup>302</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>303</sup> Rucinski et al., 'Knowledge and Use of Pre-Exposure Prophylaxis Among an Online Sample of Young Men Who Have Sex with Men in New York City'.

<sup>304</sup> Adamma Aghaizu et al., 'Who Would Use PrEP? Factors Associated with Intention to Use among MSM in London: A Community Survey', *Sexually Transmitted Infections* 89, no. 3 (May 2013): 207.

<sup>305</sup> Bauermeister et al., 'PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men'.

<sup>306</sup> Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event'.

<sup>307</sup> Goedel et al., 'HIV Risk Behaviors, Perceptions, and Testing and Preexposure Prophylaxis (PrEP) Awareness/Use in Grindr-Using Men Who Have Sex With Men in Atlanta, Georgia'.

<sup>308</sup> Underhill et al., 'Could FDA Approval of Pre-Exposure Prophylaxis Make a Difference?'

<sup>309</sup> Lachowsky et al., 'Pre-Exposure Prophylaxis Awareness Among Gay and Other Men Who Have Sex with Men in Vancouver, British Columbia, Canada'.

<sup>310</sup> Hood et al., 'Dramatic Increase in Preexposure Prophylaxis Use among MSM in Washington State'.

### Willingness to use PrEP

Willingness to use PrEP is discussed in the majority of this literature. The reported figures of MSM willing to adopt PrEP was 28.2%,<sup>311</sup> 46.1%,<sup>312</sup> 47.8%,<sup>313</sup> 50%,<sup>314</sup> 50.2%,<sup>315</sup> 51%,<sup>316</sup> 54.3%,<sup>317</sup> 55.4%,<sup>318</sup> 56%,<sup>319</sup> 56.7%,<sup>320</sup> 60.3%,<sup>321</sup> 67.8%,<sup>322</sup> 74%,<sup>323</sup> 76%,<sup>324</sup> and 86.6%.<sup>325</sup> Four studies measured the interest in PrEP in a different way. Firstly, one study compared the proportion of MSM willing to use PrEP in Peru, India and South Africa. Only 45% of MSM in Peru were interested in PrEP, compared to 92% of MSM in India and 70% in South Africa.<sup>326</sup> A second study found that 41% of MSM were willing to use PrEP compared to 37% of TGW.<sup>327</sup> A third study did not use quantitative research methods but stated that the majority of the MSM in the focus groups were willing to use PrEP.<sup>328</sup> One cross-sectional study found that before the iPrEx trial, 76.1% of MSM were interested in PrEP, compared to 78.5% of MSM after the trial results were released.<sup>329</sup> Interestingly, the number of MSM willing to use PrEP

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<sup>311</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>312</sup> Grov et al., 'Willingness to Take PrEP and Potential for Risk Compensation Among Highly Sexually Active Gay and Bisexual Men'.

<sup>313</sup> Frankis et al., 'Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?'

<sup>314</sup> Aghaizu et al., 'Who Would Use PrEP?'

<sup>315</sup> Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado'.

<sup>316</sup> Eric William Hall et al., 'Preexposure Prophylaxis Modality Preferences Among Men Who Have Sex With Men and Use Social Media in the United States', *Journal of Medical Internet Research* 18, no. 5 (19 May 2016): e111 p.1-10.

<sup>317</sup> Young, Li, and McDaid, 'Awareness and Willingness to Use HIV Pre-Exposure Prophylaxis amongst Gay and Bisexual Men in Scotland'.

<sup>318</sup> Sarit A. Golub et al., 'From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence Among MSM and Transgender Women in New York City', *AIDS Patient Care & STDs* 27, no. 4 (April 2013): 248–54.

<sup>319</sup> Nai-Ying Ko et al., 'Willingness to Self-Pay for Pre-Exposure Prophylaxis in Men Who Have Sex With Men: A National Online Survey in Taiwan', *AIDS Education & Prevention* 28, no. 2 (April 2016): 128–137 10p.

<sup>320</sup> Kristi E. Gamarel and Sarit A. Golub, 'Intimacy Motivations and Pre-Exposure Prophylaxis (PrEP) Adoption Intentions Among HIV-Negative Men Who Have Sex with Men (MSM) in Romantic Relationships', *Annals of Behavioral Medicine* 49, no. 2 (April 2015): 177–86.

<sup>321</sup> Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event'.

<sup>322</sup> Zhou et al., 'Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men'.

<sup>323</sup> Mimiaga et al., 'Preexposure Antiretroviral Prophylaxis Attitudes in High-Risk Boston Area Men Who Report Having Sex With Men'.

<sup>324</sup> Galindo et al., 'Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy'.

<sup>325</sup> Ana Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention? An Analysis of Attitudes, Preferences and Acceptance', *PLoS One* 8, no. 1 (January 2013).

<sup>326</sup> Andreas B. Eisingerich et al., 'Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups: A Multinational Study', *PLoS ONE* 7, no. 1 (11 January 2012).

<sup>327</sup> Yang et al., 'Acceptability of Pre-Exposure Prophylaxis among Men Who Have Sex with Men and Transgender Women in Northern Thailand'.

<sup>328</sup> Underhill et al., 'Could FDA Approval of Pre-Exposure Prophylaxis Make a Difference?'

<sup>329</sup> Krakower et al., 'Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site'.

in one study dropped considerably when participants had to pay for their PrEP prescription. 56% of MSM were interested in PrEP initially but this proportion dropped to 23% when MSM had to pay \$340 for PrEP themselves.<sup>330</sup> It was not explained whether the payment was monthly or annually.

### PrEP barriers and concerns

The following section explores the concerns that MSM reported when discussing PrEP as an HIV prevention method. The final portion of this literature review is split into four key identified barriers to PrEP use: health concerns, personal concerns, behavioural concerns, and concerns that are out of the control of MSM. It will become clear that the MSM share many of the same concerns as physicians.

#### **Health concerns**

Health concerns are specific issues that MSM have identified regarding PrEP's impact on their health and wellbeing. There are three main concerns: side effects, efficacy, and antiretroviral resistance. All of these barriers have been discussed in the previous two sections of the literature review.

#### Side effects

As mentioned, most side effects reported in the six RCTs were mild and lasted around one month. The proportions of MSM with concerns about potential side effects were 18.8%,<sup>331</sup> 36.4%,<sup>332</sup> 57.1%,<sup>333</sup> and 69%.<sup>334</sup> Figures from one cross-sectional study found that 33% of MSM were not willing to use PrEP because of side effects in 2008. This figure rose to 37% in 2011.<sup>335</sup> It is essential to note that some studies mentioned what side effects have been linked to PrEP whereas others did not go into such detail. This disparity could have impacted the proportion of MSM who reported concerns about PrEP's side effects. Three qualitative studies analysed how MSM viewed PrEP's side effects. The first study reported that side effects played a role in the MSM's willingness to use PrEP because if side effects were mild or lessened over a period of time, MSM were more likely to consider adopting PrEP.<sup>336</sup> However a select few MSM from the same sample were less deterred by potential side effects, arguing that "there's gonna be side effects to everything, no matter what you do." The second study stated that side effects were a frequently mentioned barrier to PrEP uptake, as a

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<sup>330</sup> Ko et al., 'Willingness to Self-Pay for Pre-Exposure Prophylaxis in Men Who Have Sex With Men'.

<sup>331</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>332</sup> Bauermeister et al., 'PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men'.

<sup>333</sup> Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event'.

<sup>334</sup> Golub et al., 'From Efficacy to Effectiveness'.

<sup>335</sup> Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado', S343.

<sup>336</sup> Galindo et al., 'Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy'.

number of MSM argued that every drug had associated side effects.<sup>337</sup> A third study reported that a large majority of MSM cited vomiting, dizziness, and a change in skin colour induced by PrEP as concerning.<sup>338</sup>

Two studies presented data regarding side effects and MSM categorised by their ethnicity. One study found that Indian MSM were considerably less deterred by potential side effects of PrEP compared to MSM from Peru and South Africa.<sup>339</sup> A second study found that African-American and Latino YMSM were more likely to be deterred by the side effects of PrEP than white YMSM.<sup>340</sup>

### *Long-term effects*

As discussed, the long-term effects of PrEP are generally unknown at this stage so it is unsurprising that this was a concern for MSM. There was only one study that reported figures linked to long-term effects of PrEP quantitatively. This study found that 78.3% of MSM were worried about the long-term health effects of PrEP.<sup>341</sup> This was also the top ranked barrier to PrEP use in this study (the second ranked barrier was concerns about side effects). There were two qualitative studies that discussed long-term side effects with MSM. The first study found that MSM were less willing to consider using PrEP if the side effects were severe or did not fade over time.<sup>342</sup> Furthermore, these MSM saw PrEP-induced “long-term damage to kidneys, sexual dysfunction... and ‘serious bone damage’” as definite reasons to avoid PrEP.<sup>343</sup> A second study reported that MSM were concerned about the lack of information available about long-term side effects of PrEP, especially the impact on sperm count.<sup>344</sup>

### *Impact on lifestyle*

A number of studies revealed that MSM were uncertain about using PrEP if the side effects could negatively impact their lifestyle. One study cited concerns about complications of PrEP with existing health conditions, such as diabetes.<sup>345</sup> A second study reported that MSM believe there is always a ‘down’ when taking medicine and PrEP would be no different, so it was highly likely to negatively impact their

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<sup>337</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’.

<sup>338</sup> Kubicek, Arauz-Cuadra, and Kipke, ‘Attitudes and Perceptions of Biomedical HIV Prevention Methods’.

<sup>339</sup> Eisingerich et al., ‘Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups’.

<sup>340</sup> Bauermeister et al., ‘PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men’.

<sup>341</sup> Golub et al., ‘From Efficacy to Effectiveness’.

<sup>342</sup> Galindo et al., ‘Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy’.

<sup>343</sup> Ibid., 7.

<sup>344</sup> Kubicek, Arauz-Cuadra, and Kipke, ‘Attitudes and Perceptions of Biomedical HIV Prevention Methods’.

<sup>345</sup> Galindo et al., ‘Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy’.



lifestyle.<sup>346</sup> Furthermore, the same respondents were also deterred by the potential of additional side effects if PrEP was taken with alcohol or drugs. The final study stated that 63.8% of MSM surveyed were worried that they would not be able to work due to the side effects from PrEP, and 44.7% were concerned that PrEP would have a negative impact on their diet and sleep.<sup>347</sup>

### Efficacy and adherence

The level of PrEP's efficacy for preventing HIV transmission was cited by multiple studies of MSM as a concern. As stated previously, the more consistently PrEP is taken, the higher the level of protection it offers the user. The general trend from the studies was that the lower the predicted efficacy of PrEP, the less likely MSM are to consider using PrEP.<sup>348, 349, 350</sup> 44.1% of MSM in Beijing were worried that PrEP was not effective at preventing HIV,<sup>351</sup> 62.5% of MSM and TGW in New York City were concerned that PrEP was not 100% effective,<sup>352</sup> and 55.6% of Taiwanese MSM were not willing to use PrEP if it was not 100% effective.<sup>353</sup> One cross-sectional study measured the percentage of MSM who were not willing to use PrEP at 50% and 75% efficacy in 2008 and 2011.<sup>354</sup> As with other studies, MSM were less likely to use PrEP as the level of efficacy decreased. 40% of MSM were unwilling to use PrEP at 75% efficacy in 2008, compared to 44% of MSM in 2011. However, when PrEP was only 50% effective, 55% and 56% of MSM were unwilling to use PrEP in 2008 and in 2011, respectively.

All potential PrEP-users should be provided with accurate information about the link between PrEP's efficacy and adherence. Many ongoing or planned demonstration studies focus on more complex factors, such as "adherence education and/or counselling" using community-focused campaigns and technology approaches, such as text reminders to take PrEP.<sup>355</sup> The general consensus between academia and health policy is that PrEP adherence is a multifaceted issue that requires more than just one or two key interventions. To successfully help high-risk individuals take PrEP

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<sup>346</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>347</sup> Zhou et al., 'Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men'.

<sup>348</sup> Galindo et al., 'Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy'.

<sup>349</sup> Mustanski et al., 'Perceived Likelihood of Using HIV Pre-Exposure Prophylaxis Medications Among Young Men Who Have Sex with Men'.

<sup>350</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>351</sup> Zhou et al., 'Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men'.

<sup>352</sup> Golub et al., 'From Efficacy to Effectiveness'.

<sup>353</sup> Ko et al., 'Willingness to Self-Pay for Pre-Exposure Prophylaxis in Men Who Have Sex With Men'.

<sup>354</sup> Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado'.

<sup>355</sup> K. Rivet Amico and Michael J. Stirratt, 'Adherence to Preexposure Prophylaxis: Current, Emerging, and Anticipated Bases of Evidence', *Clinical Infectious Diseases* 59, no. suppl 1 (1 July 2014): S58.

regularly, policies must consider “social, psychological, cultural, and structural factors” that encourage adherence.<sup>356</sup>

### Antiretroviral resistance

Only two studies of MSM discussed antiretroviral resistance. 21.7% of MSM in Beijing<sup>357</sup> and 64.7% of MSM from New York City<sup>358</sup> expressed anxiety about antiretroviral resistance from PrEP. It is interesting to compare the emphasis that physicians and MSM put on antiretroviral resistance. Overall, physicians were much more likely to be concerned about antiretroviral resistance when taking PrEP than MSM. However, this seems unsurprising given it is the doctors’ jobs to ensure they are aware of PrEP’s clinical risks.

### Personal barriers

The second barrier to PrEP identified by MSM are personal concerns, which are how MSM perceive using PrEP in relation to themselves. The three concerns are embarrassment, self-perceived HIV risk, and a lack of interest in PrEP.

### Embarrassment about PrEP

Given the politically turbulent history of HIV, it is not surprising that some MSM are anxious about a new prevention technique. However, the proportion of MSM who reported feeling embarrassed about using PrEP appears to be relatively low. One study found that fewer than 25% of all MSM surveyed in India, Peru, and South Africa reported using PrEP as ‘fairly’ or ‘very embarrassing.’<sup>359</sup> While a study of MSM in Thailand found that only 8.5% saw PrEP as ‘fairly’ or ‘very embarrassing,’ 38.1% were ‘fairly’ or ‘very anxious’ to use PrEP.<sup>360</sup> One qualitative study of MSM found that an undisclosed number of MSM would not use PrEP because there was a potential to feel embarrassed.<sup>361</sup> These MSM may have been concerned with outsiders who judge PrEP-users and make assumptions that the MSM engaged in high-risk activities. It is likely that the small portion of MSM that felt embarrassed or anxious to use PrEP are concerned with PrEP-associated stigmatisation, which will be discussed later.

### Self-perceived HIV risk

Health professionals give patients a risk-level regarding a certain illness, and individuals now also label themselves, which is known as self-perceived risk. The literature shows when MSM deem their self-perceived risk of HIV to be low, they are

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<sup>356</sup> Amico 2012, cited in Bridget G Haire, ‘Preexposure Prophylaxis-Related Stigma: Strategies to Improve Uptake and Adherence – a Narrative Review’, *HIV/AIDS (Auckland, N.Z.)* 7 (13 October 2015): 242.

<sup>357</sup> Zhou et al., ‘Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men’.

<sup>358</sup> Golub et al., ‘From Efficacy to Effectiveness’.

<sup>359</sup> Eisingerich et al., ‘Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups’.

<sup>360</sup> Wheelock et al., ‘Are Thai MSM Willing to Take PrEP for HIV Prevention?’

<sup>361</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’.



far less likely to consider using PrEP. The literature cites two main reasons for low self-perceived HIV risk, stating that the MSM may not engage in risky behaviour as they practice safe sex, or have limited and/or regular sexual partners.<sup>362, 363, 364</sup> One study found that of the MSM who were uncertain about using PrEP, 58% considered themselves low-risk of HIV acquisition.<sup>365</sup> Of the Australian MSM who were unlikely to use PrEP, 98.4% claimed to have a low self-perceived risk of HIV.<sup>366</sup> Similarly, a study of MSM in Canada found that 85.3% claimed it was 'very unlikely' that they would contract HIV, despite 27.7% stating they do not always use condoms when having sex.<sup>367</sup> There may be a relationship between low self-perceived HIV risk and the willingness of MSM to use PrEP but this will not be explored further in this research.

### Lack of interest

Two studies mentioned the proportion of MSM who were not interested in using PrEP. One Australian study found that the majority of MSM were not interested in using PrEP.<sup>368</sup> A study of MSM from Rhode Island found that 10.7% were not interested in PrEP at all (compared to 89.3% who ranged between 'a little interested' and 'very interested' in PrEP).<sup>369</sup> Furthermore, 8.4% of these MSM also ranked 'not enough interest' as the main barrier to learning more about PrEP. Not being interested in PrEP is obviously why some MSM are not engaging with this new HIV prevention technique. The next section will discuss some of the behavioural concerns linked to PrEP.

### **Behavioural barriers**

The third section of barriers to PrEP use is behavioural concerns. These concerns are linked to behaviour, which can be reduced depending on how MSM act. This section discusses risk compensation, and a lack of information.

### Risk compensation

As discussed in the previous section, risk compensation is a common concern associated with PrEP because it can reduce the drug's efficacy and encourage the spread of HIV and STIs. However, some studies have shown that MSM are willing to

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<sup>362</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>363</sup> Young, Li, and McDaid, 'Awareness and Willingness to Use HIV Pre-Exposure Prophylaxis amongst Gay and Bisexual Men in Scotland'.

<sup>364</sup> Merchant et al., 'Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings'.

<sup>365</sup> Young, Li, and McDaid, 'Awareness and Willingness to Use HIV Pre-Exposure Prophylaxis amongst Gay and Bisexual Men in Scotland'.

<sup>366</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>367</sup> Lachowsky et al., 'Pre-Exposure Prophylaxis Awareness Among Gay and Other Men Who Have Sex with Men in Vancouver, British Columbia, Canada'.

<sup>368</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>369</sup> Merchant et al., 'Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings'.

admit that their condom use may decline when using PrEP. The proportions of MSM who hypothesised less frequent condom use were 8%,<sup>370</sup> 23.1%,<sup>371</sup> and 44.6%.<sup>372</sup> One study found that 41.1% of MSM were not likely to use condoms with PrEP, however this figure dropped to 26.3% when the MSM who were not willing to pay for their own prescription were removed.<sup>373</sup> 10.4% of Thai MSM were not willing to take PrEP if it meant having to use condoms at the same time,<sup>374</sup> compared to 43.7% of MSM from America.<sup>375</sup> Risk compensation was also discussed in the qualitative research studies. A small proportion of MSM from two focus groups states that predicted risk compensation was a reason not to take PrEP, as they would be less likely to use condoms.<sup>376, 377</sup> Only one cross-sectional study compared anticipated condom use when taking PrEP in 2008 and in 2011. This study found that 10% of MSM anticipated less frequent condom use when using PrEP in 2008, compared to 11% in 2011.<sup>378</sup>

### Lack of information

A lack of information about PrEP is considered a barrier for some MSM. 23.6% of MSM from Rhode Island said that not knowing where to find information about PrEP was a major barrier to their uptake of the prevention method.<sup>379</sup> Furthermore, 23% of these MSM cited a lack of time to search for the necessary information about PrEP. Similarly, a portion of MSM in California were concerned that PrEP may be more effective for some people compared to others and thought that the efficacy could decline over time.<sup>380</sup> A number of American MSM brought up the efficacy-effectiveness gap, stating that the promise of 100% efficacy is not translated to total protection against HIV transmission.<sup>381</sup> These concerns about PrEP's efficacy show there is an absence of necessary information about PrEP, which is a barrier to uptake.

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<sup>370</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>371</sup> Grov et al., 'Willingness to Take PrEP and Potential for Risk Compensation Among Highly Sexually Active Gay and Bisexual Men'.

<sup>372</sup> Golub et al., 'From Efficacy to Effectiveness'.

<sup>373</sup> Ko et al., 'Willingness to Self-Pay for Pre-Exposure Prophylaxis in Men Who Have Sex With Men'.

<sup>374</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>375</sup> Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event'.

<sup>376</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>377</sup> Kubicek, Arauz-Cuadra, and Kipke, 'Attitudes and Perceptions of Biomedical HIV Prevention Methods'.

<sup>378</sup> Al-Tayyib et al., 'Knowledge of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men in Denver, Colorado'.

<sup>379</sup> Merchant et al., 'Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings'.

<sup>380</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>381</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

### ***Concerns out of the patients' control***

The final section of concerns collates together the issues that are out the control of MSM. These examples are barriers to PrEP uptake that MSM cannot solely minimise or remove. There are three key concerns in this section: cost, stigmatisation and labels, and negative impact on personal relationships.

#### **Cost**

As previously mentioned, until Truvada's patent ends, it is almost certain that the price of branded PrEP will continue to exclude the majority of MSM from accessing the drug.<sup>382, 383</sup> The general trend shows that PrEP would be more popular if it was cheaper because the cost is a deterrent,<sup>384, 385</sup> and the higher the cost of PrEP, fewer MSM will be able to afford the drug.<sup>386</sup> The percentages of MSM who were concerned about the cost of PrEP or could not afford to pay for it were 11.8%,<sup>387</sup> 23.6%,<sup>388</sup> 61.2%,<sup>389</sup> and 77%.<sup>390</sup> The majority of MSM were happy to pay around \$20-\$25 per month in their local currency for a prescription of PrEP.<sup>391, 392, 393, 394</sup> One study found that MSM from Peru and South Africa were less likely to be willing to pay for PrEP compared to MSM from India.<sup>395</sup> Given the results of this literature, it can be assumed that if the price of PrEP drops to an 'acceptable level' (whatever this may be), fewer MSM would find cost a barrier. Unfortunately this barrier is out of the control of PrEP-users.

#### **Stigmatisation and labels**

Four studies explored the stigmatisation and labels associated with MSM who use PrEP. A study of MSM in New York City found that 28.8% had concerns that others will

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<sup>382</sup> Mark Fisher, Interview with Mark Fisher, Director of Body Positive, interview by Alice Hartley, Skype, 20 September 2016.

<sup>383</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic, interview by Alice Hartley, Face-to-face, 23 September 2016.

<sup>384</sup> Mimiaga et al., 'Preexposure Antiretroviral Prophylaxis Attitudes in High-Risk Boston Area Men Who Report Having Sex With Men'.

<sup>385</sup> Underhill et al., 'Could FDA Approval of Pre-Exposure Prophylaxis Make a Difference?'

<sup>386</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>387</sup> Merchant et al., 'Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings'.

<sup>388</sup> Zhou et al., 'Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men'.

<sup>389</sup> Bauermeister et al., 'PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men'.

<sup>390</sup> Ko et al., 'Willingness to Self-Pay for Pre-Exposure Prophylaxis in Men Who Have Sex With Men'.

<sup>391</sup> Galindo et al., 'Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy'.

<sup>392</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>393</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>394</sup> Kubicek, Arauz-Cuadra, and Kipke, 'Attitudes and Perceptions of Biomedical HIV Prevention Methods'.

<sup>395</sup> Eisingerich et al., 'Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups'.

see them taking PrEP and incorrectly assume that they are HIV-positive.<sup>396</sup> One African-American MSM argued that PrEP will “put a irrelevant stigma on you... But if people are ignorant, they’ll be like, ‘ooo, you’re taking [PrEP]. Oh, you must got [HIV]” (sic).<sup>397</sup> Similarly, 20.1% of Chinese MSM were worried that taking PrEP would cause people to treat them like they had AIDS.<sup>398</sup> Two qualitative studies discussed the labels that would be attached to PrEP-users. Both studies stated that outsiders might assume MSM want to engage in risky behaviour regularly, particularly when HIV stigma is prominent in their community.<sup>399, 400</sup> Unfortunately stigmatisation and labels are out of the control of MSM who use PrEP, but it is easy to see why they may stop MSM from accessing PrEP.

### Negative impact on personal relationships

The final concern is the negative impact that PrEP could have on personal relationships. One study found that 34.2% of MSM and TGW in New York City were concerned that using PrEP would cause their sexual partners to expect them to not use condoms for sex.<sup>401</sup> This pressure to engage in condomless sex could negatively impact their personal relationships. The second study found that 14.5% of Chinese MSM from Beijing were worried that future sexual partners would refuse to have sex with them if they used PrEP.<sup>402</sup> It is interesting to note that 24.6% of MSM from Thailand would not want their partner to know that they are taking PrEP, which could be due to a potential negative impact on the relationship. How potential partners perceive and react to PrEP is out of the control of the MSM who use the drug, but could easily have a negative impact on personal relationships.

## Conclusion

The purpose of this literature review was to explore the current complexities of PrEP as a HIV prevention technique. The first section of the literature review looked at the basics of the six first-generation PrEP RCTs: iPrEx, Partners PrEP, TDF2, VOICE, FEM-PrEP, and the Bangkok Tenofovir Study. This section was crucial because without these six RCTs, PrEP would not be an approved option for HIV prevention. The level of unadjusted-efficacy of PrEP varied hugely from -49.0% to 75.0%, and thus, four of the six studies found that PrEP was effective at preventing HIV transmission. The percentage of HIV infections that occurred throughout the trials ranged between 0.017% and 0.04%.

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<sup>396</sup> Golub et al., ‘From Efficacy to Effectiveness’.

<sup>397</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’, 416.

<sup>398</sup> Zhou et al., ‘Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men’.

<sup>399</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’.

<sup>400</sup> Kubicek, Arauz-Cuadra, and Kipke, ‘Attitudes and Perceptions of Biomedical HIV Prevention Methods’.

<sup>401</sup> Golub et al., ‘From Efficacy to Effectiveness’.

<sup>402</sup> Zhou et al., ‘Willingness to Accept HIV Pre-Exposure Prophylaxis among Chinese Men Who Have Sex with Men’.

The second section of the literature review focused on the physicians and their attitudes towards PrEP. This section was important because without doctors prescribing PrEP, MSM cannot access this new technology. It is crucial that the concerns doctors have with PrEP are explored so they can be minimised and managed to make future PrEP implementation as successful as possible. There were more than 2,000 doctors and medical specialists involved in these studies. This review grouped concerns into two categories: provider concerns, and social concerns. The provider concerns were antiretroviral resistance, adherence, biomedical prevention, efficacy-effectiveness gap, lack of guidelines, and time and resources. The social concerns were the cost of PrEP, and potential risk compensation.

The final section explored how MSM perceived PrEP. This section was essential because if PrEP is going to be a successful HIV prevention method, it is necessary to have a good understanding of MSM's attitudes towards PrEP. There were more than 19,000 MSM and TGW used in a mixture of studies. The literature focused on awareness and willingness to use PrEP for HIV prevention, and barriers associated with the drug. The issues with PrEP were grouped into four categories: health concerns, personal concerns, behavioural concerns, and concerns out of the patients' control. Health concerns include side effects, efficacy and adherence, and antiretroviral resistance. The personal issues highlighted by MSM were embarrassment about PrEP, self-perceived HIV risk, and lack of interest. The behavioural concerns were risk compensation, and a lack of information. The concerns that are out of MSM's control were cost, stigmatisation and labels, and a negative impact on personal relationships.

### The gap in the literature

As at September 2017, there have been no studies published about PrEP as an HIV prevention method in New Zealand or using New Zealand MSM. This wide gap in the literature provides the motivation for this research into MSM in Canterbury to gain a better understanding of what potential users think of PrEP. However, the gap for this research is further reinforced using the concept of optimisation, which is the attempt to create the best possible future using biomedical means.<sup>403</sup> Optimisation is put into practice when we use

Empirical social science research to better understand how users/consumers/patients and providers/scientists/producers engage new technologies so that policies and procedures for their use might be improved to better and more equitably meet people's needs and desires – as individuals, health social movement activists, and biological citizens.<sup>404</sup>

Optimisation is generally used when discussing human enhancement technologies, however, it can also be discussed when examining PrEP. PrEP prevents the occurrence of an HIV infection occurring, so individuals use the prophylactic drug to secure the

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<sup>403</sup> Nikolas Rose, *Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century* (Princeton: Princeton University Press, 2007), 7.

<sup>404</sup> Clarke et al., 'Biomedicalization: A Theoretical and Substantive Introduction', 23.

best possible potential future: an HIV-negative future. New Zealand MSM and other potential PrEP consumers are currently unable to use PrEP for HIV prevention because there is a limited framework in place for its use. Thus, the goal for this research is to produce a policy option for the implementation of PrEP for HIV prevention following Carol H. Weiss's problem-solving model. As mentioned previously, there are multiple key consumer groups for PrEP, but this research will only focus on MSM. The rationale behind this choice and the overall research design will be explained in greater depth in the next chapter, Methodology.



## Chapter 3: Methodology

*Do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties faced overseas?*

This chapter provides an in-depth discussion of the methodology used throughout this thesis. It reviews important factors such as research design, data processing and analysis, ethical considerations, and validity.

### Research design

This thesis develops a pilot health policy for the implementation of PrEP for men who have sex with men (MSM) in New Zealand to reduce the incidence of HIV infections. As previously mentioned, PrEP can reduce HIV infections by over 92% when taken consistently and combined with additional prevention methods.<sup>405, 406, 407, 408</sup> However, PrEP uptake has been slow worldwide, and Chapter 2 discussed concerns patients and providers have with PrEP. This thesis explores the opinions and attitudes regarding PrEP to gain an understanding of community reactions to the drug. The thesis research questions are: Do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties faced overseas? There were two key research aims that will help answer the research questions:

1. Uncover and analyse the attitudes of MSM towards PrEP and HIV in the Canterbury region, and
2. Gain a greater understanding of current HIV trends in New Zealand.

The plan to answer the research questions is discussed throughout this chapter, which explains the research design and methods chosen.

In order to achieve the research aims, the thesis follows the problem-solving model, as originated by Carol H. Weiss. This model uses a combination of “evidence and conclusions” to find solutions to a particular policy problem that currently exists.<sup>409, 410</sup> Weiss's problem-solving model states that the problem “drives the

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<sup>405</sup> Robert M. Grant et al., 'Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men', *The New England Journal of Medicine* 363, no. 27 (30 December 2010): 2587–99.

<sup>406</sup> James Wilton, 'Moving PrEP into Practice: An Update on Research and Implementation', *CATIE: Canada's Source for HIV and Hepatitis C Information*, 2014, <http://www.catie.ca/en/pif/spring-2014/moving-prep-practice-update-research-and-implementation>.

<sup>407</sup> Centers for Disease Control and Prevention, 'HIV/AIDS: HIV Basics: PrEP', *Centers for Disease Control and Prevention*, 25 June 2015, <http://www.cdc.gov/hiv/basics/prep.html>.

<sup>408</sup> Dawn K. Smith et al., 'Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition - United States, 2015', *Morbidity and Mortality Weekly Report (USA: Centers for Disease Control and Prevention, 27 November 2015)*, 1291, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s\\_cid=mm6446a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s_cid=mm6446a5_w).

<sup>409</sup> Carol H. Weiss, 'The Many Meanings of Research Utilization', *Public Administration Review* 39, no. 5 (1979): 427.

<sup>410</sup> Carol H. Weiss, 'The Many Meanings of Research Utilization', in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 445.

application of research,” and high-quality research is required to fill the gaps in the knowledge.<sup>411, 412</sup> The type of research conducted does not matter so long as it reduces the uncertainty regarding the problem and provides clear policy options.<sup>413, 414</sup> In this case, the policy problem is the successful implementation of PrEP, taking into consideration the uncertainties linked to the complexities of the drug and that no PrEP-focused studies have been undertaken in New Zealand prior to this research. (However, in the course of this research, the researcher was made aware that the Ministry of Health (MOH) is currently developing a policy for PrEP in New Zealand. The researcher has limited information about the scope of MOH’s policy, but this research may be able to contribute to the MOH’s policy.) Therefore, this thesis follows the problem-solving method by using multiple research methods to reduce uncertainty regarding PrEP, allowing for the development a successful PrEP policy designed for MSM in New Zealand. This research consists of one quantitative method and two qualitative methods. The quantitative method is an attitude scaling survey, and the qualitative methods are interviews, and document analysis. Qualitative methods provide a rich<sup>415</sup> context to a policy problem, while quantitative methods fill in the contextual blanks that occur in qualitative research.<sup>416</sup> Subsequently, mixed-methods research design produces arguably better quality<sup>417</sup> and more targeted results. Furthermore, using multiple methods gives the researcher a sense of confidence: if one method falls short or does not produce adequate results, there are additional methods that can still fulfil the research aims.

The mixed-methods are discussed in more detail below but Table 1 briefly shows which method is used to achieve each research aim.

**Table 1: Research aims and methods**

Research aim	Research method	Method type
Uncover and analyse the attitudes of MSM towards PrEP and HIV in the Canterbury region	Survey (Document analysis)	Quantitative
Gain a greater understanding of current HIV trends in New Zealand	Interviews (Document analysis)	Qualitative

It is important to note that the survey and interviews fulfil a different research aim of the thesis, while the document analysis provides additional contextual and

<sup>411</sup> Weiss, ‘The Many Meanings of Research Utilization’, 1979, 427.

<sup>412</sup> Weiss, ‘The Many Meanings of Research Utilization’, 2004, 445.

<sup>413</sup> Weiss, ‘The Many Meanings of Research Utilization’, 1979, 427.

<sup>414</sup> Weiss, ‘The Many Meanings of Research Utilization’, 2004, 445.

<sup>415</sup> Steven M. Albert, Jessica G. Burke, and Jeanette Trauth, ‘Community Health Research in the 21st Century’, in *Methods for Community Health Public Research: Integrated and Engaged Approaches*, by Steven M. Albert and Jessica G. Burke, 1st ed. (New York: Springer Publishing Company, 2014), 8.

<sup>416</sup> Alan Bryman, ‘Quantitative and Qualitative Research: Further Reflections on Their Integration’, in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 507.

<sup>417</sup> Darrell P. Wheeler, ‘Methodological Issues in Conducting Community-Based Health and Social Services Research among Urban Black and African American LGBT Populations’, in *Research Methods with Gay, Lesbian, Bisexual, and Transgender Populations*, ed. William Meezan and James I. Martin (Binghamton, NY: Harrington Park Press, 2003), 74.



background knowledge of the policy issue. A focus group was planned for late May 2017, with a mixture of survey and interview participants from around Christchurch. Unfortunately the focus group was cancelled due to low participation levels.

### Online survey

#### **Sampling, administration method, and participants**

The quantitative method for this research was a self-administered, online, anonymous survey of MSM. LGBTI- and minority-focused research cannot use probability sampling methods, as it is highly unlikely that a random sample of the population will produce enough LGBTI participants. As a result, this research used non-probability sampling methods to gain enough participants.<sup>418</sup> Non-probability sampling methods are a collection of “sampling technique[s] for which the probability of a person being selected into the sample is unknown.”<sup>419</sup> The biases of non-probability sampling are well-known and will be discussed in further detail in the Ethical Considerations section, but it is important to recognise that non-probability sampling methods provide a good option when there is no requirement to assess the particular population prevalence of a variable.<sup>420</sup> Participants for the online survey were targeted using purposive sampling where subjects are carefully selected based on characteristics that are of interest to the researcher.<sup>421, 422, 423, 424</sup> Participants for this survey were targeted based on their self-identification as MSM and their potential to have an opinion about PrEP for HIV prevention. The survey was voluntary so if potential subjects did not identify as MSM they did not have to participate.

The survey was hosted on Qualtrics using the University of Canterbury’s license. The decision to post the survey online was based on three key factors. Firstly, an online survey makes it easier to ensure that the participants remain anonymous and their associated answers cannot be identified<sup>425</sup> compared to paper surveys that participants complete in front of the researcher. This guarantee of anonymity is more important when conducting surveys on sexual behaviour compared to less sensitive

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<sup>418</sup> Greenwood 1999, cited in Gerard Sullivan and Warren Losberg, ‘A Study of Sampling in Research in the Field of Lesbian and Gay Studies’, in *Research Methods with Gay, Lesbian, Bisexual, and Transgender Populations*, ed. William Meezan and James I. Martin (Binghamton, NY: Harrington Park Press, 2003), 149.

<sup>419</sup> Ilan H. Meyer and Patrick A. Wilson, ‘Sampling Lesbian, Gay, and Bisexual Populations’, *Journal of Counseling Psychology*, Advances in Research With Sexual Minority People, 56, no. 1 (January 2009): 25.

<sup>420</sup> Ibid.

<sup>421</sup> N. Mays and C. Pope, ‘Rigour and Qualitative Research.’, *BMJ : British Medical Journal* 311, no. 6997 (8 July 1995): 110.

<sup>422</sup> David R. Thomas and Ian D. Hodges, *Designing and Managing Your Research Project: Core Skills for Social and Health Research* (Los Angeles, USA: SAGE Publications, Inc, 2010), 19.

<sup>423</sup> Erin E. Donovan, Laura E. Miller, and Goldsmith, “‘Tell Me about a Time When...’: Studying Health Communication through in-Depth Interviews’, in *Research Methods in Health Communication: Principles and Application*, ed. Bryan B. Whaley (New York, NY: Routledge, 2014), 26.

<sup>424</sup> Susan E. Morgan and Nick Carcioppolo, ‘Survey Research Methodology in Health Communication’, in *Research Methods in Health Communication: Principles and Application*, ed. Bryan B. Whaley (New York, NY: Routledge, 2014), 81.

<sup>425</sup> Ellen D. B. Riggle, Sharon S. Rostosky, and C. Stuart Reedy, ‘Online Surveys for BGLT Research’, *Journal of Homosexuality* 49, no. 2 (9 August 2005): 15.

topics.<sup>426</sup> Secondly, HIV behavioural researchers claim that MSM are frequent users of the Internet for social and dating purposes, which contributes to their large online community.<sup>427</sup> Finally, online surveys are less time-consuming for researchers than alternatives like venue-based sampling and require limited data entry once the survey closes.

The University of Canterbury Human Ethics Committee (HEC), a lecturer in the Political Science department, and a member of QCanterbury (the LGBTI club at the University of Canterbury) checked the survey prior to its release. The survey link was posted in four Facebook groups/pages, and sent through one email list. The researcher approached other LGBTI groups but did not receive any replies so the survey link was not sent to them. Administrators or executive members of the groups/pages confirmed the advertisement of the survey before it was posted online (see Appendix 2). The survey was promoted using open access so participants did not need to contact the researcher to get a link for the study, which is useful for promoting a “sense of anonymity.”<sup>428</sup> Open access surveys can result in ineligible participants taking the survey,<sup>429, 430</sup> however this was unlikely to happen for two reasons. Firstly, the survey was only promoted to certain LGBTI online community groups, rather than the wider Internet. This decision was made to ensure that the survey was presented in groups of support and unity, rather than larger online groups where the topic could be taken out of context or mocked. And secondly, there was no compensation for the participants taking the survey, so there was no gain for a participant to take the survey as a joke or if they did not fit the criteria.

The survey promotion was released via Facebook groups, Facebook pages, and email contacts depending on when the survey was initially approved. The first release was on March 1 2017. These groups were all sent the same advert and link to the survey. A second batch of survey advertising was sent on March 6 2017. These groups were sent the same advert as the first release, but the researcher did not post the advert on this occasion due to the group’s privacy settings. The second round of the survey was advertised on March 22 and March 27 2017, exactly three weeks after the adverts were initially posted. The researcher posted all of these advertisements. The final round of the survey advertisements were posted on the April 12 and April 17, another three weeks after the second round. The survey was active online for 7 weeks and closed on the April 20. Given the format of the survey’s sampling and advertising design, it is not possible to know what the response rate of participants was. There were 42 surveys, two of which were incomplete.

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<sup>426</sup> Yitzchak M. Binik, Kenneth Mah, and Sara Kiesler, ‘Ethical Issues in Conducting Sex Research on the Internet’, *The Journal of Sex Research* 36, no. 1 (1999): 82.

<sup>427</sup> Mary Ann Chiasson et al., ‘HIV Behavioral Research Online’, *Journal of Urban Health* 83, no. 1 (January 2006): 74, 75.

<sup>428</sup> Riggle, Rostosky, and Reedy, ‘Online Surveys for BGLT Research’, 15.

<sup>429</sup> Ibid.

<sup>430</sup> Chiasson et al., ‘HIV Behavioral Research Online’, 78.

### **Instrumentation**

The survey consisted of four sections: an introduction, and three sections of questions on demographics, HIV and condom use, and PrEP. There were twenty-seven questions in this survey, two of which were compulsory. The rationale behind making almost all of the questions voluntary was to ensure that participants felt comfortable when taking the survey. Some, if not all, of the questions could be considered personal so it was important that respondents were not forced to reveal anything they did not want to. A full copy of the survey can be found in Appendix 3.

The introduction provided background information to PrEP, including its highest recorded efficacy level, associated side effects, the average cost of PrEP in NZ \$ per month, and an example of the survey questions. It had a clause stating that the results from the survey were anonymous but would be used for data analysis for a Master's thesis. Respondents were required to give consent to participate in the survey as a requirement of the University's HEC. Only participants that ticked 'yes' to this question were given access to the survey. Any participants that ticked 'no' to the question regarding consent were automatically taken to the 'end of survey' page.

The demographics section consisted of four questions. The first two questions, age and gender, were compulsory. Age was presented using common age brackets (18-24, 25-34, etc.) and there were three options for gender (male, female, and prefer not to say). The questions on ethnicity and sexual orientation were optional and required participants to write in their answers. This decision was made to allow participants to openly provide their sexual identification without the researcher assuming that participants would only fit into a certain number of options.

The HIV and condom usage section had twelve voluntary questions that measured attitudes towards using condoms during sex and HIV. The PrEP section had eleven voluntary questions, which assessed the respondents' opinions of PrEP as a HIV prevention method. Once the participants submitted their answers, they were taken to the 'end of survey' page that advertised the need for participants for the focus group, which was later cancelled.

The majority of the questions in the HIV and condom usage and PrEP sections were presented using a Likert scale, which is a category of the attitude scaling method. Rensis Likert designed this scale as a method to measure attitudes of individuals, and it is considered the most useful of the various scales for behavioural research.<sup>431</sup> A Likert scale compromises of a statement that the participant is required to agree or disagree with. Attitude scaling surveys simply portion respondents into broad categories based on their perceived attitude towards a statement but do not provide robust statistical insights.<sup>432</sup> An example of the Likert scale questions used was "I don't care about the HIV status of my sexual partners." The Likert scale questions in the

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<sup>431</sup> Stephen Isaac, *Handbook in Research and Evaluation: A Collection of Principles, Methods, and Strategies Useful in the Planning, Design, and Evaluation of Studies in Education and the Behavioral Sciences*, 1st ed. (San Diego, Calif: R. R. Knapp, 1971), 100.

<sup>432</sup> A.N. Oppenheim, 'Attitude Scaling Methods', in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 96.

survey had four pre-fixed attitude answers: strongly agree, agree, disagree, and strongly disagree. A Likert scale typically has five options for an answer, as it includes a neutral choice, however it is not uncommon to change the number of responses.<sup>433</sup>,<sup>434</sup> Upon the development of the survey it was decided that removing the neutral response would force respondents to pick an attitude, thus providing potentially stronger results. There were three questions in the HIV and condom usage section that only had two pre-fixed answers: yes, and no. This is because these questions were not focused on an attitude but on past behaviour.

## Interviews

### **Sampling and participants**

The first qualitative method used was interviews with HIV experts from around New Zealand. The purpose of the semi-structured interviews was to gain a better understanding of the current HIV infection trends. Interviews are a well-known qualitative method that uncovers experts' thoughts "on events, processes, and perceptions" of trends.<sup>435</sup> Interviews were used to fulfil the second research aim to gain a greater understanding of current HIV trends in New Zealand. Potential interviewees were picked using purposive sampling, as their expertise in HIV provided a meaningful contribution to this research. Some potential interviewees that were identified prior to the interviews included New Zealand AIDS Foundation staff members, researchers, epidemiologists, community workers specialising in HIV, and health professionals. A specific number of interviews were not required but it was assumed that there would be between five and eight interviewees to gain a rich insight into HIV in New Zealand. All potential interviewees were invited to participate via email correspondence. The email contained an information sheet and consent form as required by the University's HEC (see Appendix 4).

Interviewees were encouraged to talk in a free and frank manner during the interviews. All interviewees chose how to be identified in the research, but it was presumed that interviewees would remain confidential unless stated otherwise. The following individuals took part in the interviews:

- Sean Kelly, Manager Health Services, New Zealand AIDS Foundation, Christchurch;
- Akira Le Fevre, Community Engagement Coordinator, New Zealand AIDS Foundation, Christchurch;
- Associate Professor Nigel Dickson, epidemiologist and former Director of AIDS Epidemiology Group, Dunedin;
- HIV/AIDS researcher, Auckland;

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<sup>433</sup> Rensis Likert, 'A Technique for the Measurement of Attitudes' (PhD, Columbia University, 1932).

<sup>434</sup> Dennis L Clason and Thomas J Dormody, 'Analyzing Data Measured by Individual Likert-Type Items', *Journal of Agricultural Education* 35, no. 4 (1994): 31.

<sup>435</sup> Donovan, Miller, and Goldsmith, "'Tell Me about a Time When...': Studying Health Communication through in-Depth Interviews", 25.

- Mark Fisher, Director of Body Positive, Auckland;
- Sexual health doctor, Christchurch;
- Dr Nigel Raymond, Infectious Disease Specialist, Capital and Coast District Health Board, Wellington.

It is important to note that only two interviewees acknowledged that they were authorised to speak on behalf of their institution (Dr Nigel Raymond, Capital and Coast District Health Board, and Mark Fisher, Body Positive). All other interviewees were speaking on behalf of themselves.

### **Instrumentation**

Once interviewees agreed to participate and had returned the consent form, they were sent a general overview of the format of the interview, including preferred discussion topics. The interviewer used open questions so the respondent had the ability to provide as much detail as desired<sup>436</sup> and could freely bounce between topics. The majority of the questions asked were the same throughout the interviews, though there were additional questions based on the interviewees' specialisations. This flexible format ensured that 'off-topic' conversations could still offer important insights<sup>437</sup> needed to answer the research aims. Some examples of the consistent questions asked include:

- Can you please tell me about your work with HIV? How long have you been involved in this area of health?
- The rates of HIV infections are rising in New Zealand. What are your thoughts on this? Is it expected or shocking? Why do you think this is happening?
- Should PrEP be provided by sexual health clinics, the primary doctor, or infectious disease specialists?

Interviews took place in person or via Skype. All of the interviews were recorded on an iPhone with permission from the interviewee. Recording the full interview allowed the researcher to facilitate discussion with the interviewee instead of concentrating on transcribing the conversation accurately. Interviews were transcribed in full and emailed to the interviewee to confirm within five working days. The researcher assumed that if there was no response, the interviewee was happy with the transcript. The information sheet and consent forms notified participants that the interviews would be used for this thesis.

### **Document analysis**

The final qualitative method used in this research was document analysis. Document analysis is the examination of documents to "elicit meaning, gain understanding, and

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<sup>436</sup> Sir Claus Moser and Graham Kalton, 'Questionnaires', in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 83.

<sup>437</sup> Richard G. Parker, Gilbert Herdt, and Manuel Carballo, 'Sexual Culture, HIV Transmission, and AIDS Research', *The Journal of Sex Research* 28, no. 1 (February 1991): 92.

develop empirical knowledge.”<sup>438</sup> Documents can include journal articles, books, policy papers, and legislation. Document analysis was chosen as the final method for this research because it provides supplementary information that is highly valuable to achieving the second research aim and the overall study. In addition, when combined with further methods, document analysis validates common trends, minimises potential biases that could occur, and increases the integrity of findings.<sup>439</sup> For example, the majority of the information that was examined in Chapters 1 and 2 was found using document analysis. This method provided the researcher with a clear understanding of how this thesis fits in to the bigger picture of HIV and PrEP research in New Zealand. The results from this document analysis were also used to structure the questions<sup>440</sup> for the survey and interviews.

### Focus group

A focus group was planned as a third qualitative research method. Focus groups are group interviews that are characterised by the “collective discussion” of a particular subject facilitated by the researcher.<sup>441</sup> The response rate for the focus group was too low so it was cancelled. The participants who were able to attend the focus group were all interested in helping advise a PrEP policy, which suggests that this may be a useful research method for future development of PrEP policies in New Zealand. While the focus group did not ultimately occur, the use of the three other methods ensured the comprehensiveness of the data collected and the research questions were still answered.

## Data processing and analysis

### Survey

Once the survey was complete, the data was exported using Qualtrics for analysis and the results are presented in Chapter 4. According to the literature, there is no particular way to analyse Likert scale data that is more correct than other methods.<sup>442</sup> The researcher was aware that the data needed to be analysed in a way that fulfilled the first research aim and answered the overall thesis research questions. With this in mind, the researcher consulted with a statistician to ensure that the analysis of the results would be adequate. It was agreed that given the use of the Likert scale, the relatively small sample (although considered large in statistical terms), and the research aims, it would be acceptable to present the data in its raw form. The rationale behind this decision was that the data was exploratory and there was no need to highlight particular responses or variables, but rather provide a broad overview of

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<sup>438</sup> Corbin and Strauss 2008, as cited in Glenn A. Bowen, ‘Document Analysis as a Qualitative Research Method’, *Qualitative Research Journal* 9, no. 2 (3 August 2009): 27.

<sup>439</sup> Ibid., 30, 38.

<sup>440</sup> Ibid., 30, 31–32.

<sup>441</sup> Hannah Frith, ‘Focusing on Sex: Using Focus Groups in Sex Research’, *Sexualities* 3, no. 3 (1 August 2000): 276.

<sup>442</sup> Clason and Dormody, ‘Analyzing Data Measured by Individual Likert-Type Items’, 34.

attitudes towards the survey topics. Furthermore, the results from the survey are complimented by the additional research methods. Therefore, there was no statistical analysis of the survey; Chapter 4 simply presents the spread of attitudes to each question.

### Interviews

The data processing for the interviews is the transcript; the transcripts were completed within five working days of the interview to ensure that what was discussed was still fresh in the interviewee's mind. The analysis of the interviews was conducted using NVivo 11.4.0 for Mac. The interviews were coded using NVivo to highlight themes that were shared between the interviewees on specific topics. The coding also showed the discrepancies between what interviewees said. The analysis of the interviews is not presented in a subsequent chapter, but the trends and insights that were revealed through NVivo coding are used to complement the policy recommendation for PrEP that is presented in Chapter 5.

### Ethical considerations

As with all research, there are ethical considerations that must be factored in to the overall project. Every methodological decision that was made needed to ensure that the participants who volunteered their time were treated respectfully. This section will discuss three ethical considerations that occurred throughout the research: LGBTI subjects, discussing sexual behaviour and HIV, and Human Ethics approval. This comprehensive discussion of research ethics, given both the sensitive nature of the research topic and the fact that this thesis constituted a valuable learning-by-doing experience, may inform future work on PrEP and HIV prevention in New Zealand.

### Research focusing on LGBTI

The methodological difficulties of studying LGBTI populations are well documented: identifying LGBTI populations that are easily defined, gaining ethics approval, reaching the population to advertise the research, getting enough participants for a credible sample size, and avoiding any discrimination or offence.<sup>443, 444, 445</sup> As mentioned, it is almost impossible to use probability sampling for LGBTI groups because they are a minority of the wider population, so the chance of finding a representative group in the sample is highly unlikely. The population is even smaller when researching specific groups within the LGBTI community, such as MSM, which makes the sample harder to find.<sup>446</sup> Furthermore, finding respondents requires participants to openly identify as part of this minority community, and many may not want to disclose their "stigmatized

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<sup>443</sup> James I. Martin and William Meezan, 'Exploring Current Themes in Research on Gay, Lesbian, Bisexual and Transgender Populations', in *Research Methods with Gay, Lesbian, Bisexual, and Transgender Populations*, ed. William Meezan and James I. Martin (Binghamton, NY: Harrington Park Press, 2003), 8.

<sup>444</sup> Sullivan and Losberg, 'A Study of Sampling in Research in the Field of Lesbian and Gay Studies', 148.

<sup>445</sup> Peter A. Guarnero and Jacquelyn H. Flaskerud, 'Health and Health Research Needs of the LGBTI Community', *Issues in Mental Health Nursing* 35, no. 9 (September 2014): 722.

<sup>446</sup> Ibid.



sexual or gender identity”<sup>447</sup> to a researcher.<sup>448, 449, 450</sup> Subsequently these sampling issues mean that the generalisability of the research is almost impossible.<sup>451, 452, 453, 454</sup> It was important that these issues were considered when designing this research and thus, it was a simple choice to use non-probability sampling to reach members of the LGBTI community. This decision limits the generalisability of the findings and the sample cannot be considered representative, but it was the best choice to ensure that the sample size was large enough to provide meaningful results. Despite these methodological challenges, purposive sampling using LGBTI groups in Christchurch still ensures that the participants recruited for the survey made a credible sample to fulfil the research objectives.<sup>455</sup>

One ethical consideration raised by a member of an online LGBTI group was that the survey needed to include more trans- and gender-diverse terms. This point had not been considered by the researcher, the University’s HEC or the people who proofed the survey before it went live. There was an agreement between at least two members of the online group that it was unclear whether the survey was for cis MSM only (someone whose gender matches their sex at birth) or could include transgender men (TGM) and transgender women (TGW). There was a recommendation that the survey incorporates TGM for greater inclusion and acknowledges that TGW are also at high-risk of HIV even if they are not used in the survey. This advice was well received because the researcher was very aware of the sensitivities associated with research of LGBTI communities. Unfortunately the researcher received this advice after the survey had been live for nearly one week so any changes to the survey while it was active would introduce a bias to the findings. Furthermore, the research was specifically designed to be manageable, which is why the thesis’s focus remained solely on MSM. The researcher thanked the participants for their comments about greater inclusion of trans- and gender-diverse groups, and ensured that the survey would be adjusted if it were released for a second time. This valuable input also seems to reflect the increasing attention being given to issues of gender identity and intersectionality in the broader literature on social movements and health (for example, a Canadian baby

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<sup>447</sup> Bonnie Moradi et al., ‘Counseling Psychology Research on Sexual (Orientation) Minority Issues: Conceptual and Methodological Challenges and Opportunities’, *Journal of Counseling Psychology*, Advances in Research With Sexual Minority People, 56, no. 1 (January 2009): 13.

<sup>448</sup> James I. Martin and Jo Knox, ‘Methodological and Ethical Issues in Research on Lesbians and Gay Men’, *Social Work Research* 24, no. 1 (March 2000): 53.

<sup>449</sup> Guarnero and Flaskerud, ‘Health and Health Research Needs of the LGBTI Community’, 722.

<sup>450</sup> Kathryn Greene and Kate Magsamen-Conrad, ‘Methodological Challenges for Health Research with Stigmatized Populations’, in *Research Methods in Health Communication: Principles and Application*, ed. Bryan B. Whaley (New York, NY: Routledge, 2014), 307.

<sup>451</sup> Martin and Knox, ‘Methodological and Ethical Issues in Research on Lesbians and Gay Men’, 55.

<sup>452</sup> Joan C. McClelland, ‘Researching Gay and Lesbian Domestic Violence: The Journey of a Non-LGBT Researcher’, in *Research Methods with Gay, Lesbian, Bisexual, and Transgender Populations*, ed. William Meezan and James I. Martin (Binghamton, NY: Harrington Park Press, 2003), 32.

<sup>453</sup> Martin and Meezan, ‘Exploring Current Themes in Research on Gay, Lesbian, Bisexual and Transgender Populations’, 8.

<sup>454</sup> Meyer and Wilson, ‘Sampling Lesbian, Gay, and Bisexual Populations’, 24.

<sup>455</sup> Thomas and Hodges, *Designing and Managing Your Research Project: Core Skills for Social and Health Research*, 19.



marked as U for sex on their health card in July 2017). Future research on PrEP and health issues more broadly will need to incorporate this feedback and the author appreciated the opportunity to learn from the study community.

### Research focusing on sexual behaviour and HIV

Further to the complications regarding LGBTI respondents, the research design also needed to consider the sensitivity of exploring sexual behaviour and attitudes towards HIV. Sensitive research is defined by asking questions about a topic that is normally considered personal and may cause the respondent to feel offended or uncomfortable.<sup>456</sup> Of the three methods used for this research, the survey is most likely to be considered sensitive research given the frank nature of the questions, which could elicit a negative reaction (see Appendix 3). However, a meta-analysis of sex research has found that the anonymity of online research methods can encourage participants to share 'frowned upon' behaviour, such as risky or illegal activities.<sup>457</sup> In order to make the potential respondents feel as comfortable as possible answering the survey, the researcher ensured that all of the questions about sensitive information were voluntary. This decision guaranteed that the participants did not feel pressured to provide an answer for any question that was too personal or intrusive. It was also mentioned in the survey adverts and before the participants provided consent that all answers would remain anonymous and the subjects would not be identifiable.

### Human Ethics Committee approval

As a requirement of the University of Canterbury, any research involving human participants must be approved by the HEC. The first application for this research was submitted to the HEC on June 1 2016. The HEC returned the application on June 22 2016 with the request for changes to the application. The only major concern raised by the HEC was that the research could cause moral/cultural offence by presuming that:

Gay/Bi/MSM have multiple partners, and have anal intercourse. However, some gay couples show exclusive fidelity and may be offended by the suggestion that they should take PrEP. There are also people who identify as Gay or Bi but are celibate for religious or other reasons. It would be worth considering these possible causes of offence when discussing sexual behaviour, and also having a plan of response in place for when unexpected offence occurs.<sup>458</sup>

The researcher responded in writing to the HEC and said that there was no intention to cause moral/cultural offence by presuming MSM's sexual behaviour. However, the researcher cited statistics from the 2002-2014 Gay Auckland Periodic Sex Surveys (GAPSS) and 2006-2014 Gay men's Online Sex Surveys (GOSS) where 66.2% and

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<sup>456</sup> Kaye Wellings, Patrick Branigan, and Kirsti Mitchell, 'Discomfort, Discord and Discontinuity as Data: Using Focus Groups to Research Sensitive Topics', *Culture, Health & Sexuality* 2, no. 3 (2000): 256.

<sup>457</sup> Wendy L. Richman et al., 'A Meta-Analytic Study of Social Desirability Distortion in Computer-Administered Questionnaires, Traditional Questionnaires, and Interviews', *Journal of Applied Psychology* 84, no. 5 (October 1999): 769.

<sup>458</sup> University of Canterbury Human Ethics Committee, 'Ref: HEC Application 2016/55 - Hartley', 22 June 2016.

76.9% of respondents had between 2 and over 50 sexual partners in the six months prior to the surveys, respectively.<sup>459</sup> More than 80% of MSM from both the GAPSS and GOSS engaged in anal intercourse with a regular and irregular sexual partner.<sup>460, 461</sup> The researcher justified their thesis, stating that it does not intend to make assumptions about the sexual behavior of MSM, but is simply based on recent statistics of MSM from New Zealand.

The researcher also responded to the HEC's concern that there are MSM who remain celibate for personal reasons and may take offence to the suggestion that they should use PrEP. It was argued that MSM who are monogamous, celibate or do not engage in anal intercourse are unlikely to need PrEP given their low HIV-risk. Higher-risk MSM that may benefit from using PrEP include members of serodiscordant couples, MSM with multiple sexual partners, and MSM that do not regularly use condoms. Therefore, there should be no need for MSM who have a low-risk of contracting HIV to feel offended by the research, as they are not the target population for PrEP. The researcher also stated that if individuals feel that they are not high-risk they are free to ignore the call for participants. Regardless, the researcher added the following to the survey advertisement: "PrEP is an additional HIV prevention method for gay and bisexual males/men who have sex with men who have a high risk of HIV." This additional statement reduced the insinuation that all MSM are at-risk of HIV and must use PrEP. However, the researcher did agree that it was important to have a plan in place to deal with potentially offended individuals, as it was not the researcher's intent to generalise all MSM into a one-size-fits-all category. The researcher provided contact details so participants could get in touch if they did take offence to the research.

The research application was approved by the HEC on June 24 2016. The Qualtrics survey was designed in September 2016. Due to the researcher being heavily involved in interviews and writing the literature review, the survey was not released at this time. A decision was made in late October to release the survey at the beginning of the 2017 university year to ensure that more potential participants could be captured in the online groups. However, in late-February 2017, it was discovered that the University of Canterbury was the only tertiary institute in the Canterbury region with a large LGBTI community. Upon the recommendation of members from various LGBTI groups around Christchurch, the researcher decided to widen the sample of the survey to all members of LGBTI groups in Christchurch. The HEC was notified of the increase in sampling on February 22 2017, and the change was accepted on February 27 2017. The HEC's acceptance of the new sampling method was approved on the premise that the researcher ensures organisational consent before posting the advertisement to Facebook pages or email groups. Prior to receiving approval from the LGBTI community groups, a QCanterbury leader proofread the survey. This leader was

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<sup>459</sup> Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) / Te Rangahau Tane Ai Tane: Basic Frequency Tables 2002-2014', 17.

<sup>460</sup> Ibid., 27.

<sup>461</sup> Ibid., 28.

happy with the survey, which provided the researcher with peace of mind that the survey was acceptable and should not cause offence to potential respondents.

The HEC also required that all participants of the survey and interviews submit their consent prior to partaking. If participants selected 'no' they were directed to the end of the survey. Interviewees were required to sign the interview consent form before it took place (see Appendix 4). This form also informed the researcher of the interviewee's ability to talk on behalf of their institution.

### Validity

Validity is a crucial aspect of research because it ensures that the findings are "plausible, credible, trustworthy, and, therefore, defensible."<sup>462</sup> Donald T. Campbell and Julian C. Stanley claimed that there are two types of validities in primary research: internal validity, and external validity. Internal validity is the level "with which we can infer that a relationship between two variables is casual or that the absence of a relationship" shows limited causality.<sup>463</sup> External validity focuses on the level of generalisability that occurs from the research results,<sup>464</sup> and "the extent to which conclusions can be applied across different populations or situations."<sup>465</sup>

This research is high in internal validity, as none of the eight elements of internal validity as identified by Campbell and Stanley were jeopardised. This conclusion is based on the fact that all of the chosen research methods were only completed once rather than being repeated multiple times to measure potential changes. However, achieving high levels of both internal and external validity can be difficult, as "increasing one may jeopardize the other."<sup>466</sup> Therefore, it can be seen that the external validity of this research is limited because the survey and interviews used non-probability sampling methods to find participants.

### Triangulation

Due to the limited external validity of this thesis, the researcher employed the use of triangulation, which occurs when a research project uses multiple methods to test a hypothesis or subject.<sup>467</sup> Triangulation can be used numerous ways, such as "measuring variables in more than one way or addressing hypotheses/research questions using more than one method."<sup>468</sup> There are two key benefits of using

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<sup>462</sup> R. Burke Johnson, 'Examining the Validity Structure of Qualitative Research', *Education* 118, no. 2 (Winter 1997): 282.

<sup>463</sup> Thomas D Cook and Donald T Campbell, 'Validity', in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 48.

<sup>464</sup> Donald Thomas Campbell and Julian C. Stanley, *Experimental and Quasi-Experimental Designs for Research* (Chicago: R. McNally, 1966), 5.

<sup>465</sup> McDermott, 'Internal and External Validity', in *Cambridge Handbook of Experimental Political Science*, ed. James N. Druckman et al. (Cambridge University Press, 2011), 34.

<sup>466</sup> Campbell and Stanley, *Experimental and Quasi-Experimental Designs for Research*, 5.

<sup>467</sup> Denzin 1978, as cited by Todd G Jick, 'Mixing Qualitative and Quantitative Methods: Triangulation in Action', *Administrative Science Quarterly* 24, no. 4 (December 1979): 602.

<sup>468</sup> Teresa L Thompson, Louis P Cusella, and Brian G Southwell, 'Method Matters', in *Research Methods in Health Communication: Principles and Application*, ed. Bryan B. Whaley (New York, NY: Routledge, 2014), 13.

triangulation for research: it produces higher confidence in the results when they are consistent between the multiple methods, and the variety in methods allows the same theme to be analysed in different ways.<sup>469, 470</sup>

This study used 'between methods' triangulation, which occurs when the researcher uses a variety of differing methods to achieve a shared research objective.<sup>471</sup> As briefly discussed in the Research Design section, multiple mixed-methods were chosen because if one method fell through, the triangulation of the other methods ensured the research aims could still be achieved. This occurred when the focus group was cancelled but the researcher could still rely on the other three methods to answer the research questions. Furthermore, triangulation was picked because it ensures that the weaknesses of one method are compensated by the strengths of the other chosen methods.<sup>472, 473</sup> As a result, the researcher's work benefitted from the statistical data collected through the survey and the rich qualitative data that was drawn out by exploring opinions, ideas, and attitudes through interviews and document analysis. When the results from the research were reinforced through triangulation, the findings of this study gained validity.<sup>474</sup>

However, it is worthwhile to note that replicating studies to ensure external validity is much harder when the studies use triangulation.<sup>475</sup> Likewise, qualitative methods are more difficult to replicate than quantitative research.<sup>476</sup> Therefore, it is important to recognise that the increased validity of findings when a trend is reinforced through multiple methods can be diminished by complications associated with potential research replication.

## Conclusion

This chapter provided an in-depth explanation of the research design used throughout this thesis. As mentioned, the overall research questions are: Do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties faced overseas? This question can be answered using the two key research aims:

1. Uncover and analyse the attitudes of MSM towards PrEP and HIV in the Canterbury region, and
2. Gain a greater understanding of current HIV trends in New Zealand.

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<sup>469</sup> Ibid.

<sup>470</sup> Robert Bogdan and Sari Knopp Biklen, *Qualitative Research for Education: An Introduction to Theories and Methods*, 5th ed (Boston, Mass: Pearson A & B, 2007), 115–16.

<sup>471</sup> Norman K Denzin, *The Research Act: A Theoretical Introduction to Sociological Methods*, 2nd ed. (New York: McGraw-Hill, 1978), 302.

<sup>472</sup> Jick, 'Mixing Qualitative and Quantitative Methods', 604.

<sup>473</sup> John W Creswell et al., 'Best Practices for Mixed Methods Research in the Health Sciences' (Bethesda, MD: National Institutes of Health, August 2011), 5.

<sup>474</sup> Thomas J. Bouchard, 'Unobtrusive Measures: An Inventory of Uses', *Sociological Methods & Research* 4, no. 3 (1 February 1976): 268.

<sup>475</sup> Jick, 'Mixing Qualitative and Quantitative Methods', 609.

<sup>476</sup> Ibid.

This research follows Weiss's problem-solving model where research is used to reduce uncertainty and provide a policy recommendation. The thesis uses multiple, mixed-methods to achieve these aims and answer the overall research questions. The quantitative online survey using the Likert scale was used to fulfil the first research aim. Participants were recruited using non-probability purposive sampling and the survey was hosted on Qualtrics. The second research aim was achieved through in-depth Skype or face-to-face interviews with HIV/AIDS experts from around New Zealand. Interviewees were invited to participate via email and recruited using purposive sampling. There were 6 interviews and 7 interviewees. The research aims were complemented by the use of document analysis.

The analysis of each research methods differed. The results from the online survey were not statistically analysed, but have been presented in a raw form due to the exploratory nature of the results. These can be seen in Chapter 4. The expert interviews were analysed using NVivo qualitative coding software to identify themes. These themes are not presented individually, but have been incorporated into Chapter 5.

The researcher noted a number of ethical considerations that were taken into account throughout the thesis. Firstly, there were methodological challenges that needed to be overcome due to the complexities of researching LGBTI populations. Similarly, topics such as sexual behaviour and HIV are sensitive to those involved in the research. As a result, the researcher had to be very careful about dealing with the participants to ensure they were respected and felt comfortable to participate. As a requirement of the HEC, all of the research methods and sampling methods had to be approved. Gaining human ethics approval from the HEC ensured that the researcher was approaching the LGBTI communities with respect and treating their participation sensitively.

As discussed, the internal validity of this research appears to be high. However, when internal validity is high, external validity is often jeopardised. It is important to note the triangulation of research methods, which can validate the results of the research further despite the lack of external validity.

The next chapter, Chapter 4, will display the exploratory results from the online, anonymous attitude scaling survey of MSM from the Canterbury region. The survey took place between March and April 2017.

## Chapter 4: Canterbury MSM and their attitudes towards PrEP

*100% of participants 'strongly agree' or 'agree' that PrEP is a worthwhile HIV prevention method for MSM; 100% of participants 'strongly agree' or 'agree' that PrEP is a good way to reduce one's chance of HIV infection; and 97.5% of participants 'strongly agree' or 'agree' that PrEP should be subsidised in New Zealand.*

This chapter presents the results from the quantitative online, attitude scaling survey that was conducted in March and April 2017. It is important to note that the sample size is small compared to other behavioural surveys and the generalisability of the results must be viewed carefully.

### Introduction

As discussed in Chapter 3, the aim of this thesis is to design a health policy for PrEP implementation for MSM in New Zealand. The overall research questions are: Do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties faced overseas? The objective of the anonymous, online attitude scaling survey is to accomplish the first research aim, which is to uncover and analyse the attitudes of MSM towards PrEP and HIV in the Canterbury region.

The researcher based the frank questions of the survey on the Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS). The GAPSS has been running since 2002, and the GOSS was added to the NZAF and Auckland Gay Men's Sexual Health Group's agenda in 2006 when the researchers noticed the impact the Internet and social media were having on MSM.<sup>477</sup> Each cycle of the GAPSS/GOSS "surveys attitudes and behaviours of [over 3,000] gay and bisexual men" and provides the opportunity to create evidence-based and scientific HIV/AIDS campaigns.<sup>478</sup> The GAPSS/GOSS were initially conducted biannually, but the cycle recently changed to every three years. In March 2017, the Ministry of Health (MOH) announced that it would not fund the 2017 cycle of the GAPSS/GOSS; the Ministry's cease in funding the survey was "not a reflection of its value but that the prioritisation of the current work programme means that we are unable to provide funding at this time."<sup>479</sup> The removal of funding for the GAPSS/GOSS goes against the advice of an independent cost-benefit analysis conducted in 2013, which found that "having high quality information about the sexual practices of gay and bisexual men is vital" and "strongly supported continuing the survey."<sup>480</sup> Furthermore, not continuing the GAPSS/GOSS goes against

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<sup>477</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher, interview by Alice Hartley, Skype, 6 September 2016.

<sup>478</sup> Kathryn Ryan, 'Why Is Govt Not funding "vital" HIV Survey?', Online, *Radio New Zealand* (Radio New Zealand, 21 March 2017), <http://www.radionz.co.nz/national/programmes/ninetoonoon/audio/201837389/why-is-govt-not-funding-vital-hiv-survey>.

<sup>479</sup> Ibid.

<sup>480</sup> Covec report, 2013, as cited by Ryan, 'Why Is Govt Not funding "vital" HIV Survey?'

advice from organisations like UNAIDS and the World Health Organization (WHO).<sup>481</sup>,  
<sup>482</sup> For example, Family Health International states that behavioural and attitude surveys are imperative because

It can help communities and program planners come up with initiatives carefully focused on breaking the links in the chain of transmission in a particular country, region or group. Without information on HIV-related risk behavior, public health officials and others are unlikely to be able to prioritize their interventions so that they have the greatest impact on curbing the spread of HIV.<sup>483</sup>

This survey primarily measured attitudes through the use of a Likert scale, however, it also features three yes/no questions based on previous behaviour. Just as large-scale nationwide surveys like GAPSS and GOSS direct future HIV policymaking, the researcher's small-scale survey of MSM aims to achieve the overall research questions, which is to inform grassroots, evidence-based policy for PrEP implementation in New Zealand. The survey is used to uncover the attitudes of MSM towards PrEP and HIV in the Canterbury region.

## Method

### Participants and sampling

The methods used for the online survey are presented in detail in Chapter 3. To summarise, the participants were asked to complete a self-administered, online survey via Facebook groups, Facebook pages, and email databases of LGBTI groups. The survey used non-probability purposive sampling, as participants were invited to take the survey based on characteristics that were of interest to the researcher.<sup>484, 485, 486, 487</sup> The researcher was interested in individuals that self-identified as MSM and had an opinion on PrEP. The survey was open access, which meant that any individual with the URL link could participate. Participation in the survey was voluntary. Due to a lack of funding, the researcher was limited to promoting the survey for free and no compensation was offered. There was no pilot testing undertaken before the survey was promoted, however the researcher's supervisor, the University's Human Ethics Committee (HEC), and a member of a LGBTI group all proofread it.

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<sup>481</sup> Ibid.

<sup>482</sup> Scoop, 'Government Abandons HIV Battle | Scoop News' (Press Release, Wellington, N.Z, 12 March 2017), <http://www.scoop.co.nz/stories/PA1703/S00189/government-abandons-hiv-battle.htm>.

<sup>483</sup> Joseph Amon et al., 'Behavioral Surveillance Surveys (BSS): Guidelines for Repeat Behavioral Surveys in Populations at Risk of HIV' (Arlington, VA: Family Health International, 2000), 2.

<sup>484</sup> Mays and Pope, 'Rigour and Qualitative Research.', 110.

<sup>485</sup> Thomas and Hodges, *Designing and Managing Your Research Project: Core Skills for Social and Health Research*, 19.

<sup>486</sup> Donovan, Miller, and Goldsmith, "'Tell Me about a Time When...': Studying Health Communication through in-Depth Interviews', 26.

<sup>487</sup> Morgan and Carcioppolo, 'Survey Research Methodology in Health Communication', 81.



### Measures and data collection

As discussed in Chapter 3, the questionnaire was presented on Qualtrics and contained four sections: an introduction; a demographics section; an HIV and condom use section; and a section on attitudes towards PrEP. To reiterate, the introduction provided background information for the survey, including important information about PrEP such as efficacy, cost, side effects, and an example of the survey questions. The introduction also had a consent question as required by the University's HEC. The demographic section gathered data on age, gender, ethnicity, and sexuality. This section contained the only two questions that were compulsory (age, presented in age brackets, and gender, which also included a 'prefer not to disclose' option). The third section, HIV and condom use, measured attitudes towards condoms during sex and HIV. The majority of section three's questions were presented using the 4-point Likert scale. There were three questions in section three that were yes/no behavioural questions. The final section measured attitudes towards PrEP and all of these questions were presented using the Likert scale. While most typical Likert scales use 5-points (strongly agree, agree, neutral, disagree, strongly disagree), a decision was made to remove the neutral option and use a 4-point scale. The researcher acknowledges that Likert scales measure broad attitudes but do not provide results that can be used to make generalisations or future predictions about the participants.<sup>488</sup>

### Results

Between March 1 2017 and April 20 2017, forty-two participants took part in the attitude scaling survey of Canterbury MSM. Given the voluntary nature of the questions, there was a mix of 38 to 42 respondents for each question. The mean number of respondents was 39, excluding the questions where participants were asked to write their sexuality and ethnicity. No participants were excluded from this study, as it was voluntary to complete the survey.

After discussion with the Statistics Consulting Group at the University of Canterbury, the researcher made the decision to present the following results in their raw form because the data is exploratory. There has been no statistical analysis for the results provided below, as the Likert scale results "show clear-cut and reliable differences in attitude."<sup>489</sup> Furthermore, the survey's results are complimented by the other research methods undertaken in this thesis.

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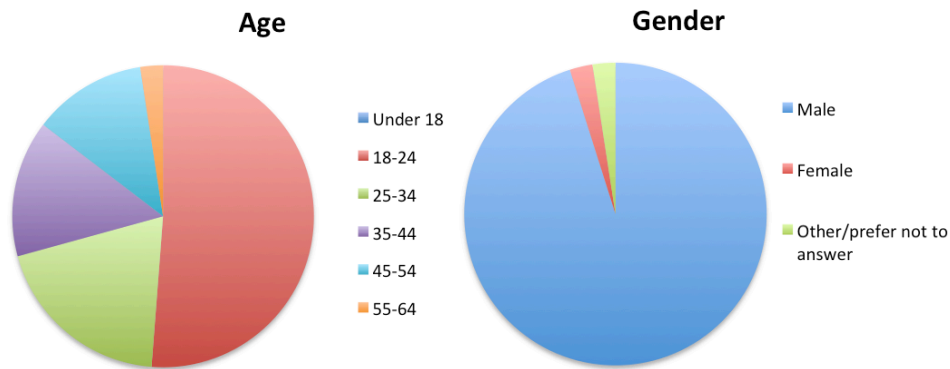
<sup>488</sup> Oppenheim, 'Attitude Scaling Methods', 104.

<sup>489</sup> Likert, 'A Technique for the Measurement of Attitudes', 39.



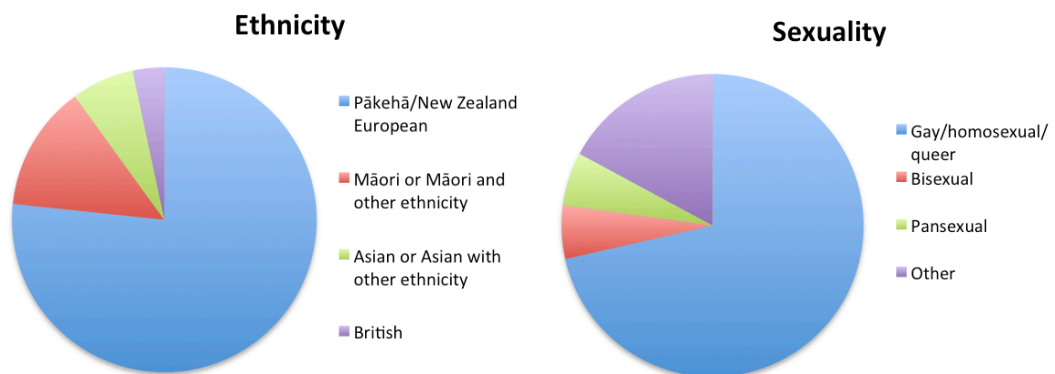
### Demographic characteristics

The spread of the respondents' ages were as follows: 18-24 years, 51.22%; 25-34 years, 19.51%; 35-44 years, 14.63%; 45-54 years, 12.2%; and 55-64 years, 2.44%. 39 respondents identified as male (95.12%), one participant identified as female (2.44%) and one participant chose the option 'other/prefer not to answer' (2.44%). Figure 4 present the distribution of the participants' ages and genders.



**Figure 4: Age and Gender**

30 participants provided their ethnicity. Of these, twenty-three (76%) identified as Pākehā/New Zealand European/New Zealand Caucasian/white, four (12%) identified as Māori or Māori and another ethnicity, two (6%) identified as Asian or Asian with another ethnicity, and one (3%) identified as British. 35 participants provided their sexual orientation. Of these, twenty-five (71%) identified as gay/homosexual/queer, two (5%) as bisexual, two (5%) as pansexual, and six (17%) as other. 'Other' categories include bisexual/gay, 'top', 'Kinsey 5,' transgender woman, homoflexible, and non-labelled. These are shown in Figure 5.



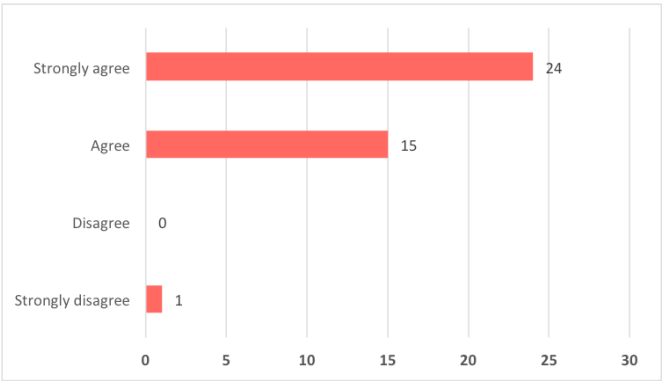
**Figure 5: Ethnicity and Sexual Orientation**

### HIV and condom usage section

The following questions in this section were inspired by the questions from the GAPSS/GOSS studies. 34 (89.47%) of the participants knew their HIV status, while four

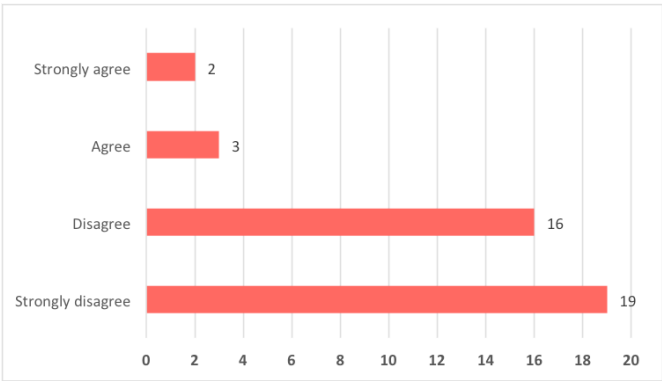
(10.53%) did not. This question was the least answered in the survey with only thirty-eight participants submitting a response, despite the researcher not asking any further details about the HIV status. The following graphs show the results from the section on attitudes towards HIV and condom use.

In general, participants seem to share reasonably similar attitudes towards HIV, including about HIV testing and sharing their HIV status with their sexual partners. As Figure 6 shows, 97.5% of participants ‘agreed’ or ‘strongly agreed’ that it is important to get regular HIV tests.



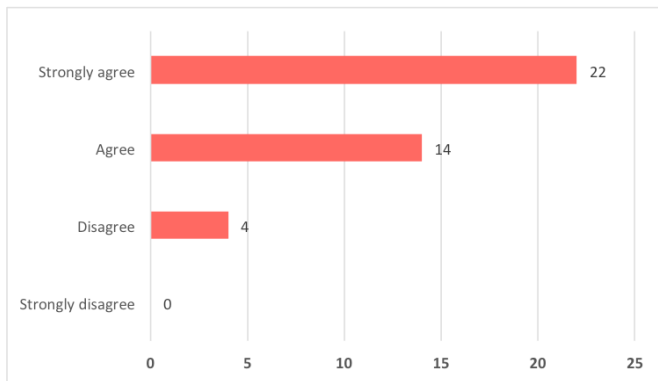
**Figure 6: I believe that it is important to get regular HIV tests**

Similarly, Figure 7 displays that 87.5% of respondents ‘disagreed’ or ‘strongly disagreed’ that HIV is not a serious issue for MSM/gay and bisexual men. There were three participants who ‘agreed’ and two who ‘strongly agreed’ with this statement.

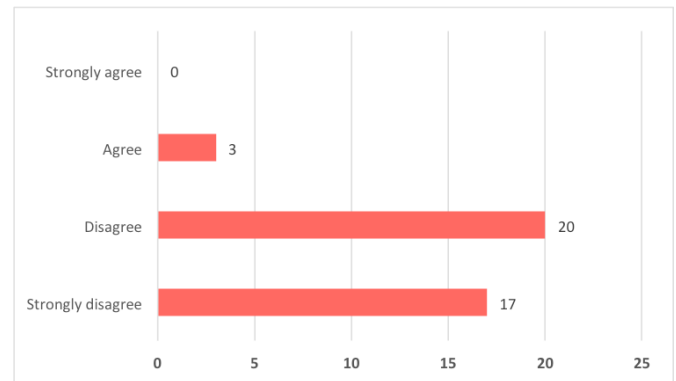


**Figure 7: HIV is not a serious issue for MSM/gay and bisexual men**

Likewise, the majority of the respondents also shared similar attitudes towards sharing one’s HIV status with sexual partners. Figure 8 displays that 90% of participants ‘agreed’ or ‘strongly agreed’ that it is important to tell their sexual partners about their HIV status. 4 participants ‘disagreed’ with this statement. The results from Figure 9 show a similar attitude to the importance of knowing the HIV status of one’s sexual partners. Only three participants ‘agreed’ that they did not care about their sexual partners’ HIV statuses. 4 participants from Figure 8 and three participants from Figure 9 did not share the same attitudes as the majority of the other



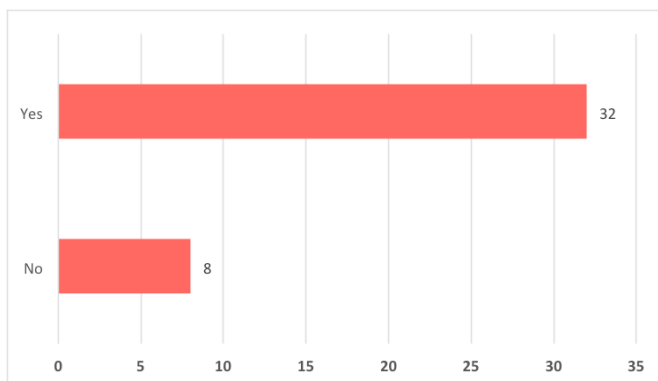
**Figure 8: It is important to tell my sexual partners about my HIV status**



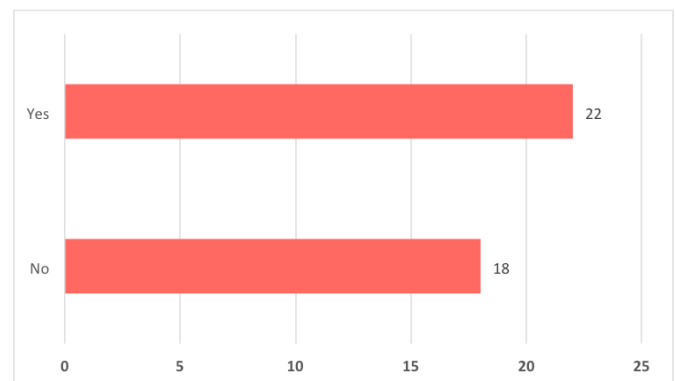
**Figure 9: I don't care about the HIV status of my sexual partners**

respondents. Given the nature of the questions, these answers may suggest important avenues for further research on sexual health and behaviour.

Figures 10 and 11 did not follow the Likert scale format that was used in the majority of the survey; these two statements were the second and third of the yes/no questions (the first was the whether participants knew their HIV status). Figure 10 shows the proportion of respondents who had engaged in anal sexual intercourse with another male with a condom in the last twelve months. This statement was used to provide a comparison to Figure 11, which depicts the proportion of participants who had engaged in anal sexual intercourse with another male in the last twelve months without a condom.

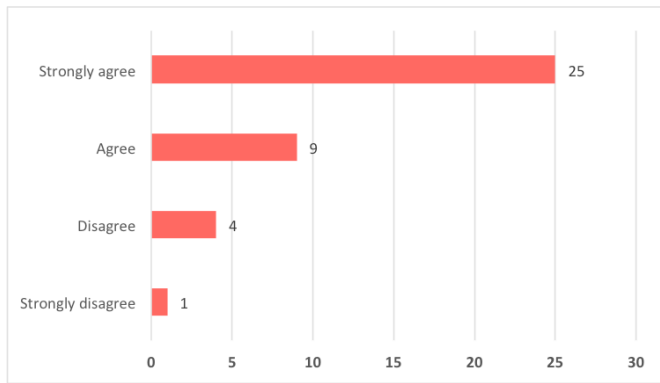


**Figure 10: I have engaged in anal sexual intercourse with another male with a condom in the last 12 months**

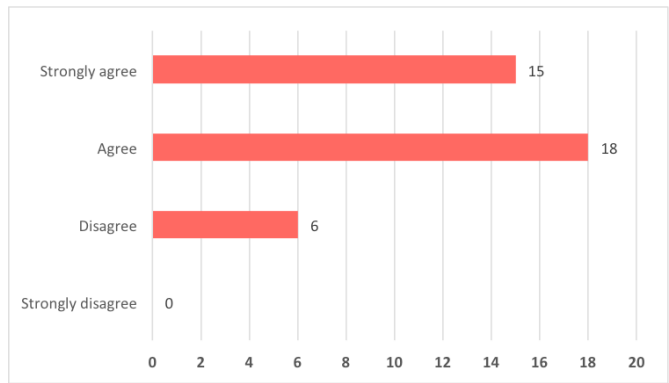


**Figure 11: I have engaged in anal sexual intercourse with another male without a condom in the last 12 months**

Figures 12 and 13 were also designed for comparison. Figure 12 shows the spread of attitudes when asking an irregular sexual partner to use a condom for anal sex. 87.18% of participants felt comfortable asking a one night stand, friend with benefits, or new sexual partner to use a condom. The proportion of participants who 'disagreed' or 'strongly disagreed' with this statement was less than Figure 13 where the respondent was engaging in anal sex with a regular partner. Nearly 85% of participants 'agreed' or 'strongly agreed' that they felt comfortable asking a regular partner to use a condom. 6 participants 'disagreed' with this statement.

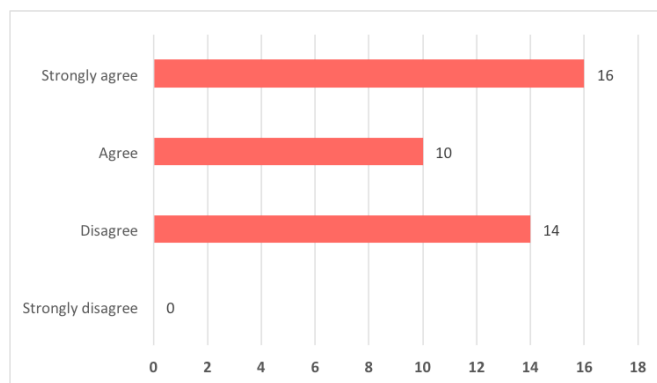


**Figure 12: I feel comfortable asking an irregular sexual partner (one night stand/friend with benefits/new sexual partner) to use a condom for anal sexual intercourse**



**Figure 13: I feel comfortable asking my partner (regular sexual partner) to use a condom for anal sexual intercourse**

The distribution of the participants' answers in Figures 12 and 13 was unexpected. Figure 12 showed a large skew of subjects stating that they 'strongly agreed' about feeling comfortable when asking an irregular partner to use condoms and there was a large difference between the distribution of 'strongly agreed' and 'agreed' responses. By contrast, Figure 13 shows the majority of participants were comfortable asking a regular partner to use a condom and there was little difference between those who 'strongly agreed' compared to 'agreed.' The distribution of participants who either 'disagreed' or 'strongly agreed' to the two statements was also relatively similar.

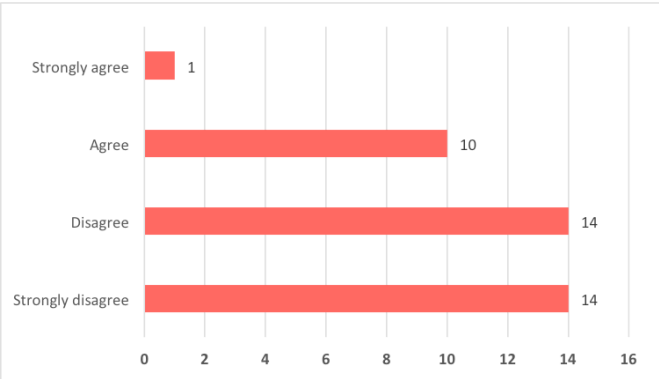


**Figure 14: If a partner refused to wear a condom, I would not engage in anal sexual intercourse (insertive or receptive)**

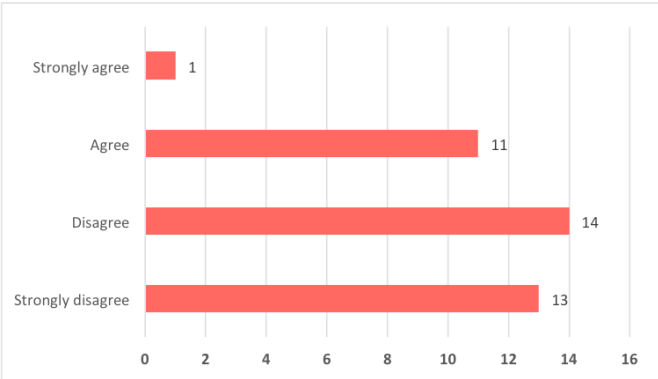
As shown in Figure 14, almost two-thirds of participants 'agreed' or 'strongly agreed' that if a partner refused to wear a condom, they would not engage in insertive or receptive anal sex. Sixteen participants 'strongly agreed' and ten 'agreed' compared to fourteen participants who 'disagreed' that they would not have anal sex if their partner would not use a condom.

Figure 15 depicts the proportion of attitudes towards whether condoms are not necessary for safe anal sexual intercourse between two men. 71.8% of participants 'disagreed' or 'strongly disagreed' with this comment. The researcher noted that interestingly, one participant 'strongly agreed' and ten participants 'agreed' with this statement. Figure 16 measures the attitudes towards the comment that if participants

did not have condoms handy, they would still have anal sex. Over two-thirds of participants ‘disagreed’ or ‘strongly disagreed’ with this statement, compared to 30.77% who ‘agreed’ or ‘strongly agreed’ to this statement. It is interesting to note that of the participants who provided a positive attitude in Figures 15 and 16, there was a great difference in the distribution between ‘strongly agree’ and ‘agree.’



**Figure 15: Condoms are not necessary for safe anal sexual intercourse between two men**

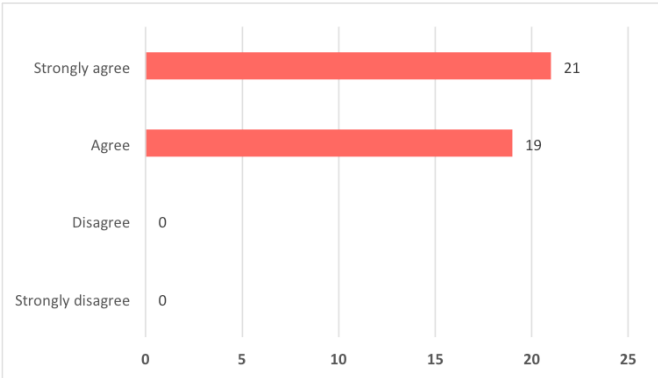


**Figure 16: If I do not have condoms handy I will still have anal sexual intercourse**

**PrEP section**

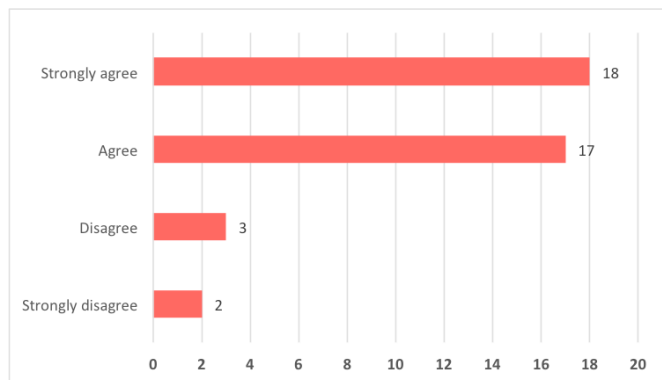
The questions in the following section were purposefully picked to address specific complications that have arisen since the emergence of PrEP. Some of these concerns include embarrassment associated with using PrEP, cost, the claim that PrEP encourages promiscuity, and adherence to the daily drug regimen and regular testing.

100% of participants shared a positive attitude towards the statement that PrEP is a good way to reduce the chances of HIV infection. Figure 17 depicts the nineteen ‘agreed’ and twenty-one ‘strongly agreed’ responses.

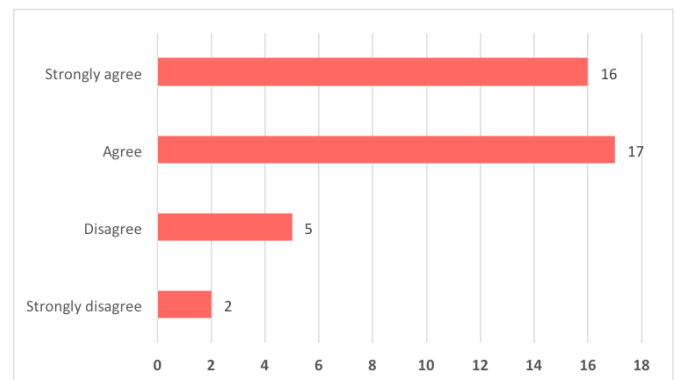


**Figure 17: Taking PrEP is a good way to reduce my chances of HIV infection**

Figures 18 and 19 show the attitudes towards discussing sexuality and PrEP with a general practitioner or doctor. As shown in Figure 18, 87.5% of participants 'strongly agreed' or 'agreed' that they feel comfortable talking to their doctor about their sexual orientation. 3 participants 'disagreed' and two participants 'strongly disagreed' with this statement. Figure 19 shows the results for the statement that respondents felt comfortable asking their doctor for PrEP. 82.5% of participants 'strongly agreed' or 'agreed' with this comment. The number of subjects that had a negative attitude towards asking their doctor for PrEP was slightly higher than the statement about discussing sexuality with a doctor.

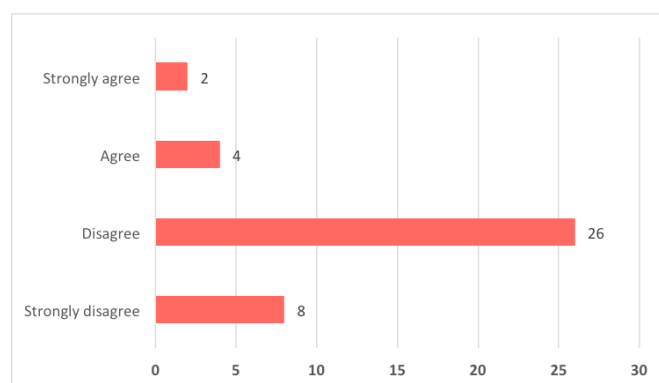


**Figure 18: I feel comfortable talking to my doctor about my sexual orientation**



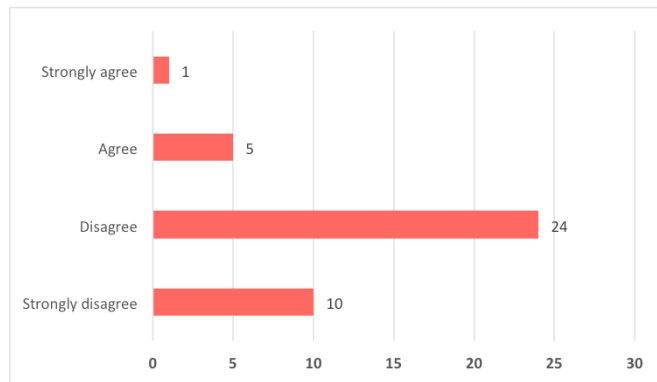
**Figure 19: I feel comfortable asking my doctor for PrEP**

The vast majority of the respondents shared a similar attitude towards taking PrEP everyday, as shown in Figure 20. 85% of respondents 'disagreed' or 'strongly disagreed' that remembering to take PrEP everyday would be too hard, while four participants 'agreed' and two 'strongly agreed.'

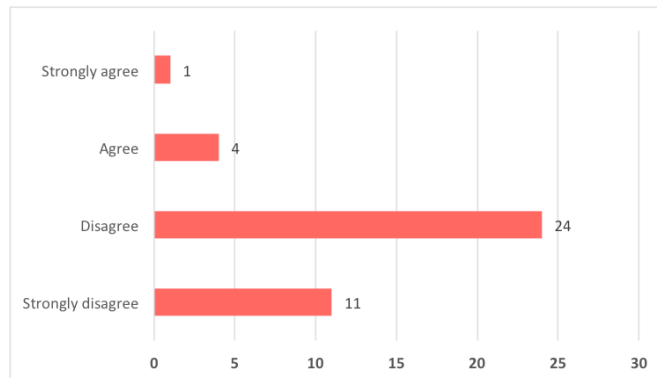


**Figure 20: Remembering to take PrEP everyday would be too hard**

Figure 21 shows the results for the statement that the requirement for regular HIV tests while using PrEP would be a hassle for potential users. 15% of participants 'strongly agreed' or 'agreed' with this comment, compared to 60% who 'disagreed' and 25% who 'strongly disagreed.'

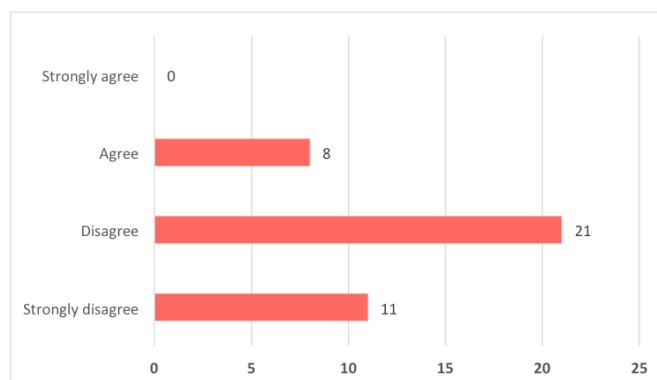


**Figure 21: The requirement for regular HIV tests while using PrEP would be a hassle**



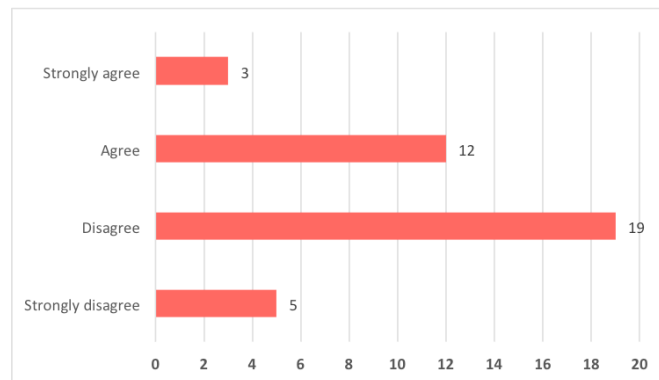
**Figure 22: Taking PrEP means I don't need to use condoms for anal sexual intercourse**

87.5% of subjects 'disagreed' or 'strongly disagreed' that taking PrEP means that they do not need to use condoms for anal sexual intercourse, as shown in Figure 22. A small minority of respondents submitted a positive answer to this statement: one participant 'strongly agreed' (2.5%) and four participants 'agreed' (10%).



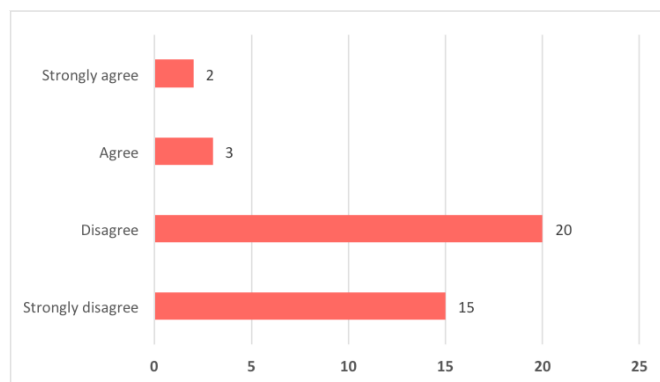
**Figure 23: People who take PrEP do it so they can have sex with lots of men**

Figure 23 displays the answers to the comment that people take PrEP so they can have sex with lots of different partners. One-fifth of participants agreed with this statement, while 52.5% of participants 'disagreed' and 27.5% 'strongly disagreed.'



**Figure 24: If I took PrEP, I would be less likely to use condoms**

Many of the advocates against PrEP argue that it will result in decreased condom use. Figure 24 depicts the spread of attitudes that if individuals took PrEP, they would be less likely to use condoms. The majority of the respondents held a negative attitude towards this statement. 3 participants 'strongly agreed' (7.69%), twelve participants 'agreed' (30.77%), nineteen participants 'disagreed' (48.72%), and five participants 'strongly disagreed' (12.82%).



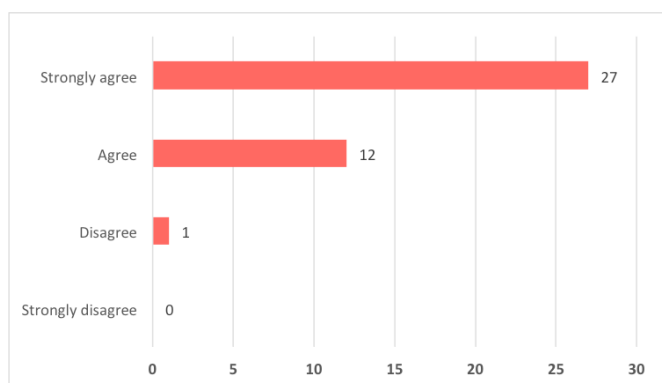
**Figure 25: I would be embarrassed if people knew I took PrEP**

Figure 25 shows the levels of embarrassment the participants associated with using PrEP. A minority (12.5%) of participants 'agreed' or 'strongly agreed' that they would be embarrassed if people knew they took PrEP. As a contrast, 87.5% 'disagreed' or 'strongly disagreed' that they would feel embarrassed about others knowing they used PrEP.

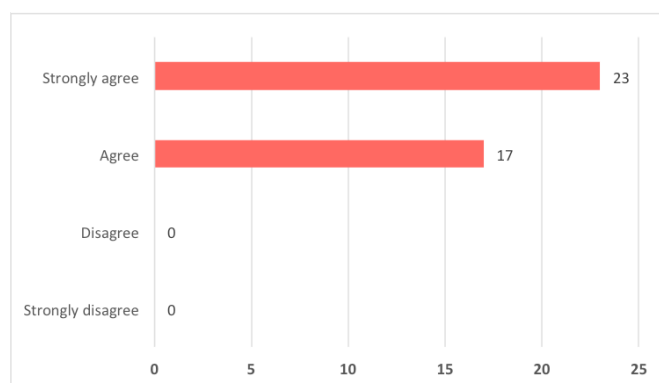
Figure 26 shows whether participants believe that PrEP should be subsidised for MSM/gay and bisexual men in New Zealand for HIV prevention. 1 participant 'disagreed' (2.5%), while 97.5% of respondents 'strongly agreed' or 'agreed' that PrEP should be subsidised for MSM/gay and bisexual men.

The final question in the PrEP section measured whether participants believe that PrEP is a worthwhile method of HIV prevention for MSM/gay and bisexual men in New Zealand. These results are shown in Figure 27. 100% of subjects responded positively to this comment; 57.5% 'strongly agreed' and 42.5% 'agreed.'





**Figure 26: PrEP should be subsidised for MSM/gay and bisexual men in NZ**



**Figure 27: PrEP is a worthwhile HIV prevention method for MSM/gay and bisexual men**

## Discussion

This survey aimed to uncover the attitudes that MSM from the Canterbury region have towards HIV, condom use, and PrEP using a 4-point Likert scale. The following discussion of the results is split into the two sections of the survey. The trends from the HIV and condom usage section have been linked back to the GAPSS/GOSS tables from 2002-2014 where possible given that this section of the survey was based on these behavioural studies. The attitudes towards PrEP have been compared to topics that were covered in the MSM section of Chapter 2. This online questionnaire served as one way to answer the overall research questions of the thesis.

### HIV and condom usage section

The results are discussed in a similar order to how they are presented above in the Results section for ease. However, it is important to note that some of the questions are not exactly the same as the GAPSS/GOSS questions, so any conclusions that have been drawn by the researcher are not entirely concrete.

Overall, it appeared that the participants generally shared similar attitudes towards HIV and using condoms, with a small proportion picking the opposing attitude. For example, 97.5% of participants agreed that it is important to get regular HIV tests, and 87.5% of respondents opposed the statement that HIV is not a serious issue for MSM. It was interesting to see that one in eight respondents 'strongly agreed' or 'agreed' that HIV is not a serious issue for MSM, particularly given the rising rates of HIV in New Zealand and that up to 80% of new infections can occur in the MSM cohort.<sup>490</sup> It is possible those participants read the negatively phrased statement incorrectly and did not mean to respond positively, or that these participants are not considered at-risk of HIV based on their behaviour. But it is also conceivable that this response is a true reflection of certain respondents' attitudes towards the risk of HIV for MSM. Results from the GAPSS and GOSS showed that 24.7% and 22.3% of participants believed that 'HIV is a less serious threat than it used to be because of new

<sup>490</sup> New Zealand AIDS Foundation, 'Life with HIV', *New Zealand AIDS Foundation*, n.d., <https://www.nzaf.org.nz/living-with-hiv/life-with-hiv/>.

treatments,' respectively.<sup>491</sup> So while the vast majority share a common attitude that HIV is a serious issue for MSM and that it is important to get regular HIV tests, there is still a small proportion that do not agree with these ideas and may need targeting by future prevention campaigns.

Knowing one's HIV status and the status of a sexual partner is important to ensure that all appropriate steps can be taken to prevent the spread of HIV. Overall, survey participants had a common attitude that it is important to share their HIV status with a sexual partner and visa versa. However, 10% of respondents 'disagreed' that it was important to tell their partners about their HIV status and 7.5% of participants 'agreed' that they did not care about their sexual partner's HIV status. These results show that future HIV prevention programmes may need to place a higher priority on the importance of sharing HIV statuses with sexual partners to ensure that both parties can avoid passing on the virus. However, it is important to consider that the proportion of participants who had alternate attitudes towards sharing HIV statuses was much smaller in this survey than the GAPSS/GOSS. The GAPSS showed that 42.2% of participants 'disagreed' and 24.8% 'strongly disagreed' that an HIV-positive man would tell them his status before they had sex. Similarly, 58.7% 'disagreed' or 'strongly disagreed' with this statement in the GOSS.<sup>492</sup> Despite the small sample size of this survey, it is important to recognise that a small minority of MSM do not see the importance in disclosing HIV statuses with sexual partners, which may need addressing in future policy initiatives.

80% of participants had engaged in anal sex with another male using a condom in the last twelve months. It is not clear whether the other one-fifth of participants had simply not engaged in anal sexual intercourse with another male within that time period, or they do not use condoms at all. However, it is more important to acknowledge that more than half of the respondents did engage in condomless sex in the last twelve months. The researcher cannot assume whether this result is because the two partners were both HIV-negative, an exclusive couple, or considered undetectable and uninfected (U=U)<sup>493</sup> because there were no further questions to discuss the background information behind these occasions. However, these results are not surprising when compared to self-reported condom use with boyfriends and casual partners in the GAPSS and GOSS. Only 26.5% and 23.6% of participants from the GAPSS and GOSS always used condoms with a boyfriend, respectively.<sup>494</sup> Unsurprisingly, self-reported condom use was higher among irregular partners, with 64.2% and 48.5% of participants stating they always use condoms with casual

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<sup>491</sup> Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) / Te Rangahau Tane Ai Tane: Basic Frequency Tables 2002-2014', 80.

<sup>492</sup> Ibid., 84.

<sup>493</sup> Body Positive, 'Undetectable Equals Uninfected (U=U)' (Media release, Auckland, N.Z, 25 January 2017), [http://www.bodypositive.org.nz/Pages/News/index\\_files/32bd70f129b9663567f52879b68340eb-38.php](http://www.bodypositive.org.nz/Pages/News/index_files/32bd70f129b9663567f52879b68340eb-38.php).

<sup>494</sup> Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) / Te Rangahau Tane Ai Tane: Basic Frequency Tables 2002-2014', 28.

partners in the GAPSS and GOSS, respectively.<sup>495</sup> Therefore, condom use should continue to remain a key part of the fight to prevent the spread of HIV.

Nearly 85% of respondents reported that they feel comfortable asking a regular partner to use a condom during sex; 87% of participants were happy to ask a casual partner to use a condom. Both of these statements generated a similar number of negative responses. However, 10% of the participants 'disagreed' and 2.5% 'strongly disagreed' that they were comfortable asking an irregular partner to use a condom. This surprised the researcher given the results discussed above from the GAPSS/GOSS where condom use between irregular partners was much higher than between regular partners. Despite the negative responses making up a small proportion of the final answers, more effort may need to be made to promote the importance of being confident and comfortable when asking any sexual partner to use a condom to prevent HIV.

One-third of the participants reported that they would still engage in anal sex even if the partner refused to wear a condom. Similarly, 30.77% of participants 'strongly agreed' or 'agreed' that they would still have sex even if they did not have condoms with them. These results seem quite high given the importance of using condoms to prevent HIV, particularly when compared to related attitudinal questions from GAPSS and GOSS. These studies showed that in general, attitudes towards condoms were relatively positive; 95.1% of GAPSS and 93.9% of GOSS participants 'strongly agreed' or 'agreed' that condoms are okay as part of sex.<sup>496</sup> Only 11.1% and 14.6% of respective GAPSS and GOSS respondents stated that they would rather risk HIV transmission than use a condom during anal sex,<sup>497</sup> which is lower than the 35% of MSM from this survey who would still engage in anal sex even if a partner refused to wear condoms. Furthermore, 17.7% and 19.9% of participants from the 2014 GAPSS and GOSS 'strongly agreed' or 'agreed' that they would not use condoms if a sexual partner didn't want to use them, respectively.<sup>498</sup> Combining the results from this GAPSS/GOSS question and the respondents from the Canterbury survey, between one in three and one in five participants are happy to engage in sex even if their partner does not want to use a condom. Despite the NZAF's claims that around 20% of MSM will not use condoms at all (these MSM are the ideal candidates for PrEP),<sup>499</sup> the figures from this survey seem to be much higher than they should be. It is possible that those participants who would still engage in anal sex if the partner refused to use a condom are practicing safe sex through alternate methods, such as serosorting. Regardless of the context, these results show an inconsistency from the GAPSS/GOSS research, which may need further investigation.

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<sup>495</sup> Ibid., 31.

<sup>496</sup> Ibid., 81.

<sup>497</sup> Ibid., 82.

<sup>498</sup> Ibid., 91.

<sup>499</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

More than one in four participants ‘agreed’ or ‘strongly agreed’ with the statement that condoms are not necessary for safe sex. This proportion is higher than expected and is worrying given that condoms have been the primary HIV prevention method since the 1980s. New Zealand’s condom culture between MSM is extremely important,<sup>500</sup> and self-reported knowledge of condoms is very high between MSM in the GAPSS/GOSS. Results from 2006 and 2008 surveys show that 98.4% of GAPSS participants and 96% of GOSS participants knew that anal sex without a condom has a high risk of HIV transmission.<sup>501</sup> Given that the vast majority of GAPSS/GOSS participants have knowledge about the importance of condoms, it is very surprising that 28.2% of the Canterbury MSM believe that condoms are not necessary for safe anal sex between two men. Once again, it is possible that there is context behind these answers that the researcher cannot assume to know. Furthermore, there is a chance that participants were thinking of PrEP as an option for safe sex instead of condoms, due to the topic of the survey. The finer details of this result are not known, and it is not possible for the researcher to make sweeping generalisations due to the limited external validity. Condom usage will never be at 100%, though there may need to be greater educational campaigns that promote the importance of condoms for safe sex between MSM.

### PrEP section

The trends from this survey are compared to the wider literature that focuses on MSM and PrEP, which was presented in Chapter 2. As above, the results are discussed in relatively the same order as they were shown in the Results section, but are grouped by the related concerns that were discussed in the literature review.

Most importantly, the overall attitudes of the participants towards PrEP are positive and generally shared. 100% of participants were supportive of the statement that taking PrEP is a good way to reduce one’s chance of HIV infection. Furthermore, 100% of MSM surveyed responded positively that PrEP is a worthwhile HIV prevention method for MSM/gay and bisexual men. This is the most important result from the survey because despite the small sample size compared to the GAPSS/GOSS or studies presented in Chapter 2, it cannot be denied that Canterbury MSM are interested in and supportive of PrEP as a new HIV biomedical prevention technology. Given that this is the first study measuring attitudes towards PrEP in New Zealand, the researcher is unable to compare these results to other studies. However, it is worth noting that other studies around the world reported MSM’s willingness to use PrEP between 28.2%<sup>502</sup> and 86.6%.<sup>503</sup> The support for the statements that ‘PrEP is a worthwhile HIV prevention method for MSM/gay and bisexual men,’ and ‘Taking PrEP

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<sup>500</sup> Ibid.

<sup>501</sup> Saxton et al., ‘Gay Auckland Periodic Sex Survey (GAPSS) and Gay men’s Online Sex Survey (GOSS) / Te Rangahau Tane Ai Tane: Basic Frequency Tables 2002-2014’, 76.

<sup>502</sup> Holt et al., ‘Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men’.

<sup>503</sup> Wheelock et al., ‘Are Thai MSM Willing to Take PrEP for HIV Prevention?’

is a good way to reduce my chances of HIV infection' do not mean that all participants would be willing to use PrEP. Similarly, these surveys that measured willingness to use PrEP at 28.2% and 86.6% took place in 2012 and 2013, and the promotion of PrEP has increased dramatically since then. Regardless, it is crucial to note the total support from all of the Canterbury MSM for PrEP.

However, PrEP will not be successful if potential PrEP-users are not comfortable talking with their doctor about the drug. 87.5% of participants were comfortable discussing their sexual orientation with their doctor, which is imperative if patients are to receive adequate healthcare and relevant advice about preventing HIV. However, it is important to note that these figures are higher than the 2014 GAPSS/GOSS. Only 60.4% and 42.8% of GAPSS and GOSS participants, respectively, had told their regular doctor about their sexuality.<sup>504</sup> 82.5% of MSM were comfortable asking their doctor for PrEP. Furthermore, 87.5% of respondents would not be embarrassed if people knew they took PrEP, compared to 12.5% of participants who would be. When paralleled to other studies, the 17.5% of MSM who were not comfortable asking their doctor for PrEP and 12.5% of MSM who would be embarrassed that others knew they used PrEP is in the middle of the range; other studies reported embarrassment levels ranging from 8.5%<sup>505</sup> to 25%.<sup>506</sup> Given the recent increase in PrEP's promotion and use, it is not surprising that the proportion of MSM who are embarrassed to ask for PrEP is slightly lower than previously recorded. It is also assumed that if individuals are not comfortable discussing their sexuality with their doctor then they would not want to discuss PrEP as a potential HIV prevention technique either, due to embarrassment about their sexual practices. Despite the relatively low levels of embarrassment about discussing one's sexuality (12.5%) and PrEP (17.5%) with their doctor, future PrEP implementation policies need to ensure that individuals feel supported to talk about such topics with doctors.

One of the most important aspects to effective PrEP use is remembering to take the medication every single day and having regular HIV tests. 85% of Canterbury MSM said that the requirement for regular HIV tests while using PrEP would not be a hassle, compared to 15% who did think it would be. Having regular HIV tests is important, as it should ensure that patients do not continue to take PrEP after seroconversion, which can lead to antiretroviral resistance. Likewise, 85% of the survey participants said that remembering to take PrEP everyday would not be too hard, while 15% of respondents thought that it would be. This result is much lower than a study of MSM and TGW in New York City, where 54.9% of the participants saw taking a pill everyday as a barrier to the drug.<sup>507</sup> The difference between respondents who were dissuaded by the need to take PrEP in Canterbury compared to New York City is considerable, and reflects

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<sup>504</sup> Saxton et al., 'Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) / Te Rangahau Tane Ai Tane: Basic Frequency Tables 2002-2014', 63.

<sup>505</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>506</sup> Eisingerich et al., 'Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups'.

<sup>507</sup> Golub et al., 'From Efficacy to Effectiveness'.

positively on potential PrEP-users in New Zealand. Adherence is a crucial part of PrEP implementation because it ensures that individuals have the best chance against HIV transmission and can prevent antiretroviral resistance. Thus, the high percentage of MSM from Canterbury who do not believe that the daily regime of PrEP is a burden shows great promise when implementing the drug in New Zealand.

PrEP is often targeted at the high-risk MSM that do not use condoms regularly<sup>508, 509</sup> but continuing to still use condoms is an important part of using PrEP because they prevent STIs. A drop in condom use while taking PrEP is known as risk compensation. Of the MSM surveyed, only 10% of participants 'agreed' and 2.5% 'strongly agreed' taking PrEP means individuals do not need to use condoms. However, the proportion of respondents who said they would be less likely to use condoms when taking PrEP was significantly higher. Nearly two-fifths of MSM said they would be less likely to use condoms when taking PrEP, while 61.54% 'disagreed' or 'strongly disagreed' with this statement. It is clear that participants know they still need to use condoms while taking PrEP but more are willing to admit that they might not always use additional protection. Overseas studies showed self-reported predicted risk compensation through reduced condom use as 8%,<sup>510</sup> 23.1%,<sup>511</sup> and 44.6%.<sup>512</sup> Furthermore, 10.4% of Thai MSM<sup>513</sup> and 43.7% of African-American MSM<sup>514</sup> were not willing to take PrEP if they were also required to use condoms at the same time. It is clear the proportion of Canterbury MSM who predicted less condom use while taking PrEP is above the average rate of risk compensation described in international studies, despite the majority acknowledging the importance of wearing condoms when using PrEP. Combining both prevention methods provides MSM with their best chance to avoid transmission, as recent deterministic modelling suggests that protection against HIV is highest when MSM pair PrEP with condoms.<sup>515</sup> Therefore, any future policy for PrEP should place a strong emphasis on combining both HIV prevention methods, not just to ensure that STI rates do not increase dramatically, but also to maximise the number of potential HIV infections prevented. The MSM from Canterbury showed that while knowledge about safe sex is high, more resources should be put into making sure individuals are using condoms while taking PrEP.

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<sup>508</sup> AVAC, 'What Does PrEP Mean for Condom Use?', AVAC, 5 August 2014, <http://www.avac.org/blog/what-does-prep-mean-condom-use>.

<sup>509</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>510</sup> Holt et al., 'Willingness to Use HIV Pre-Exposure Prophylaxis and the Likelihood of Decreased Condom Use Are Both Associated with Unprotected Anal Intercourse and the Perceived Likelihood of Becoming HIV Positive among Australian Gay and Bisexual Men'.

<sup>511</sup> Grov et al., 'Willingness to Take PrEP and Potential for Risk Compensation Among Highly Sexually Active Gay and Bisexual Men'.

<sup>512</sup> Golub et al., 'From Efficacy to Effectiveness'.

<sup>513</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>514</sup> Eaton et al., 'Psychosocial Factors Related to Willingness to Use Pre-Exposure Prophylaxis for HIV Prevention among Black Men Who Have Sex with Men Attending a Community Event'.

<sup>515</sup> Dawn K. Smith, Jeffrey H. Herbst, and Charles E. Rose, 'Estimating HIV Protective Effects of Method Adherence with Combinations of Preexposure Prophylaxis and Condom Use among African American Men Who Have Sex with Men', *Sexually Transmitted Diseases* 42, no. 2 (February 2015): 88–92.

Stigmatisation and labels have been associated with HIV since its emergence in the 1980s. As PrEP gains traction as a new biomedical HIV prevention method, critics have often accused the drug as a way for users, particularly MSM, to be promiscuous. PrEP-users have been called ‘Truvada whores.’<sup>516, 517</sup> This label has stigmatised the drug and may have contributed to the slow uptake of PrEP after it was first released. One-fifth of MSM from Canterbury ‘agreed’ that people take PrEP to have sex with lots of men, while 52.5% ‘disagreed’ and 27.5% ‘strongly disagreed’. While it is important to note that the majority of the sample did not agree, a minority still believed the labels associated with PrEP. Unfortunately for PrEP-users, the stigma and labels connected to the drug are often out of their control. Various studies from around the world explored at how stigma and labels impacted potential users. 28.8% of MSM surveyed in New York City had concerns that if they were seen taking PrEP, others would think they were HIV-positive.<sup>518</sup> African-American MSM iterated the same concerns in a different study.<sup>519</sup> There were also concerns that outsiders might assume individuals took PrEP to engage in risky behaviour regularly, particularly if there was a lot of HIV stigmatisation in the community.<sup>520, 521</sup> In order to support potential PrEP-users and dispel stigma and labels, future policy programmes must include accurate education about the medication. Furthermore, PrEP-users should feel comfortable taking the drug without backlash or judgement about their actions from others. Thus, more emphasis needs to be placed on the fact that while PrEP does allow for safer sex between men, it does not promote promiscuity any more than condoms.

The cost of PrEP is a commonly cited barrier to uptake, and has been discussed in-depth in both Chapters 1 and 2. 97.5% of the MSM surveyed were in favour of subsidised PrEP for MSM in New Zealand. The question did not state whether it was generic or branded PrEP, yet it is clear that MSM see PrEP as a key role in HIV prevention and want the government and PHARMAC to provide monetary support. The general trend in academic literature is that PrEP would be more popular if it was cheaper, as the cost was a barrier to use.<sup>522, 523, 524</sup> Numerous studies show most MSM are happy to pay \$20-\$25 per month for PrEP.<sup>525, 526, 527, 528</sup> Although it is not possible

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<sup>516</sup> Calabrese and Underhill, ‘How Stigma Surrounding the Use of HIV Pre-Exposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize “Truvada Whores”’.

<sup>517</sup> Haire, ‘Preexposure Prophylaxis-Related Stigma’.

<sup>518</sup> Eisingerich et al., ‘Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups’.

<sup>519</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’.

<sup>520</sup> Ibid.

<sup>521</sup> Kubicek, Arauz-Cuadra, and Kipke, ‘Attitudes and Perceptions of Biomedical HIV Prevention Methods’.

<sup>522</sup> Mimiaga et al., ‘Preexposure Antiretroviral Prophylaxis Attitudes in High-Risk Boston Area Men Who Report Having Sex With Men’.

<sup>523</sup> Underhill et al., ‘Could FDA Approval of Pre-Exposure Prophylaxis Make a Difference?’

<sup>524</sup> Smith et al., ‘Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)’.

<sup>525</sup> Galindo et al., ‘Community Member Perspectives from Transgender Women and Men Who Have Sex with Men on Pre-Exposure Prophylaxis as an HIV Prevention Strategy’.



to know how much the Canterbury MSM would be willing to pay for a monthly prescription of PrEP, a decrease in the price of generic PrEP would undoubtedly increase access for more potential users. Making PrEP cheaper is imperative, especially in regards to minimising all potential inequalities that can occur in healthcare.<sup>529, 530</sup> However, as with everything in public health, there is always a winner and a loser: when funding is given to one healthcare initiative, it is often taken from another. Any subsidies would be examined as a part of an in-depth economic analysis by PHARMAC. Therefore, it is fundamental that future PrEP policies take into consideration cost and subsidies of the drug, particularly in terms of problems of access and inequality.

### Conclusion

This online, anonymous survey aimed to uncover and analyse the attitudes that MSM from around Canterbury had towards HIV, condom use, and PrEP. The survey used a 4-point Likert scale to measure attitudes, and despite the exploratory nature of the results, they provide a good starting point for PrEP policy. The survey of MSM from Canterbury found that 100% of participants agreed that PrEP is a worthwhile HIV prevention method for MSM, 100% agreed that PrEP is a good way to reduce one's chances of HIV infection, and 97.5% believe that PrEP should be subsidised in New Zealand. However, future policy recommendations need to take into consideration the following factors: adherence to the daily regime; embarrassment about one's sexuality and taking PrEP; preventing antiretroviral resistance through regular HIV tests; promotion of simultaneous PrEP and condom use; stigmatisation and labels associated with the drug; and the cost of PrEP. All of these issues have been raised in the wider literature based on studies of MSM and were presented in previous chapters. Overall, the results of attitudes towards PrEP are not overly surprising; none of the questions had data that showed a distinct skew away from overseas trends. While this does not help guide policy in a particular direction, it provides a sense of comfort that the issues and controversies that occurred overseas are similar in New Zealand. Thus, the policy implementation that is presented in Chapter 5 can take inspiration from other studies and policies on PrEP.

The results from the HIV and condom usage section were less uniform and predictable than those in the PrEP section. In general, it seemed that knowledge about HIV and using condoms was correct. However, there were some outlying attitudes that the researcher noted, such as the 12.5% who did not think HIV was a serious issue for MSM; one in ten participants did not think it was important to disclose their HIV status

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<sup>526</sup> Smith et al., 'Attitudes and Program Preferences of African-American Urban Young Adults about Pre-Exposure Prophylaxis (PrEP)'.

<sup>527</sup> Wheelock et al., 'Are Thai MSM Willing to Take PrEP for HIV Prevention?'

<sup>528</sup> Kubicek, Arauz-Cuadra, and Kipke, 'Attitudes and Perceptions of Biomedical HIV Prevention Methods'.

<sup>529</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>530</sup> Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group.

with sexual partners; and more than half of the participants who engaged in anal sex without a condom in the last twelve months. Furthermore, 35% of respondents would still have sex even if their partner refused to wear a condom and 28.2% of MSM thought that condoms are not necessary for safe anal sex between two men. It is clear that there will never be 100% condom use, but some of the attitudes towards condoms shared by the Canterbury MSM indicate that more work needs to be done to endorse the importance of safe sex and preventing HIV transmission. The results from the HIV and condom use section provide a good starting point for future PrEP policies, as condom use must be promoted as essential for PrEP-users.

There are numerous limitations to this survey. Firstly, as discussed throughout Chapter 3, the use of non-probability sampling reduces the external validity of the results. This sample is not representative of the LGBTI population; while the sample size of forty-two is technically a large statistical sample, it is clear that this is a minute proportion of the New Zealand's LGBTI population. During one interview, the researcher was told by a prominent HIV researcher that if you "get 50 or 30 respondents... you can't do an awful lot with that."<sup>531</sup> Because the survey was only promoted online using social media and through one LGBTI email group of tertiary students, it is not surprising that more than half of the participants were in the 18-24 years age bracket. Unfortunately due to time and funding constraints, the promotion of the survey online without offering an incentive was the only way the researcher could do the research. If the researcher did have access to funding, there would have been the option to pay for the promotion on the survey on further channels like dating apps to gain a larger sample. Furthermore, using dating apps could have gained a greater portion of middle-aged MSM so younger participants are not overrepresented.

Similarly, the use of a Likert scale provides a quick overview of general attitudes towards certain statements but it does not provide any context to the answers. The researcher could only infer why certain options had been picked, particularly with questions where it was assumed that the answers should be similar. For example, more than one in four participants thought that condoms are not necessary for safe anal sex between two men. Many different interpretations could be made for this result, but the nature of a Likert scale means that there is no context to make any valid assumptions.

If the researcher were to promote this survey again, there would be more specific questions added to the section about PrEP use. For example, questions could include 'Would you pay \$X for generic PrEP per month?', and 'Would mild side effects that last around a month deter you from using PrEP?' These more focused questions would enable the researcher to gain a better understanding of what aspects may persuade or deter potential PrEP-users from using this medication.

Despite the limited generalisability, the small sample size compared to other behavioural studies, and the low external validity, this survey still achieved the research aim of uncovering attitudes held by MSM about PrEP. While it is important to

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<sup>531</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

use these results with caution when designing a policy for PrEP, it is also imperative to note that this is the first survey of its kind in New Zealand. This survey offers an insight into a small portion of MSM, and provides real-world data that could be used to drive an empirical policy for PrEP. With appropriate resources, further evidence-based research initiatives could broaden the sample beyond the Canterbury region with alternate methods of sampling, such as online advertisements. This would gather a bigger and more diverse sample, which offers a better understanding of attitudes towards PrEP, HIV, and health behaviour among at-risk groups in New Zealand. More data could also provide better quality evidence to use when designing health policies. The subsequent chapter collates the results from the multiple, mixed-methods research and presents a case for PrEP policy in New Zealand, including a Base Case to justify the need for this new policy. This policy follows Carol H. Weiss's problem-solving model.

## Chapter 5: PrEPared Against HIV: 2.0

*PrEPared Against HIV: 2.0, New Zealand's first policy for PrEP implementation for men who have sex with men at-risk of HIV.*

Following Carol H. Weiss's problem-solving model, this chapter presents a policy for PrEP for MSM in New Zealand. The chapter uses a Base Case to analyse the current situation and explore the impact of using the existing HIV prevention policy compared to an alternative recommendation, such as a new policy. The Base Case suggests that the government needs to prioritise HIV prevention efforts over increased access for treatment for HIV-positive individuals. The conclusion of the Base Case is to implement PrEPared Against HIV: 2.0 as part of a multi-pronged HIV prevention package.

### Introduction

Policy is defined as “a set of actions taken by an administration to control the system, to help solve problems within it, or to obtain benefits from it.”<sup>532</sup> Much of policy that is undertaken is a result of a ‘policy problem,’ which is described as certain “tensions, barriers, and challenges” that are linked to a particular policy or situation.<sup>533</sup> As problems obviously differ, so do the types of policies that are used to solve such issues. The policy presented in this chapter for the implementation of PrEP in New Zealand follows Carol H. Weiss's problem-solving model<sup>534</sup> and is a population-focused health policy.<sup>535</sup> The policy is called PrEPared Against HIV: 2.0. The problem-solving model uses “empirical evidence and conclusions to help solve a policy problem” that currently exists.<sup>536, 537</sup> Weiss's model states that there is a level of uncertainty regarding each policy problem that requires further, high-quality research to formulate an effective solution.<sup>538</sup> The model suggests that it does not matter whether the research is primary or secondary, but primary research is more likely to have “direct and immediate applicability and will be used for decision making.”<sup>539</sup> Through the multiple, mixed methods design of this thesis, the author has been able to use qualitative and quantitative methods to specifically reduce uncertainty<sup>540</sup> regarding PrEP in New Zealand for men who have sex with men (MSM). Following the problem-solving model, the findings from the interviews, attitude scaling survey, and document

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<sup>532</sup> W. E. Walker et al., ‘Defining Uncertainty: A Conceptual Basis for Uncertainty Management in Model-Based Decision Support’, *Integrated Assessment* 4, no. 1 (1 March 2003): 6.

<sup>533</sup> Erica Bell, *Research for Health Policy* (Oxford ; New York: Oxford University Press, 2010), 5.

<sup>534</sup> Carol H. Weiss, ‘The Many Meanings of Research Utilization’, *Public Administration Review* 39, no. 5 (1979): 426–31.

<sup>535</sup> John N. Lavis et al., ‘Examining the Role of Health Services Research in Public Policymaking’, *The Milbank Quarterly* 80, no. 1 (2002): 125–54.

<sup>536</sup> Weiss, ‘The Many Meanings of Research Utilization’, 1979, 427.

<sup>537</sup> Carol H. Weiss, ‘The Many Meanings of Research Utilization’, in *Social Research Method: A Reader*, ed. Clive Seale, 1st ed., Routledge Student Readers (London; New York: Routledge, 2004), 447.

<sup>538</sup> Weiss, ‘The Many Meanings of Research Utilization’, 1979, 427.

<sup>539</sup> *Ibid.*, 428.

<sup>540</sup> *Ibid.*

analysis inform the final recommendation, PrEPared Against HIV: 2.0. As this is a Master's thesis, PrEPared Against HIV: 2.0 will not be implemented. However, this policy may be useful to parties interested in developing a PrEP programme in New Zealand and researchers conducting case studies in other national contexts.

Lavis et al. state that there are four defined policies: functional, intentional, population-focused, and programmatic. By this theory, this policy is deemed a population-focused policy, which is known to feature "statements and actions that benefit or harm specific groups."<sup>541</sup> As an HIV prevention method, PrEP has been recommended for numerous population groups that are considered at-risk of contracting the virus. This policy is solely focused on providing PrEP for MSM, as mentioned multiple times, given their high prevalence of overall HIV infections each year (up to 80%) in New Zealand. As a result, PrEPared Against HIV: 2.0 can be characterised as a population-focused policy, as it provides "actions that target" MSM.<sup>542</sup> However, it is important to justify the need for a PrEP policy before discussing this new programme.

### **The Base Case – Why should we provide PrEP?**

It is commonplace in policy theory and development to begin with a problem definition to define and rationalise a topic.<sup>543</sup> Problem definitions offer policymakers or other relevant personnel the opportunity to provide a clear outline of a topic, and envisage the steps that could be taken to reach a future goal.<sup>544</sup> However, most policy that is written does not come as a chapter of a Master's thesis. The previous four chapters of this thesis have introduced PrEP as an HIV prevention tool, explored the various controversies and issues linked to the drug, and discussed the attitudes that MSM from Canterbury have towards PrEP. Therefore, it is unnecessary to provide any sort of problem definition that explains the need for PrEP implementation. However, it is important to remember that problem definitions are inherently political because the very description of the issue at hand can greatly impact its success when presented to a government.<sup>545</sup> Thus, it is imperative that the logic and rationale behind why we should provide PrEP, and why the PrEPared Against HIV: 2.0 policy matters, is clearly justified. This is done below.

#### **Base Case**

The Base Case is a policy method that describes "the current situation... [and] spells out the costs of doing nothing and the criteria against which alternative courses of

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<sup>541</sup> Lavis et al., 'Examining the Role of Health Services Research in Public Policymaking', 128.

<sup>542</sup> Bell, *Research for Health Policy*, 5.

<sup>543</sup> David Dery, 'Introduction', in *Problem Definition in Policy Analysis*, Studies in Government and Public Policy (Lawrence, Kan: University Press of Kansas, 1984), 2.

<sup>544</sup> Rittel and Webber, 1973, p. 159, as cited in David Dery, 'What Is a Problem, so That It May Be Usefully Defined?', in *Problem Definition in Policy Analysis*, Studies in Government and Public Policy (Lawrence, Kan: University Press of Kansas, 1984), 23.

<sup>545</sup> David A. Rochefort and Roger W. Cobb, 'Preface', in *The Politics of Problem Definition: Shaping the Policy Agenda*, Studies in Government and Public Policy (Lawrence, Kan: University Press of Kansas, 1994), vii.

action should be evaluated.”<sup>546</sup> The rationale behind documenting the Base Case is apparent: by clearly articulating “the Base Case (current situation)... the nature (dimensions) and the extent (quantity) of the problem” become clear for decision-makers.<sup>547</sup> In this context, the Base Case will be used to provide justification as to why continuing the current HIV prevention policies (not doing anything new) is the least preferred option and thus, PrEP implementation is crucial.

In September 2016, Associate Professor Nigel Dickson, former Director of the AIDS Epidemiology Group, provided an explanation of the recent rise in HIV (2011-onwards) in an interview. Dickson said,

The numbers have certainly went up quite steeply in the early 2000s. Since then I think it's still quite difficult to say exactly what the overall trend has been since that time. Yes, it looks like the numbers might have gone up slightly, but then we have to ask, have the number of MSM changed? Has the population changed? And things like that. So I think certainly the numbers have increased since the late '90s, possibly increased slowly over the last ten years or so, but whether that indicates a true increase... Probably over time will indicate a change in incidence.<sup>548</sup> [sic]

As an epidemiologist, Dickson was very careful to state any sort of claim that the rates of HIV were truly increasing in New Zealand. Dickson's caution was justified, as he argued that yearly fluctuations of infections do not give the full picture of true epidemiological trends: “that's why I'm trying to fend off the definitive answers of up or down [infection rates].”<sup>549</sup>

However, at the end of May 2017, the AIDS Epidemiology Group released that in 2016, there were 244 new HIV diagnoses (20 more infections than 2015).<sup>550, 551</sup> The results were hugely important, as the number of diagnosed HIV infections in 2016 was the highest number of infections since records begin in 1985.<sup>552</sup> After releasing the 2016 figures, the AIDS Epidemiology Group finally announced “the persisting increase in diagnosis of recent infections, along with the increase in total diagnoses suggests a true rise in incidence in recent years.”<sup>553</sup> As a result, it was clear that the rising number of HIV infections each year were not just fluctuations or a result of a changing population, but a real increase in HIV in New Zealand.

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<sup>546</sup> Ann Majchrzak and M. Lynne Markus, *Methods for Policy Research: Taking Socially Responsible Action*, 2nd Edition, Applied Social Research Methods Series (Thousand Oaks, Calif: SAGE Publications, Inc, 2014), 98.

<sup>547</sup> Ibid.

<sup>548</sup> Nigel Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group, interview by Alice Hartley, Skype, 7 September 2016.

<sup>549</sup> Ibid.

<sup>550</sup> AIDS Epidemiology Group, ‘AIDS - New Zealand’, Newsletter (Dunedin, New Zealand: AIDS Epidemiology Group, Dunedin School of Medicine, University of Otago, May 2017), <http://dnmeds.otago.ac.nz/deptsments/psm/research/aids/newsletters.html>.

<sup>551</sup> Joanna MacKenzie, ‘Record Number of People Diagnosed with HIV’, *Radio New Zealand*, 31 May 2017, Online edition, sec. Health, <http://www.radionz.co.nz/news/national/331951/record-number-of-people-diagnosed-with-hiv>.

<sup>552</sup> Ibid.

<sup>553</sup> AIDS Epidemiology Group, ‘AIDS - New Zealand’, 1.

The information provided by the AIDS Epidemiology Group also shows that the infections that were tracked in 2016 were not just a result of increased testing as some experts thought. When interviewed in August 2016, Sean Kelly attributed the rising rates of HIV to increased testing because

By testing more we are inevitably going to uncover more positive results so I think that there will be a peak... the numbers have gone up and I think that will peter off as our testing numbers continue to increase.<sup>554</sup>

As mentioned in Chapter 1, the progression of an HIV infection can be determined by the individual's CD4 cell count: anything above 500 CD4 cells per cubic millilitre (cells/ml<sup>3</sup>) is considered a new infection. Once the CD4 cells drop to below 200/ml<sup>3</sup>, the infection has progressed to AIDS. If Kelly's claim that the increased testing had led to uncovering old infections was correct, then the majority of the HIV infections found each year should be old infections with low CD4 cell counts.<sup>555</sup> However, in 2016, 48% of the individuals with HIV were found to have more than 500 CD4 cells/ml<sup>3</sup> of blood, and a further 26% had a CD4 cell count of 350-499.<sup>556</sup> Therefore, given that nearly 75% of new infections are considered recent based on the CD4 cell count, it is apparent that the HIV rates in New Zealand are increasing.<sup>557</sup>

With a general consensus that the rate of HIV infections is definitely increasing in New Zealand, it is important to consider the cost of treating an HIV-positive individual for the Base Case. It is well-known that antiretroviral therapy (ART) is expensive; Peter Saxton from the Gay Men's Sexual Health Research Group states that "for every 20 year old infected with HIV, it's going to cost the taxpayer around \$800,000 over their lifetime"<sup>558</sup> (it is interesting to note that the New Zealand AIDS Foundation (NZAF) estimates this lifetime cost at around \$400,000 per person<sup>559</sup>). Saxton argues that it is more cost-effective to invest money into HIV prevention and surveys, like the Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS), rather than cutting the prevention budget to pay for ART for HIV-positive individuals.<sup>560, 561</sup> The cost of HIV treatment in New Zealand has doubled in the last five years, and cost \$32 million in 2016.<sup>562, 563</sup> As the number of HIV-positive

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<sup>554</sup> Sean Kelly and Akira Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office, interview by Alice Hartley, Face-to-face, 24 August 2016.

<sup>555</sup> Mark Fisher, Interview with Mark Fisher, Director of Body Positive, interview by Alice Hartley, Skype, 20 September 2016.

<sup>556</sup> AIDS Epidemiology Group, 'AIDS - New Zealand'.

<sup>557</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>558</sup> MacKenzie, 'Record Number of People Diagnosed with HIV'.

<sup>559</sup> Joe Rich, 'RE: Updates about PrEP in New Zealand', 26 April 2017.

<sup>560</sup> Kathryn Ryan, 'Why Is Govt Not funding "vital" HIV Survey?', Online, *Radio New Zealand* (Radio New Zealand, 21 March 2017), <http://www.radionz.co.nz/national/programmes/ninetoonoon/audio/201837389/why-is-govt-not-funding-vital-hiv-survey>.

<sup>561</sup> MacKenzie, 'Record Number of People Diagnosed with HIV'.

<sup>562</sup> Ryan, 'Why Is Govt Not funding "vital" HIV Survey?'

<sup>563</sup> Rich, 'RE: Updates about PrEP in New Zealand'.



individuals rise and their life expectancy continues to increase due to successful ARTs, it is almost certain that the cost of HIV will continue to skyrocket.

It is evident that the current New Zealand government does not see HIV prevention as a priority, which is shown by the recent cease in funding for the GAPSS/GOSS behavioural studies and budget cuts for the NZAF.<sup>564</sup> Furthermore, the NZAF's annual funding of \$4.5 million from the government has never increased or been adjusted for inflation.<sup>565</sup> In June 2017, the government's pharmaceutical agency PHARMAC announced that the CD4 cell threshold would be removed on July 1<sup>st</sup>, meaning that HIV-positive people will finally be able to access ART as soon as they are diagnosed.<sup>566</sup> All those who campaigned for years welcomed this change enthusiastically and it is important to acknowledge how significant this is. However, the government is actually increasing their bill for HIV treatment by allowing more people to access ART earlier. This approach is the ambulance at the bottom of the cliff, rather than the fence at the top of the cliff; the government has once again chosen to invest further money into treatment rather than prevention.

However, this must change. This Base Case model strongly suggests that the cost of doing nothing new for HIV prevention is not the best option. In June 2017, the World Health Organization (WHO) announced PrEP on its Model List of Essential Medicines 2017. This list is published as the "guiding principle" for countries' health policies.<sup>567</sup> PrEP can no longer be ignored as an HIV prevention tool, and it is imperative that more money is put into prevention, as it is undoubtedly more cost-effective in the long run. More importantly, the confirmation that HIV rates are rising in New Zealand and the record number of new HIV diagnoses in 2016 suggest that current prevention efforts are not working to their maximum capacity. It is time for the government to invest in the health of its citizens and to try something new: PrEPared Against HIV: 2.0.

### ***Justification for PrEPared Against HIV: 2.0***

It has been argued that the policy problems that are worth focusing on are likely to be the most complicated and hardest to solve,<sup>568</sup> but it is imperative that this does not discourage policymakers from making courageous moves for the sake of more effective policy. Reducing HIV infections in New Zealand will not be easy, but it will be

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<sup>564</sup> Ian Pattison, 'Health Budget Cut-Backs Slash NZAF Services', *Rainbow Labour*, 9 March 2017, [http://www.rainbowlabour.org.nz/health\\_budget\\_cut\\_backs\\_slash\\_nzaf\\_services](http://www.rainbowlabour.org.nz/health_budget_cut_backs_slash_nzaf_services).

<sup>565</sup> GayNZ.com, 'Ministry in Dark on HIV Prevention Cost Benefits', *GayNZ.com*, 8 February 2017, Online edition, sec. New Zealand Daily News, [http://www.gaynz.com/articles/publish/2/printer\\_19200.php](http://www.gaynz.com/articles/publish/2/printer_19200.php).

<sup>566</sup> Perry Wilton, "'Win-Win" as Pharmac Drops Restrictions on HIV Medication', *Radio New Zealand*, 23 June 2017, Online edition, sec. Health, <http://www.radionz.co.nz/news/national/333634/win-win-as-pharmac-drops-restrictions-on-hiv-medication>.

<sup>567</sup> World Health Organization, 'WHO Updates Essential Medicines List with New Advice on Use of Antibiotics, and Adds Medicines for Hepatitis C, HIV, Tuberculosis and Cancer' (Press Release, Geneva, Switzerland, 6 June 2017), <http://www.who.int/mediacentre/news/releases/2017/essential-medicines-list/en/>.

<sup>568</sup> David Bromell, *The Art and Craft of Policy Advising: A Practical Guide* (Cham, Switzerland: Springer, 2017), 174.

made easier with PrEPared Against HIV: 2.0. This policy is a strategic<sup>569</sup> investment for the future that facilitates PrEP as an additional HIV prevention tool. Using Moore's strategic triangle, there are three types of policy work: strategic policy ("pushing the frontier"), responsive policy ("making the government's ideas work"), and operational policy ("keeping things running").<sup>570</sup> A strategic policy is characterised by "underlying drivers and trends; it has breadth... and it has reach, identifying and addressing medium-term risks and opportunities."<sup>571</sup> PrEPared Against HIV: 2.0 is an example of strategic policy, as it calls for a fresh take on HIV prevention that requires a new policy for the effective implementation of PrEP. This policy is greatly influenced by the latest trends of HIV diagnoses where infection rates have risen consistently for five consecutive years, particularly between MSM.

Furthermore, PrEPared Against HIV: 2.0 is an innovative and forward-thinking policy. The Base Case shows that changes must be made to the country's HIV prevention plan, and "we need to do something different and innovate, in discontinuity with past and current practice."<sup>572</sup> PrEPared Against HIV: 2.0 is an innovative policy that has been designed using "diverse forms of evidence, weighed for their strengths and weaknesses as solutions to particular policy challenges in particular contexts."<sup>573</sup> These forms of evidence are the multiple, mixed-methods that were used following Weiss's problem-solving model. This model has utilised research to reduce uncertainty and form an evidence-based solution to the policy problem. Similarly, PrEPared Against HIV: 2.0 is a forward-thinking policy, as it contains a framework for PrEP that could have significant impacts on HIV transmission in New Zealand. For example, an HIV researcher has argued that based on international modelling, New Zealand could beat England to become the first country in the world to eradicate new HIV infections. This claim is justified below:

So long as what's currently working [HIV prevention in New Zealand] is continued and maintained at the same levels so we don't reduce our investment in primary prevention at the community level (and that means testing services and condom promotion)... [and] we added on top of those existing programmes PrEP and early treatment, we would be able to make an even bigger and quicker impact on our epidemic.<sup>574</sup>

However, there is no way that New Zealand will achieve this historic milestone without a change in the current HIV prevention plan, which proves the need for PrEPared Against HIV: 2.0 over the Base Case.

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<sup>569</sup> Claudia Scott and Karen Baehler, *Adding Value to Policy Analysis* (NSW, Australia: University of NSW Press, 2009), 14.

<sup>570</sup> Ibid.

<sup>571</sup> Henry, 2007 p. 5, as cited in Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 69.

<sup>572</sup> Hartley, 2001, as cited in *ibid.*, 70.

<sup>573</sup> Bell, *Research for Health Policy*, 182.

<sup>574</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher, interview by Alice Hartley, Skype, 6 September 2016.

There are multiple benefits of investing in PrEP for HIV prevention that should not be ignored. Firstly, by placing more money into prevention, it is assumed that new infections will drop and the government will be able to spend less money on treatment. The social and mental benefits of having less people living with HIV are undeniable, but the government has a very real opportunity to make a monetary investment in PrEP that could result in significant savings. For example, if PrEP prevents one-third of the 224 HIV infections from 2015 in one year, 75 people would remain HIV-negative. Using the NZAF's claim that HIV treatment costs \$400,000 per person, PrEP could result in "lifetime HIV treatment savings of \$NZD30 million each year."<sup>575</sup> See the below calculation:

$$75 \text{ prevented infections} \times \$400,000 \text{ treatment cost} = \$30,000,000$$

Additional information about the cost-benefit of PrEP will be discussed in the Cost section, but it is important to note that if a PrEP "price point was developed at \$NZD1,000 per year, the annual cost of supplying PrEP to 5,000 gay and bisexual men at the highest risk of HIV would be NZ \$5 million."<sup>576</sup> The return on investment (ROI) calculation can also show how worthwhile an investment is based on the predicted return of money each year. See the ROI calculation below, which uses the yearly savings based on PrEP preventing 75 HIV infections, and the annual price point investment for PrEP:

$$\begin{aligned} &(\text{Gain from investment} - \text{cost of investment}) / \text{cost of investment} = \text{ROI} \\ &(\$30,000,000 - \$5,000,000) / \$5,000,000 = \$25,000,000 \end{aligned}$$

If the government invests \$5 million in PrEP annually and one-third of infections (based on the 2016 incidences) are prevented, there will be a yearly return of \$25 million. The calculation shows the return on investment is 500%, which can clearly be considered worthwhile. Nonetheless, it is important to note that while the calculation states that there will be a saving of \$25 million, it is likely to be lower than this figure. This is because PrEP implementation will incur additional costs that are not included in this calculation, such as:

- Funding extra testing, including HIV and STI tests,
- Strains on the healthcare system to provide this new service,
- Advertising of PrEP, and
- Education campaigns for PrEP, including producing various types of resources.

This list is not exhaustive of all the additional costs that should be considered when measuring the worth of PrEP, but they give a small idea of how the ROI may be lower than the predicted 500%. Nonetheless, it is important to provide this caveat to the ROI calculation.

Furthermore, the results from the anonymous, online attitude scaling survey of MSM from Canterbury show that there is a keen interest in PrEP. 100% of the

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<sup>575</sup> Rich, 'RE: Updates about PrEP in New Zealand'.

<sup>576</sup> Ibid.

participants agreed that PrEP is a worthwhile method of HIV prevention and that it is a good way to reduce one's chances of acquiring HIV. Despite the small sample size, this level of support for PrEP cannot be ignored.

### **PrEPared Against HIV: 2.0**

The rest of this chapter will present PrEPared Against HIV: 2.0. Policy options are made up of two parts: persuasive information, and explanatory information. The persuasive section is used to rationalise a policy recommendation,<sup>577</sup> which was discussed in the sections above using the Base Case. The explanatory section details how a policy will be implemented,<sup>578</sup> such as “who will do what, when, [and] how.”<sup>579</sup> It is important to note that while the explanatory section needs to be well thought-out and carefully designed, there will be gaps or areas of uncertainty in the policy.<sup>580</sup> This uncertainty regarding certain sections is common when designing policies because it is impossible to have all the information used to justify an option(s), so assumptions must be made.<sup>581</sup> The explanatory section of PrEPared Against HIV: 2.0 will be presented below.

Lavis et al. note that health policies can include a combination of four functional categories that are important to the healthcare industry. PrEPared Against HIV: 2.0, as presented below, features three of the four functional categories:

- Financial arrangements (i.e., financing, funding, and remuneration arrangements to support services);
- Delivery arrangements (i.e., how services will be delivered, by whom, and in what settings and how services will be accessed);
- Program content (i.e., which services will be provided and to whom).<sup>582</sup>

These three functional policy categories (financial arrangements, delivery arrangements, and program content) for the implementation of PrEP for MSM will be discussed throughout the chapter.

### **Stakeholders**

There are a number of stakeholders who will be involved in this policy or have an interest in how it plays out. Figure 28 includes some of the identified stakeholders that have been grouped by their similarities. This diagram is not exhaustive of all potential stakeholders but introduces the key players. Many of the identified stakeholders will be identified throughout the explanatory section of PrEPared Against HIV: 2.0.

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<sup>577</sup> Giandomenico Majone, *Evidence, Argument, and Persuasion in the Policy Process* (New Haven: Yale University Press, 1989).

<sup>578</sup> Ibid.

<sup>579</sup> Bell, *Research for Health Policy*, 184.

<sup>580</sup> Ibid.

<sup>581</sup> Ibid., 34.

<sup>582</sup> Lavis et al., ‘Examining the Role of Health Services Research in Public Policymaking’, 128.

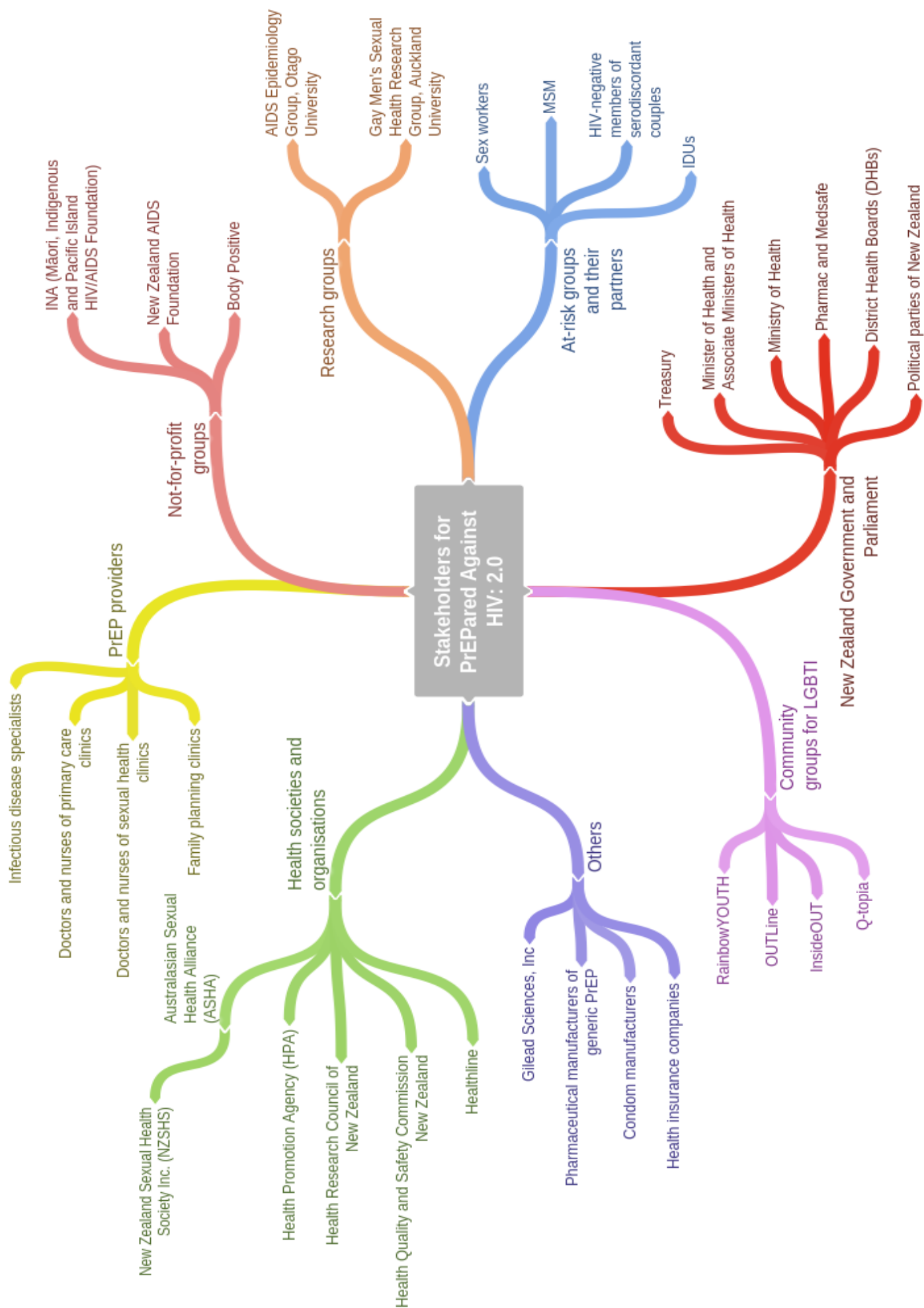
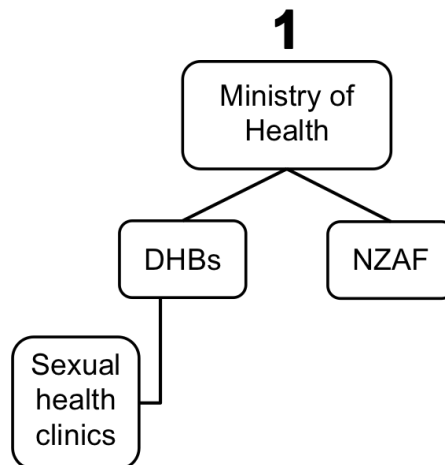


Figure 28: Stakeholder web for PrEPared Against HIV: 2.0

### PrEP providers

The Ministry of Health (MOH) will lead PrEPared Against HIV: 2.0 in collaboration with District Health Boards (DHBs), sexual health clinics, participating primary care doctors, and the NZAF. The MOH “is the best sector and agency to lead this project,” and will be supported by the DHBs and NZAF to “achieve mutually agreed objectives” for the successful implementation of PrEP.<sup>583</sup> The MOH will be the primary decision-makers for the policy, which follows the “‘command-and-control’ approach, in which the government attempts to increase access to and utilization of services largely through deployment of its own resources rather than through working with others.”<sup>584</sup> All organisations and departments work differently,<sup>585</sup> which is important to remember, as the three phases of implementing PrEP requires multiple stakeholders to work collaboratively. The PrEP providers will be released in three waves as the policy becomes more widespread and the number of MSM using PrEP increases. The following three phases are illustrated in the Figures 29-31 and described in detail below.

All PrEP providers must provide adequate support for PrEP-users throughout all three phases of implementation. One in eight Canterbury MSM are not comfortable discussing their sexuality with doctors, and 17.5% are not comfortable asking for PrEP. It is important that all providers create an environment where the patients feel safe so they can receive the necessary sexual health and HIV prevention healthcare. The NZAF and doctors with experience working with LGBTI patients may play a key role in ensuring less experienced doctors provide the right level of support.



**Figure 29: Phase 1 of PrEP providers**

Figure 29 shows the first phase of the PrEP providers for PrEPared Against HIV: 2.0. It is recommended that the sexual health clinics be in charge of PrEP when the nationwide rollout first occurs. The rationale behind this decision is based on advice from interviewees. The sexual health clinics will be able to provide a “level of wrap-

<sup>583</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 71.

<sup>584</sup> Bernard J. Turnock, *Essentials of Public Health*, 2nd ed, Essential Public Health (Sudbury, MA: Jones & Bartlett Learning, 2012), 11–12.

<sup>585</sup> Bell, *Research for Health Policy*, 193.

around care and sexual health checks” that matches “international best practice,” which is necessary when prescribing PrEP.<sup>586</sup> These experts argued that sexual health clinics already provide similar services so offering PrEP should not place much more demand on their resources.<sup>587, 588, 589</sup> The similar services include regular STI testing, counselling, and sexual health education. The sexual health doctors will discuss an individual’s suitability for PrEP, complete the necessary pre-tests, and prescribe PrEP. The nurses will be able to help with subsequent minor tests and provide supplementary information about PrEP, such as adherence strategies. Sexual health clinics also have counsellors who may be also used to provide support to PrEP-users. All those involved in providing PrEP must follow the clinical guidelines (discussed later).

The NZAF’s role is to provide support for the DHBs and MOH while promoting the importance of PrEP for HIV prevention. As recommended by current staff of the NZAF, the organisation will contribute by providing “support... [for] the stakeholders that we are involved with as much as we can in regards to counselling.”<sup>590</sup> The NZAF is highly unlikely to be in the position to provide medical support, such as testing,<sup>591</sup> so medical clinics will need to take that responsibility.

However, there are two current factors regarding sexual health clinics that may need changing to ensure the success of PrEP implementation. The first is that New Zealand sexual health clinics are currently outpatient services that require referrals.<sup>592</sup> This current system would force potential PrEP-users to visit their primary doctor to receive a referral in order to meet with a sexual health doctor. The individual would be required to pay for this appointment, which could be considered a deterrent for some potential users who cannot afford to visit their doctor. Secondly, according to the New Zealand Sexual Health Society’s (NZSHS) website, as at June 2017, there are thirty-five sexual health clinics around the country (23 in the North Island and 12 in the South Island).<sup>593</sup> While potential PrEP-users in main centres may not be disadvantaged, individuals who do not live in such big towns or cities will be. For example, an individual from Kaitia, Coromandel, Westport or Kurow would all have to travel multiple hours to reach their nearest sexual health clinic. The distance that potential users would be required to travel to access PrEP is an inequality that needs greater consideration when PrEP is offered for HIV prevention in New Zealand.<sup>594, 595</sup>

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<sup>586</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>587</sup> Ibid.

<sup>588</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>589</sup> Nigel Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital, Skype, 19 March 2017.

<sup>590</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

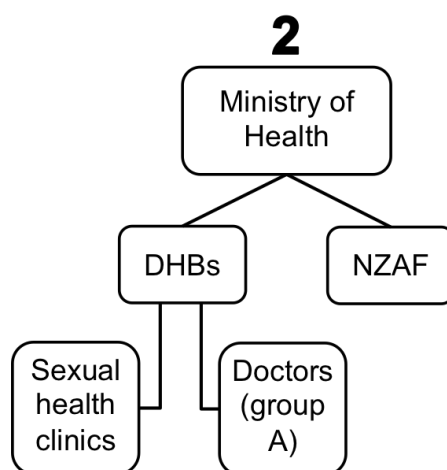
<sup>591</sup> Ibid.

<sup>592</sup> Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital.

<sup>593</sup> New Zealand Sexual Health Society Incorporated, ‘New Zealand Sexual Health Clinics’, *New Zealand Sexual Health Society Incorporated*, 2017, <http://nzshs.org/clinics>.

<sup>594</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.





**Figure 30: Phase 2 of PrEP providers**

Phase two (Figure 30) has been designed to reduce the inequalities associated with the geographical spread of sexual health clinics across the country and the requirement of a referral. The recommendation is to move into phase two of PrEP implementation as soon as there is adequate demand for more PrEP providers. Phase two allows a group of doctors (Group A) to begin prescribing PrEP to their MSM patients. The doctors who qualify to be in Group A must have experience with or an active interest in HIV prevention, PrEP, ART, and/or LGBTI patients. This is because prescribing PrEP is a large commitment for both the doctor and user; the user must commit to regular health tests and the doctor must have a very good understanding of PrEP to ensure that the patient is provided with the highest standard of care.<sup>596</sup> Therefore, it is best that the first group of doctors (Group A) providing PrEP have sufficient experience with LGBTI patients and HIV prevention. There were only three clinics around New Zealand who were registered having a sufficient interest or knowledge in PrEP in mid-2017,<sup>597</sup> but as at September 2017, there were 20 clinics registered.<sup>598</sup> As with the geographic inequalities regarding sexual health clinics, PrEP-users in Taranaki, Wairarapa, West Coast, Marlborough and areas of the Southland and Canterbury regions will still be forced to travel long distances to see these current registered doctors. As with phase one, all medical professionals involved in prescribing PrEP and providing the wider care must follow the clinical guidelines to ensure the highest standard of care.

The NZAF's role in phase two remains the same as in phase one: to provide support to the PrEP providers but stay out of anything related to the medical side of PrEP.

It is important that the implementation of PrEP matches the level of interest for the drug. Therefore, as the demand for PrEP increases, the number of doctors who can

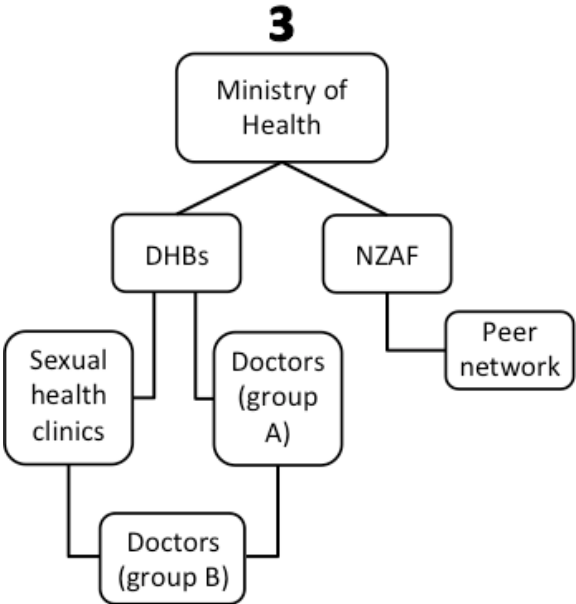
<sup>595</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic, interview by Alice Hartley, Face-to-face, 23 September 2016.

<sup>596</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>597</sup> Ending HIV, 'Getting a Prescription for PrEP' (Ending HIV, 2017), <https://endinghiv.org.nz/media/images/PDFs/170606-Doctors-with-good-knowledge-of-HIV-sexual-health.pdf>.

<sup>598</sup> Ibid.

prescribe PrEP and provide the necessary care may also need to increase. Figure 31 shows phase three, which is designed to accommodate large numbers of PrEP-users. These doctors can apply on an individual basis or as an entire practice to provide PrEP, and will be required to follow the same clinical guidelines as the sexual health clinics and Group A doctors. These guidelines will help ensure that the highest standard of care<sup>599</sup> is provided to PrEP-users, regardless of which PrEP provider they use.



**Figure 31: Phase 3 of PrEP providers**

Before being allowed to prescribe PrEP, the Group B doctors will be required to attend a conference about PrEP, which will be supported by the MOH, NZSHS, DHBs, and doctors who were prescribing PrEP in phases one and two. The conference will discuss the clinical guidelines for prescribing PrEP and providing adequate healthcare for LGBTI for HIV prevention. The conference should also contain anecdotal tips from doctors who are already providing the drug. Attending the conference is essential if doctors wish to become part of the Group B doctors. Some doctors may see this step as unnecessary, but PrEP is a complex drug and patients have the right to receive the best possible treatment from their healthcare provider. Furthermore, PrEP is a relatively new HIV prevention technique so it is crucial that all doctors are aware of the complexities of the drug before they can prescribe it. Conferences can be held as the demand requires.

Throughout phases one and two, the NZAF’s only job is to provide support to the MOH and DHBs. However once more MSM are using PrEP for HIV prevention, the NZAF is encouraged to help set up a peer network. Body Positive has used a peer network for HIV-positive men in New Zealand to help individuals feel more supported, encourage friendships, and remove social isolation.<sup>600</sup> Given the positive message

<sup>599</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.  
<sup>600</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

behind Body Positive's peer network, it is recommended that a similar network is set up for MSM currently using PrEP. The network will allow users to share stories, provide support to one another, encourage sensible choices, and facilitate open discussions about PrEP, HIV prevention and safe sex. Given the exposure that the NZAF has to HIV-negative individuals through their social media accounts, events, and Ending HIV campaign, creating a PrEP peer network should not be too cumbersome. The NZAF may consider providing the PrEP peer network through different methods. For example,

- An online forum: supported by the NZAF, the online forum can be a private and secure group on Facebook where participants from New Zealand can talk about PrEP without being excluded by geographic location. It is important that the group is secure so individuals feel safe using it. Staff from the NZAF can monitor the group. Otherwise, active community members that are interested in helping facilitate a peer network for PrEP-users could also administer this group.
  - After the development of this policy, the author became aware that a closed PrEP peer support group had been set up on Facebook for this very purpose. This group promoted open discussion about PrEP.
- Physical peer network: PrEP-users can meet up with other PrEP-users. Those interested in socialising with other PrEP-users can contact the NZAF to find others nearby who are also part of the peer network, or contact them via the online forum.
  - The NZAF has a strong community presence and hosts a number of events for MSM and other members of the LGBTI communities from around the country. There is potential for the NZAF and the PrEP peer network to schedule regular social events for PrEP-users.

Once the third phase of PrEP implementation is underway, it will be easier to see the impact that this policy will have on the healthcare system. There is the potential for strains to occur, as providing PrEP effectively requires cooperation between multiple stakeholder groups. For example, ensuring that all PrEP-users have an STI and HIV test every three months when they go in to get a new script of PrEP may put additional stress on laboratory staff and nurses. Similarly, sexual health counsellors may see an influx of patients wanting advice on adherence or other PrEP-related topics. It is important that once phase three has been operating for a reasonable length of time (i.e. 12-18 months), the MOH, DHBs, and NZAF complete an evaluation of the effect of PrEP on the healthcare system. The MOH should use an evaluation of the three phases of PrEP implementation to identify the strengths and weaknesses of the PrEP providers, and ensure resources are not stretched to an unreasonable point. Furthermore, the evaluation will also provide an opportunity for the MOH to reassess other areas of PrEPared Against HIV: 2.0, such as funding allocation and promotion campaigns.

### Clinical guidelines for PrEP

This research has repeatedly identified the medical, social, and behavioural complexities associated with PrEP. Thus, it is crucial that doctors follow a set of clinical guidelines when providing PrEP to at-risk individuals to ensure patients receive the highest quality healthcare.<sup>601</sup> The use of clinical guidelines is supported by a number of the interviewees. The experts recommended that the guidelines contain criteria needed to guide patient care. Most importantly, these guidelines will ensure that all PrEP-users receive the same high standard of care, regardless of what PrEP provider they use.<sup>602, 603, 604</sup>

One crucial aspect of the clinical guidelines is to ensure doctors follow the protocol for regular health tests.<sup>605</sup> It is recommended that PrEP-users have quarterly HIV and STI tests, biannual bone density and kidney function tests, and yearly evaluations to assess their need to continue PrEP. These recommendations are based on the Centers for Disease Control and Prevention's (CDC) *Guidelines*. The requirement for regular HIV tests should not be too much of a demand for MSM: 97.5% of Canterbury MSM surveyed agreed that it is important to get regular HIV tests, and 85% did not see the additional tests as a hassle. The researcher has not provided any further clinical guidelines but it is recommended that the authors look to current guidelines to provide a framework that can be modified to fit the New Zealand context. There are currently PrEP guidelines from the CDC, WHO, Australasian Society for HIV Medicine (ASHM), and New York State Department of Health AIDS Institute (NYSDOH AI).

### Cost

The issue regarding the cost of PrEP is well-known and does not need to be repeated, although the subsidisation of PrEP needs to be considered. The WHO argues that cost should not be the only determinant of whether PrEP is deemed a worthwhile investment for HIV prevention.<sup>606</sup> Nevertheless, the WHO also clearly states that the price of PrEP is not the only cost linked to its implementation. Other associated costs include "costs for clinical staff, laboratory testing, pharmacy services, community education, provider education and monitoring and evaluation."<sup>607</sup> These additional costs need to be considered when making the decision to provide PrEP. It is important that any inequality of access linked to the cost of PrEP is also considered.<sup>608</sup>

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<sup>601</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>602</sup> Ibid.

<sup>603</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>604</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>605</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>606</sup> World Health Organization, 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach - Second Edition' (Switzerland: World Health Organization, June 2016), 56, <http://www.who.int/hiv/pub/arv/arv-2016/en/>.

<sup>607</sup> Ibid., 61.

<sup>608</sup> Ibid., 56.

The primary organisation in charge of this policy is the MOH and therefore, the decisions regarding funding will come from the New Zealand government. The Treasury has a key role making decisions about funding for our healthcare system:

The Treasury provides advice to Ministers on the purchase and regulation of health services. This advice covers areas such as the structure and management of health spending, institutional and governance arrangements in the health sector and health sector strategies and policies. The Treasury also provides advice on the Crown's ownership interest in district health boards (DHBs). This includes monitoring the performance of the DHBs and assessing capital investments. This work is carried out in conjunction with the Ministry of Health.<sup>609</sup>

PHARMAC also has an influence on the funding decisions for PrEP. As reviewed in Chapter 1, PHARMAC chooses which medicines to subsidise based on a "cost-utility analysis (CUA) and a budget-impact analysis (BIA)."<sup>610</sup> PHARMAC's decision whether to fund PrEP is a question of "health economics," which depends "on the cost of the drugs and who takes it."<sup>611</sup>

Cost-benefit analyses (CBA) are also often used as a forecasting method to measure the worth of a potential intervention. One policy expert recommends that potential users' willingness to pay can measure the benefit of an option.<sup>612</sup> While the survey presented in Chapter 4 asked participants whether PrEP should be subsidised, it did not measure willingness to pay. PHARMAC's analysis of the cost-effectiveness of PrEP may ultimately determine whether the government decides to subsidise the drug and by how much. However, it is crucial to remember that the benefit of a policy option does not solely rely on monetary value, as stated by the WHO.<sup>613</sup> In fact, CBA and similar methods can ignore "non-quantifiable costs and benefits and may conflict with our moral intuitions."<sup>614</sup> Furthermore, economic analyses of policy options can favour cost and efficiency over "justice, liberty, democracy, the environment,"<sup>615</sup> and health and wellbeing.<sup>616</sup> Although the outcome of an economic analysis of PrEP is uncertain in a real world policy situation, it is recommended that policy advisors look further than just economics and cost-benefits when considering the funding for PrEPared Against HIV: 2.0. Therefore, this section will present multiple options for funding PrEP and ways to measure its worth as a medical intervention.

It is certain that any case put forward to PHARMAC to subsidise PrEP needs to be compelling and evidence-based. The cost of PrEP should be compared to

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<sup>609</sup> The Treasury, 'Expenditure: Health', *The Treasury*, 13 October 2016, <http://www.treasury.govt.nz/government/expenditure/health>.

<sup>610</sup> PHARMAC, 'Guidelines for Funding Applications to PHARMAC' (PHARMAC, Amended in 2015).

<sup>611</sup> Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group.

<sup>612</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 74.

<sup>613</sup> World Health Organization, 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection', 56.

<sup>614</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 75.

<sup>615</sup> Douglas J. Amy, 'Why Policy Analysis and Ethics Are Incompatible', *Journal of Policy Analysis and Management* 3, no. 4 (1984): 577.

<sup>616</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 76.

opportunity costs,<sup>617</sup> such as other behavioural prevention methods. One HIV researcher argues that persuading PHARMAC and the government comes down to acknowledging that while funding PrEP is a “burden to the state,”<sup>618</sup> it is important to critically evaluate how this new biomedical intervention could impact the current climate of HIV in New Zealand. The researcher’s argument in favour of implementing a PrEP policy reinforces the result of the Base Case; we need to change our prevention techniques because the present methods are not working.<sup>619</sup> PHARMAC could agree that the current epidemiological trends of HIV in New Zealand suggest that a “new and innovative” approach is needed,<sup>620</sup> but they may not see value-for-money in PrEP. This is because currently branded PrEP (Truvada) costs between NZ \$900 and \$1,200 each month.<sup>621, 622, 623, 624</sup> However, generic PrEP costs NZ \$60-100 per month and Mylan and Actavis, two manufacturers of generic PrEP, have both been approved as generic versions of Truvada by Medsafe.<sup>625</sup>

Until Gilead’s patent for Truvada is removed in 2017, it is highly unlikely that PHARMAC would choose to fund branded PrEP over the generic version.<sup>626</sup> This decision makes sense economically, and the majority of countries around the world that provide PrEP will also use the generic version.<sup>627</sup> However, this may change once Gilead’s patent finishes because the pharmaceutical company will want to entice health agencies and individuals to purchase their drug over generics. Gilead can do this in two ways: altering their drug to renew their patent (with proof that the new medication works), or dropping the price of their medication to just above the generic so customers are persuaded to pay slightly more for a branded version.<sup>628</sup> At this stage, what Gilead decides to do after the patent for Truvada ends is uncertain, so the following analysis of the subsidisation for PrEP is based on the cost of generic and branded PrEP while the patent is still covered.

### ***Funding options for PrEP***

PHARMAC will need to choose what parameters to include if they decide to fund PrEP. The recommended parameters are generic versus branded PrEP, the level of subsidisation, and who qualifies for this funding. It has been assumed that based on the price of branded PrEP, PHARMAC will only subsidise generic versions. The level of subsidisation is based on what PHARMAC determines the best value for money, so

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<sup>617</sup> Ibid., 74.

<sup>618</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>619</sup> Ibid.

<sup>620</sup> Ibid.

<sup>621</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>622</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>623</sup> New Zealand AIDS Foundation, ‘Pre-Exposure Prophylaxis (PrEP) Factsheet’ (New Zealand Aids Foundation, n.d.), 1.

<sup>624</sup> Shriya Chitale, ‘Cost of PrEP and HIV Treatment’, 9 March 2017.

<sup>625</sup> Joe Rich, ‘Updates about PrEP in New Zealand’, 22 August 2016.

<sup>626</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>627</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>628</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

there are multiple funding options below with different levels of investment. Finally, it has been argued that PHARMAC may wish to fund PrEP for certain population groups based on their risk of contracting HIV.<sup>629</sup> There are three options for funding PrEP and three options for who can access PrEP presented in the tables below. Table 2 shows the three options for funding PrEP, and Table 3 shows the options of who is eligible to access PrEP.

**Table 2: Funding options for PrEP**

		<b>Cost to Government</b>	<b>Cost to users</b>
<b>Option A</b>	'Full' funding of generic PrEP	\$55-95/month per person	\$5/month per person
<b>Option B</b>	Partial subsidisation of generic PrEP	\$30-50/month per person	\$30-50/month per person
<b>Option C</b>	No funding or subsidisation for generic PrEP	\$0	\$60-100/ month per person

Option A is 'full' funding of generic PrEP, which costs \$60-100 per month per person. However, PrEP-users will be required to pay \$5 each month for their prescription. This decision aligns with the usual \$5 cost of a subsidised prescription in New Zealand.<sup>630</sup> Because of the minor cost to the user, the government will pay between \$55 and \$95 per individual prescription each month.

Option B is partial subsidisation of generic PrEP. This would mean an equal split of the prescription cost between the government and the user; each would pay \$30-50 for a month's prescription of PrEP.

Option C recommends that there is no government subsidisation for PrEP. This option would result in no monetary costs to the government, while any individual who wishes to use PrEP would pay between \$60-100 per month. Only 2.5% of MSM from Canterbury agreed that the government should not subsidise PrEP.

**Table 3: Options of who is eligible for PrEP**

		<b>Number of potential users</b>
<b>Option 1</b>	PrEP is available to all who want to use it	>5,000 MSM + any others
<b>Option 2</b>	PrEP for all MSM regardless of HIV risk-status	>5,000 MSM
<b>Option 3</b>	PrEP for only high-risk MSM	Approximately 5,000 MSM

Table 3 shows the parameters of who is eligible to access PrEP. Option 1 recommends that PrEP is available to all those who want it, which follows the WHO's advice that PrEP should be made accessible to all at-risk individuals, regardless of the population group they identify with.<sup>631</sup> This includes, but is not limited to, MSM, sex workers, IDUs, HIV-negative members of serodiscordant couples, prisoners, and transgender

<sup>629</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>630</sup> New Zealand Government, 'Prescription Charges', *New Zealand Government*, 2017, <https://www.govt.nz/browse/health-system/gps-and-prescriptions/prescription-charges/>.

<sup>631</sup> World Health Organization, 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection', 52.

men (TGM) and women (TGW).<sup>632</sup> The number of potential users for PrEP could include more than 5,000 MSM who are deemed high-risk by the NZAF,<sup>633</sup> plus any other at-risk individuals who want to use PrEP. The '+ any others' is vague but the researcher could not provide any sort of accurate estimation of this group.

Option 2 states that PrEP should only be made available for MSM, regardless of their HIV risk-status. This figure was based on the 5,000 high-risk MSM identified by the NZAF, plus others who may believe PrEP is a worthwhile prevention intervention. As with Option 1, it was not possible to provide a clear estimation of the number of MSM who are not high-risk but would still be interested in PrEP. The NZAF approximates that gay and bisexual men make up 2.5% of the population, which is nearly 120,000 people.<sup>634</sup> It is almost certain that not all gay and bisexual men would express a desire to use PrEP, but it is important to note that the number of MSM eligible to use PrEP through Option 2 could be large.

Option 3 recommends that PrEP is only accessible for MSM who have a high-risk of contracting HIV. The NZAF estimates this figure to be around 5,000 MSM.<sup>635</sup> The NZAF did not expand upon the criteria they use to define high-risk.

### ***Analysis of funding options***

While there is uncertainty surrounding some the funding options presented above, they all point to the singular goal of facilitating the implementation of PrEP.<sup>636</sup> This uncertainty is common because policy recommendations always combine a mixture of known and unknown information.<sup>637</sup> The format of these funding options means that one must be chosen from Table 2 and one from Table 3, for example, A1. There are nine possible options for funding, which is presented in Matrix 1 on the following page.

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<sup>632</sup> Ibid.

<sup>633</sup> Rich, 'RE: Updates about PrEP in New Zealand'.

<sup>634</sup> New Zealand AIDS Foundation, 'HIV in New Zealand', *New Zealand AIDS Foundation*, n.d., <https://www.nzaf.org.nz/hiv-aids-stis/hiv-aids/hiv-in-new-zealand/>.

<sup>635</sup> Rich, 'RE: Updates about PrEP in New Zealand'.

<sup>636</sup> Bell, *Research for Health Policy*, 186.

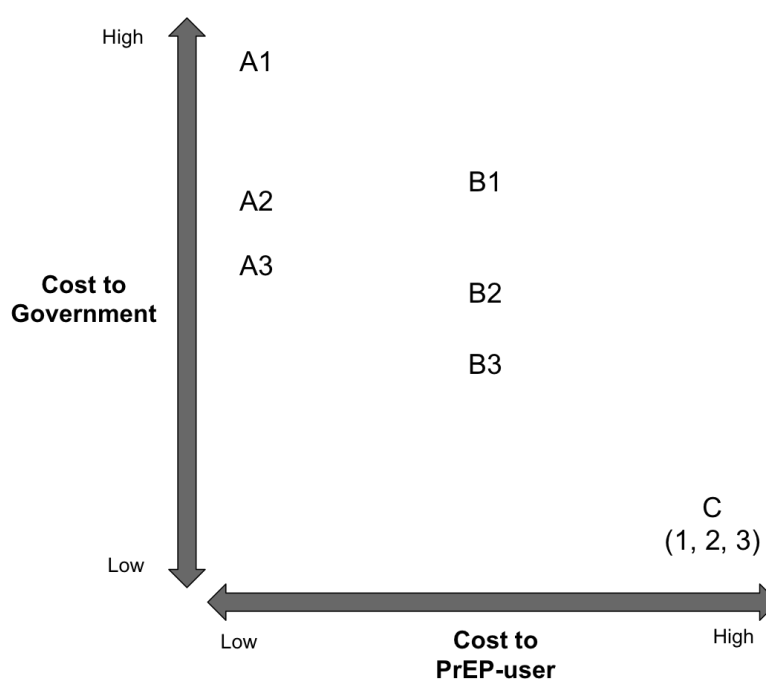
<sup>637</sup> Ibid., 183.



**Matrix 1: Nine options for PrEP funding**

	<b>Option A</b>	<b>Option B</b>	<b>Option C</b>
<b>Option 1</b>	<b>A1</b> 'Full' funding of generic PrEP; PrEP is available to all who want to use it	<b>B1</b> Partial subsidisation of generic PrEP; PrEP is available to all who want to use it	<b>C1</b> No funding or subsidisation for generic PrEP; PrEP is available to all who want to use it
<b>Option 2</b>	<b>A2</b> 'Full' funding of generic PrEP; PrEP is available for all MSM regardless of HIV risk-status	<b>B2</b> Partial subsidisation of generic PrEP; PrEP is available for all MSM regardless of HIV risk-status	<b>C2</b> No funding or subsidisation for generic PrEP; PrEP is available for all MSM regardless of HIV risk-status
<b>Option 3</b>	<b>A3</b> 'Full' funding of generic PrEP; PrEP is only available for high-risk MSM	<b>B3</b> Partial subsidisation of generic PrEP; PrEP is only available for high-risk MSM	<b>C3</b> No funding or subsidisation for generic PrEP; PrEP is only available for high-risk MSM

Figure 32 shows how the nine options are distributed regarding cost to the government versus cost to the PrEP-user. Please note that the costs of PrEP have not been adjusted for inflation, but are only shown at this point in time. Figure 32 shows that options A1, A2, and A3 are the cheapest for the PrEP-user (\$5 per month for a PrEP prescription) and the most expensive for the government (\$55-95 per month per user). Options C1, C2, and C3 are the most expensive for the PrEP-user (who will pay \$60-100 for a month's prescription of PrEP) and the least expensive option for the government (no subsidisation or funding of PrEP). Options B1, B2, and B3 require an equal investment from the PrEP-user and the government.



**Figure 32: Cost of 9 PrEP options for Government and PrEP-users**

### ***Recommendations for funding***

Based on the nine funding options, it is recommended that PrEPared Against HIV: 2.0 uses option B3, partial subsidisation of generic PrEP for high-risk MSM. B3 is the cheapest of all B options, as the government is only required to pay for half of each monthly prescription for high-risk MSM. Based on the estimation that there are 5,000 high-risk MSM, the government will be required to invest the following:

$$\text{Minimum spent on PrEP/year} = \$30 \times 12 \times 5,000 = \$1,800,000$$

$$\text{Maximum spent on PrEP/year} = \$50 \times 12 \times 5,000 = \$3,000,000$$

The government would invest between \$1.8 million and \$3 million for PrEP annually for high-risk MSM. The 50-50 split requires MSM to pay between \$360 and \$600 for PrEP annually. These costs depend on which generic PrEP PHARMAC chooses to subsidise.

B3 is also preferable because it requires an equal monetary investment from the government and PrEP-user each month. A cost of \$30-50 each month is deemed to be moderate and as one HIV expert puts it, “for gay men, sex is a recreation and actually to pay \$80 a month is like getting Sky TV.”<sup>638</sup> Dickson’s quote comes from discussing MSM paying for generic PrEP with no government funding, so this argument is even stronger with subsidisation; if HIV prevention is important to MSM, the small monthly cost for PrEP should not be a burden to fit into one’s budget. The average New Zealand salary was \$74,965 in 2015,<sup>639</sup> so with a 50% subsidisation of PrEP prescriptions the \$360-600 cost of PrEP would be 0.005-0.008% of the average annual earnings. Furthermore, it is recommended that full funding is not offered for PrEP, as it is important that MSM take a proactive approach to HIV prevention. The requirement for MSM to pay half of the medication cost should influence them to either adhere to PrEP correctly or not use it at all, thus encouraging correct adherence. However, condoms will remain fully funded (more about this in subsequent sections).

The rationale behind this recommendation is as follows: compared to option A3, where PrEP is ‘fully’ funded by the government (minus prescription charges), option B3 is significantly cheaper for the government. If the government were to choose option A3, they would pay between \$3.3-5.7 million each year for the 5,000 at-risk MSM to have PrEP. It does not seem likely that the government or PHARMAC would want to immediately ‘fully’ fund PrEP without trialling a policy for the new intervention first. A1, A2, B1 and B2 are not supported because individuals who do not have a high-risk of HIV should not use PrEP.

Options C1-3 have not been chosen, as it is recommended that the government makes some financial contribution to PrEP by investing in HIV prevention. However, there is a chance that PHARMAC or the government think that an equal split of the cost of generic PrEP is too expensive. If this occurs, it is recommended that PHARMAC and

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<sup>638</sup> Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group.

<sup>639</sup> Kate Gudsell, ‘Average Salaries Nudge \$75k... for Some’, *Radio New Zealand*, 11 August 2015, [http://www.radionz.co.nz/news/national/281067/average-salaries-nudge-\\$75k-for-some](http://www.radionz.co.nz/news/national/281067/average-salaries-nudge-$75k-for-some).

the government change the ratio rather than removing all subsidisation of PrEP prescriptions. Instead of paying 50%, the government could reduce their portion of the prescription to one-third of the price. On the other hand, if the government wants to make PrEP more accessible for high-risk MSM, they could increase their subsidisation and pay up to two-thirds of the cost of PrEP.

As discussed earlier, it is important that a price point is agreed upon to ensure that PrEP is as cost-effective as possible. The NZAF cited a price point of \$1000 per year for each PrEP prescription, which would require an investment of \$5 million to allow 5,000 high-risk MSM to access PrEP.<sup>640</sup> However, based on the advice to use option B3, the government would only be required to pay \$1.8-\$3 million each year for prescriptions for 5,000 MSM. This smaller investment gives the government an opportunity to evaluate how PrEP works on individual, community and population levels without investing so much money. Furthermore, requiring MSM to pay 50% of the monthly PrEP costs (rather than the 'full' prescription in Option A) would enable the government to consider investing more into alternative externalities<sup>641</sup> of the policy like increased staff, wider promotional material, and more education resources.

Whichever subsidisation method the government uses, it is imperative that the PrEP prescribed by the PrEP providers is cheaper than the generic PrEP that can be obtained through parallel imports. If parallel importing is cheaper than accessing PrEP through a doctor, patients may choose to import, which could cause them to miss out on essential healthcare and support while using PrEP.

The analysis of funding options did not consider health insurance. A study of MSM from three PrEP clinics in the United States of America found that individuals with insurance were four times more likely to use PrEP than those who did not have insurance.<sup>642</sup> Although the American public health and insurance systems are very different to New Zealand, it is important to note how much of an impact health insurance can have on PrEP use. The decision on whether to provide additional funding for PrEP is up to each individual insurance company.

### Adherence

Based on the six, first-generation RCTs for PrEP analysed in Chapter 2, PrEP only works when users commit to the once-daily regimen that builds up enough protection against the virus. Nevertheless, it is important to acknowledge that intermittent PrEP use, also known as event-based dosing, is another method for protection against HIV. The expert interviewees were divided on the value of intermittent PrEP use. The sexual health doctor would only recommend daily PrEP to patients,<sup>643</sup> the infectious disease doctor Nigel Raymond acknowledges the freedom of customising the two strategies to what suits each individual patient,<sup>644</sup> and Body Positive's Mark Fisher

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<sup>640</sup> Rich, 'RE: Updates about PrEP in New Zealand'.

<sup>641</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 73.

<sup>642</sup> Rupa R. Patel et al., 'Impact of Insurance Coverage on Utilization of Pre-Exposure Prophylaxis for HIV Prevention', *PLOS ONE* 12, no. 5 (30 May 2017): 1.

<sup>643</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>644</sup> Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital.

supports both options but believes that sticking to the daily regimen is less confusing for patients.<sup>645</sup> PrEPared Against HIV: 2.0 only supports the use of daily PrEP, as it is easier for patients to get into a routine by taking a pill everyday rather than based on their social calendar. Based on the survey presented in Chapter 4, 85% of participants said that remembering to take PrEP everyday would not be hard. This policy recognises that while “it is a burden to take a pill everyday,”<sup>646</sup> treating one’s self with multiple ARTs (polytherapy) each day as an HIV-positive individual is much harder. Another expert argued that PrEP adherence will undoubtedly be low because HIV-negative people do not have the same level of motivation to take their daily medication as an HIV-positive person,<sup>647</sup> but these high-risk MSM should have a strong desire to prevent this permanent illness.

Adherence is not just about persuading PrEP-users to take their medication regularly to develop good habits; low adherence can cause an individual to seroconvert and develop a resistant virus. The chances of antiretroviral resistance is incredibly low, as there have only been two confirmed cases and two unconfirmed cases of drug-resistant HIV infections despite hundreds of thousands of individuals using PrEP outside of the RCTs.<sup>648</sup> Unsurprisingly, the confirmed cases of resistant infections caused concern among PrEP communities, so it is important that adherence is promoted to prevent further instances of antiretroviral resistance.

It is essential that strong messages promoting daily adherence come from multiple sources, such as the MOH, PrEP providers, the NZAF and their Ending HIV campaign, the policy’s promotional and educational material, and peer support networks. This multipronged approach ensures that all parties promote adherence on numerous levels.<sup>649</sup> Reaching the right level of saturation is important, as users should not be inundated with information that causes them to become desensitised. However, PrEP-users should be motivated to adhere to the daily regime. It is recommended that adherence strategies be considered when the clinical guidelines for PrEP are written. One strategy that has proven to improve patient adherence is SIMPLE:

- “**S**implifying regimen characteristics” to make taking the medication as easy as possible;
- “**I**mparting knowledge” by providing the patient with enough information about the medication;
- “**M**odifying patient beliefs” by tailoring individualised plans to encourage adherence based on each patient’s lifestyle;

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<sup>645</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>646</sup> Ibid.

<sup>647</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>648</sup> Emily Woods, Henrietta Cook, and Rania Spooner, ‘Melbourne Man Tests Positive to HIV While Taking Preventative Drug’, *The Sydney Morning Herald*, 22 May 2017, Online edition, sec. Health, <http://www.smh.com.au/national/health/melbourne-man-tests-positive-to-hiv-while-taking-preventative-drug-20170522-gwaavh.html>.

<sup>649</sup> Ashish Atreja, Naresh Bellam, and Susan R. Levy, ‘Strategies to Enhance Patient Adherence: Making It Simple’, *Medscape General Medicine* 7, no. 1 (2005): 4.

- “Patient and family communication,” including regular text reminders and using family members to support adherence;
- “Leaving the bias” by removing the premise that certain demographic characteristics are linked to adherence, and tailoring the plan to each individual patient; and
- “Evaluating adherence” using methods like pill counting and self-reported adherence.<sup>650</sup>

Evaluations of the SIMPLE method have shown it can be successful at encouraging greater patient adherence and is cost-effective.<sup>651</sup> However, using SIMPLE may require extra work for health professionals, which can be hard when they are battling against stretched resources.<sup>652</sup> Other adherence strategies may include adherence counselling, advice for adherence when travelling, educational resources, and telephone or text reminders.<sup>653</sup>

### Education and promotion campaigns

There is a reasonable amount of misinformation about PrEP<sup>654</sup> that could be detrimental to the policy’s effectiveness. Educational campaigns can correct misinformation about PrEP<sup>655</sup> and promotional material can promote PrEP to at-risk MSM. The education and promotion campaigns need to match PrEPared Against HIV: 2.0 – these campaigns need to be innovative, strategic and forward-thinking. Furthermore, they need to capture the right target audiences through specific methods, such as social media and applications (apps) aimed at particular community groups.<sup>656</sup>

In addition, it is important that the education and promotional campaigns for PrEPared Against HIV: 2.0 reflect the HIV virus in the context of 2017 and onwards.<sup>657</sup> HIV should be promoted as a manageable chronic condition that can affect multiple groups, not a life sentence for gay and bisexual men leading to early death. These campaigns should help promote HIV prevention as a priority for at-risk individuals.<sup>658</sup> The following section will discuss some ideas that may be useful for the education and promotion campaigns targeted to potential and current PrEP-users.

### Education material

The education campaigns for PrEP need to provide MSM with objective patient information about PrEP. This material can be used to help support current PrEP-users

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<sup>650</sup> Ibid.

<sup>651</sup> Ibid.

<sup>652</sup> Ibid.

<sup>653</sup> JI Marcus et al., ‘Helping Our Patients Take HIV Pre-Exposure Prophylaxis (PrEP): A Systematic Review of Adherence Interventions’, *HIV Medicine* 15, no. 7 (1 August 2014): 385–95.

<sup>654</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>655</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>656</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>657</sup> Ibid.

<sup>658</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

when taking the drug, or to aid MSM when making the decision about whether PrEP would be a worthwhile prevention technique. It is recommended that the educational material be written collaboratively between health professionals (who can provide the necessary medical information), the NZAF and Ending HIV staff, and existing PrEP-users. The language that is used should be relevant to the target audience. Some other ideas for the education campaigns could include:

- A website solely for PrEP in New Zealand that includes educational and promotional material about PrEP.
  - Young people, particularly members of the LGBTI community, use the Internet and social media for research, to inform themselves, and make decisions.<sup>659</sup> It is recommended that these pages are frank and clearly written – these websites could follow the same style as the NZAF's Love Your Condom website.
  - Links to the educational information about PrEP could be advertised on social media and dating apps commonly used by MSM like Grindr and Tinder. If MSM are interested in learning more about PrEP, they can click the link which takes them to the PrEP website.
  - It is important that while this website contains enough information to help MSM understand the basics of PrEP, the information provided does not replace a conversation with a doctor.
- Further web pages of information about PrEP can be posted on the MOH, NZAF, and Ending HIV websites. There can be links to these informative web pages on the sexual health clinic and DHB websites.
- Physical resources like booklets and pamphlets should not be overlooked, as some potential users may prefer physical information about PrEP.
  - There is potential to develop different resources depending on the target audience. For example, potential PrEP-users may want to have different information compared to current users.
  - These physical educational resources could be placed in waiting rooms and clinics, and handed out by doctors, nurses, and counsellors.
- Some users may prefer to learn about PrEP through audio-visual educational material. The MOH and NZAF may consider collaborating to create some educational videos on different topics related to using PrEP. These videos can be hosted on the PrEP, MOH, NZAF, and Ending HIV websites.

The educational campaigns should also promote the peer network(s) that are set up in the third phase of the policy. These networks can help support PrEP-users and allow them to bond with others who also use PrEP. Similarly, members of the peer networks that are using PrEP may wish to feature their stories on the websites to give anecdotal experiences of using the medication.

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<sup>659</sup> Douglas S. Krakower et al., 'Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site', *PLoS ONE* 7, no. 3 (28 March 2012): 2.

The authors of the educational material may also wish to include information about HIV in New Zealand, such as rates of HIV and why MSM are more susceptible to contracting HIV. Including this information is not meant to frighten potential PrEP-users into trying the medication but should remind them that HIV is still an issue in New Zealand.<sup>660</sup>

### **Promotion campaigns**

The promotion of PrEP could have an impact on its success as an HIV prevention method and the overall policy. Promoting PrEP will be important to ensure that high-risk MSM know about this intervention and can consider whether it is right for them. As with the clinical guidelines, it is recommended that policy advisers look to other countries to see how they have successfully promoted PrEP. These campaigns can easily be tailored to target MSM from New Zealand. It will be important to promote PrEP in a way that removes stigmatisation and incorrect labels about PrEP-users.

There are two key approaches that the MOH and relevant organisations could take when producing the promotional material for PrEPared Against HIV: 2.0. The first option is a targeted campaign that is only visible to those who are considered at-risk of contracting HIV or are part of a high-risk community. The second option is a high-exposure, blunt, and eye-catching campaign that utilises multiple sources of media. The first option has previously been used in New Zealand, as the HIV public health messages were only designed to be seen by at-risk individuals and communities.<sup>661</sup> Clearly the previous promotional campaigns for HIV prevention have not been working, given the rising rates of HIV and prominence of new infections (>500 CD4 cell/ml<sup>3</sup>). Therefore, it is time to try something new, innovative and strategic that will grab people's attention. It is recommended that the MOH and NZAF collaborate to create a promotional campaign for PrEP that gets viewers thinking and talking about HIV prevention and PrEP. Two promotional campaigns, one American and one international, are analysed below which may provide guidance for the MOH.

### **PrEP4Love**

PrEP4Love is a successful campaign from Chicago that has gained attention for exploring concepts of "intimacy and relationships and empowering people" while using PrEP.<sup>662</sup> PrEP4Love is a very visible campaign advertised in public places,<sup>663</sup> and features all different types of PrEP-users, not just stereotypical white MSM.<sup>664</sup> The adverts were designed to celebrate intimacy, safe sex, and love combined with HIV prevention, rather than following the characteristic scaremongering public health campaign template.<sup>665</sup> Given that PrEPared Against HIV: 2.0 is only designed for the

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<sup>660</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>661</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>662</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>663</sup> Jim Pickett, 'PrEP4Love Lessons', *Positively Aware*, 1 March 2016, <https://www.positivelyaware.com/articles/prep4love-lessons>.

<sup>664</sup> PrEP4Love, 'PrEP4Love. One Pill. Once a Day. Protect Against HIV.', *PrEP4Love.com*, 2016, <http://prep4love.com/>.

<sup>665</sup> Pickett, 'PrEP4Love Lessons'.

implementation of PrEP for MSM, some of the advertisement images for PrEP4Love may not be applicable. However, this should not deter advisors from looking at how they could replicate a campaign for PrEP for MSM that is also attention grabbing and effective. The PrEP4Love slogan is 'PrEP. One Pill. Once a Day. Protect Against HIV.' PrEP4Love's slogan clearly describes what PrEP is and what it does. It is catchy but does not rely on graphic images or stereotypes to promote the medication. Another saying used by the Chicago campaign is 'Love is contractible. Lust is transmittable. Touch is contagious. Catch feelings, not HIV.' The catchphrase combines words linked to love, sex, and relationships with words associated with infections. Both of these slogans are clever and get the message about PrEP across without the need to rely on stereotypes, risk labels, and lengthy descriptions.

### APCOM

APCOM is an organisation that acts as a community liaison for HIV in multiple different countries. APCOM encourages the combination of PrEP and other methods for HIV prevention because "PrEP is a programme, not just a prescription."<sup>666</sup> APCOM promotes PrEP using adverts that compare the medication to other similar prevention methods. For example:

- 'PrEP is like taking anti-malaria pill. It's a good strategy before you embark on your exotic adventure.' [sic]
- 'PrEP is like protecting your body against sunburn. It's better to be ready before you get hot and sweaty.'
- 'PrEP is like wearing a life vest while travelling on a boat. You hope for the best, but plan for the unexpected.'
- 'PrEP is like taking oral contraception. Take it or leave it, the decision is yours.'<sup>667</sup>

These simple comparisons remove the negativity associated with the biomedicalisation of HIV prevention and equate PrEP to common prevention methods that are used regularly. APCOM's adverts show that PrEP is like any other prevention technique that can be used to reduce the risk of something undesired occurring<sup>668</sup> and that PrEP is a good method to prevent HIV.

### **Direct-to-consumer advertising**

Direct-to-consumer advertising (DTCA) of pharmaceutical products is currently allowed in only two developed countries, America and New Zealand. It is important that the MOH and other stakeholders are aware that Gilead Sciences and generic manufacturers of PrEP may consider DTCA of PrEP. To summarise briefly, DTCA is controversial because it can convince individuals that they may suffer from a certain

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<sup>666</sup> APCOM, 'Pre-Exposure Prophylaxis (PrEP) 101', APCOM, 10 September 2015, <https://apcom.org/2015/09/10/prep101/>.

<sup>667</sup> Ibid.

<sup>668</sup> Ulrich Beck, 'Living in the World Risk Society', *Economy and Society* 35, no. 3 (1 August 2006): 329–45.



condition, influencing them to approach their healthcare provider and request the medication advertised to them. DTCA allows the individual to self-diagnose their conditions and puts pressure on the doctor to prescribe a particular medication.<sup>669</sup> The MOH and PrEP providers will need to be aware of any impact that DTCA of PrEP could have on PrEP prescriptions, such as persuading low- or medium-risk MSM to try and use the medication. The impact may be small if the government only decides to subsidise one brand of generic PrEP, but it could cause some uninformed PrEP-users to demand more expensive PrEP under the assumption that a more costly medicine is more effective at preventing HIV.

### **Risk compensation and antiretroviral resistance**

PrEP is not the silver bullet for HIV. Slip-ups can happen: missed PrEP pills result in less active components in the body to prevent the virus from taking hold, which can lead to seroconversion and potential antiretroviral resistance. Both risk compensation and antiretroviral resistance were discussed in Chapter 2 from provider and patient perspectives. The most likely instance of risk compensation between MSM would be reduced condom use, but could also include increased sexual partners.

There is a general consensus between the HIV experts that were interviewed that risk compensation is a real problem associated with PrEP use.<sup>670, 671, 672, 673</sup> For PrEP to be most effective, and for this policy to have an impact on HIV infections, it is imperative that the potential for risk compensation is minimised and users are dissuaded from doing so. Infectious disease doctor Nigel Raymond, who has extensive experience treating HIV-positive patients, argues that risk compensation needs to be minimised because “you can have a... better roll cage or air cushion in your car but if you drive faster as well, you might lose some of the benefit.”<sup>674</sup> Fortunately, New Zealand has a history of condom use that has led to a strong condom culture today. The NZAF hands out around 700,000 condoms each year and estimates that 80% of MSM use condoms regularly.<sup>675</sup> Those who do not support PrEP commonly argue that PrEP will detract from the condom culture,<sup>676</sup> which could undo the decades of support for this important public health tool. Similarly, PrEP does not prevent individuals from STIs, which are extremely prevalent among MSM. As a result, the NZAF states that they will only promote PrEP as a partner to condoms, not as a sole intervention.<sup>677</sup>

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<sup>669</sup> World Health Organization, ‘Direct-to-Consumer Advertising under Fire’, *WHO*, 2009, <http://www.who.int/bulletin/volumes/87/8/09-040809/en/>.

<sup>670</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>671</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>672</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>673</sup> Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital.

<sup>674</sup> Ibid.

<sup>675</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>676</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>677</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

Therefore, it is recommended that risk compensation be minimised using an approach with multiple strategies including an emphasis on condom use, combined prescriptions, and utilising the education and promotion campaigns. Instead of presuming that all PrEP-users will engage in risky behaviour, PrEPared Against HIV: 2.0 should contain effective strategies to promote condom use and remove the temptation. Firstly, all healthcare professionals should help PrEP-users develop habits that minimise the temptation to engage in risk compensation. This includes ensuring PrEP-users always have access to condoms and make it a habit to use them during sex to prevent STIs. As well as encouraging good habits, PrEP providers will promote multiple methods of HIV prevention to minimise the negative impacts if risk compensation does occur. This approach acknowledges that mistakes such as missed pills can happen but using multiple prevention methods increases one's overall protection against HIV.

Secondly, it is recommended that PrEP and condoms be prescribed together each time the doctor writes a new script. More than 38% of the Canterbury MSM said that they would be less likely to use condoms if they took PrEP but if users have easy access to condoms, it is possible that they may be more willing to use them. Pairing condoms with the PrEP prescription may prevent the 30% of Canterbury MSM who would still have unprotected anal intercourse if they did not have access to condoms. Condoms are currently subsidised by PHARMAC so twelve boxes (144 condoms) costs \$5. Depending on the government's investment in PrEP, they may consider offering free condoms to PrEP-users to ensure that access and availability of condoms remains as high as possible. However even if the government does not remove the cost of a condom prescription, an additional \$5 for each prescription should not be too much for MSM to pay. Furthermore, MSM can always get free condoms from the NZAF.<sup>678</sup>

The third recommendation to reduce risk compensation is increased STI testing for MSM. Doctors and nurses should require regular HIV and STI tests at least four times each year as recommended in the clinical guidelines for PrEP. An American modelling study estimates that if 40% of at-risk MSM used PrEP, twice yearly STI screenings would prevent "42% of [gonorrhoea] infections and 40% of [chlamydia] infections" in ten years.<sup>679</sup> Quarterly STI tests may have an even bigger impact on future STIs, as it gives doctors twice as many chances to pick up infections each year and prevent them from being passed on to more individuals.<sup>680</sup> 85% of MSM from the attitude scaling survey said the requirement for regular HIV tests is not a burden, so it is possible that they would feel the same about frequent STI tests.

Finally, the educational and promotional campaigns for PrEP should highlight the importance of condoms as a companion to PrEP. Promoting common prevention pairs may help to reinforce the message, like being sun safe; using sunscreen is

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<sup>678</sup> Ibid.

<sup>679</sup> Samuel M. Jenness et al., 'Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis Among Men Who Have Sex With Men: A Modeling Study', *Clinical Infectious Diseases* 65, no. 5 (1 September 2017): 717.

<sup>680</sup> Ibid.

important but wearing a sunhat and sunglasses, and sitting in the shade are all additional methods to avoid sunburn. The MOH and PrEP providers will need to reinforce the messages shown in the education and promotion campaigns by offering condoms and regular STI and HIV tests. However, it is imperative to remember that for some MSM who never use condoms, using PrEP as one protection method is better than using nothing at all.

### Stigmatisation

Stigmatisation related to PrEP is widely known, and potential PrEP-users factor this into their decision to use the medication. No one wants to be labelled a 'Truvada whore'<sup>681</sup>,<sup>682</sup> or mistaken to be HIV-positive when taking PrEP.<sup>683</sup> The stigma associated with PrEP comes in three main forms: misinformation about PrEP, preconceived judgements from individuals who see PrEP as an excuse to be promiscuous,<sup>684</sup> or out-dated knowledge of HIV. It is hard to dispel rumours and reduce stigmatisation, but it is recommended that the MOH and other stakeholders utilise both top-down and bottom-up approaches.

The top-down approaches can be lead by the MOH and NZAF. The promotional campaigns can be used to correct rumours or labels associated with PrEP. One idea is to compare PrEP to the oral contraceptive pill. In reality, the oral contraceptive pill is similar to PrEP because both medications prevent something unwanted. This is similar to APCOM's comparison advertisements discussed earlier. The educational campaigns can emphasise to PrEP-users that the labels are not true. Furthermore, continual education about HIV prevention is important for all individuals, not just those who are statistically more likely to acquire the infection. This may start with better sexual health education in schools to remove stigmatisation, including more about same-sex relationships and LGBTI topics in the curriculum.<sup>685</sup> The NZAF can support the MOH and Ministry of Education to facilitate better education about HIV.

The bottom-up approach will be supported by the NZAF but begins at the individual level, as confident PrEP-users and members of the peer network can show that the labels are not true. Some of the stigma towards PrEP comes from inside the gay community.<sup>686</sup> For example, one in five Canterbury MSM from the survey agreed that people take PrEP so they can have lots of sexual partners. Similarly, research in Seattle found that MSM were stigmatised for using PrEP when using online websites to

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<sup>681</sup> Sarah K. Calabrese and Kristen Underhill, 'How Stigma Surrounding the Use of HIV Pre-Exposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize "Truvada Whores"', *American Journal of Public Health* 105, no. 10 (October 2015): 1960–64.

<sup>682</sup> Bridget G Haire, 'Preexposure Prophylaxis-Related Stigma: Strategies to Improve Uptake and Adherence – a Narrative Review', *HIV/AIDS (Auckland, N.Z.)* 7 (13 October 2015): 241–49.

<sup>683</sup> Sarit A. Golub et al., 'From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence Among MSM and Transgender Women in New York City', *AIDS Patient Care & STDs* 27, no. 4 (April 2013): 248–54.

<sup>684</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>685</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>686</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

chat to others. One user states that after telling people that he used PrEP, others would shame him by saying “Oh you’re on PrEP, you must be a slut. You must be irresponsible. You must make really bad choices to think you need to be on this.”<sup>687</sup> Thus, it is important that this bottom-up method tries to change the way people perceive PrEP. Anecdotal stories may prove effective at reducing stigmatisation as it provides a relatable story. The NZAF did this recently with HIV-positive individuals to remove the stigma from HIV so it may work with PrEP too.

The UNAIDS recommends that campaigns to reduce HIV stigmatisation are paired with other HIV policies,<sup>688</sup> which is why the bottom-up and top-down approaches to reduce PrEP discrimination are part of PrEPared Against HIV: 2.0. It is possible that as PrEP gains more attention and more MSM use the medication, the stigma associated with the drug will reduce. The MOH’s strategy to remove labels related to PrEP and PrEP-users will need to be monitored and evaluated to ensure it is effective. Similarly, the strategy may need refreshing regularly to match the levels of stigmatisation or types of labels associated with PrEP. The ideas discussed above are not concrete or the only methods to reduce discrimination towards PrEP-users.

The next section will discuss limitations associated with the overall policy. These limitations are a lack of risk management, exclusivity, and a missing rung on the ladder of citizen participation.

## Limitations

### ***Risk management analysis***

Weiss’s problem-solving model uses research to reduce uncertainty and create a policy solution, but as with the majority of policy recommendations, the design of the programme is incomplete and there are risks.<sup>689</sup> HIV prevention has remained relatively unchanged since the emergence of the virus in the 1980s with the promotion of behavioural methods. This lack of change was not an issue because up until now, there was no option to try new prevention techniques. But now policy advisors and health officials have the option to make a change and switch up New Zealand’s HIV prevention policies. Changing tack is not as simple as reallocating funding and designing a policy because new, innovative options can be riskier than not changing. As a result, it is common practice for policy advisors to engage in risk management strategies when developing and implementing policy.<sup>690</sup> Risk management follows Beck’s risk society theory where potential hazards are acknowledged, assessed for

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<sup>687</sup> Shane P. Collins, Vanessa M. McMahan, and Joanne D. Stekler, ‘The Impact of HIV Pre-Exposure Prophylaxis (PrEP) Use on the Sexual Health of Men Who Have Sex with Men: A Qualitative Study in Seattle, WA’, *International Journal of Sexual Health* 29, no. 1 (2 January 2017): 61.

<sup>688</sup> UNAIDS, ‘Reduction of HIV-Related Stigma and Discrimination | UNAIDS’ (UNAIDS, 2014), 12, <http://www.unaids.org/en/resources/documents/2014/ReductionofHIV-relatedstigmaanddiscrimination>.

<sup>689</sup> Bell, *Research for Health Policy*, 34.

<sup>690</sup> HM Treasury, ‘The Green Book: Appraisal and Evaluation in Central Government’ (London: HM Treasury, 2003), 29, <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>.

their predicted harm, and plans are put in place to minimise the negative outcomes should these risks occur.<sup>691, 692</sup> Unfortunately, this research had little room left to delve into risk management for PrEPared Against HIV: 2.0, which is a disadvantage if this research is used for further development of policies. The policy did discuss briefly risks identified through the literature review, such as stigmatisation, risk compensation leading to increased STIs, and antiretroviral resistance. However, highlighting these risks is not enough; there is great potential that risks may occur that the researcher did not identify, which could result in the policy being poorly implemented. If there was room for more detail, it is recommended that PrEPared Against HIV: 2.0 is presented to healthcare professionals, policy advisors, politicians and other key stakeholders with an adequate risk management section. This risk analysis should include techniques to plan against risks and stop them from impacting further sections of the policy. The risk management should include risks associated with the overall policy, not just with using the medication.

### ***Exclusivity***

PrEPared Against HIV: 2.0 provides a framework for the implementation of PrEP for MSM, thus excluding all other potentially at-risk users. Due to research constraints, it was more beneficial that the researcher focused on one at-risk population group. As discussed earlier, MSM were chosen because they make up the vast majority of new HIV diagnoses each year, therefore offering the greatest potential impact. However, the exclusivity of PrEPared Against HIV: 2.0 is undeniable and a clear limitation of the overall policy. The statistical profiles of high-risk HIV users are well-known but the most recent recommendation from the WHO is that PrEP should be provided to all high-risk individuals, regardless of what cohort they fit into.<sup>693</sup> The researcher is uncertain how much interest PrEP would gather among at-risk individuals in New Zealand who do not identify as MSM, so this should be explored further. If non-MSM fit the criteria to use PrEP (this criteria may be different to what is used to judge MSM) they should be offered the opportunity to use PrEP to prevent HIV transmission.

### ***A missing rung on the ladder***

The aim of the focus group was to discuss parts of the policy to get an in-depth, grassroots insight into complex components of PrEP implementation. For example, the researcher wanted to discuss the best ways to target at-risk MSM for PrEP and their thoughts on stigmatisation of the medication. According to Sherry Arnstein's Ladder of Citizen Participation, both the focus group and attitude scaling survey fit on the consultation rung of citizen engagement and participation. The consultation rung is defined as an exercise where the citizens' attitudes and opinions of a certain subject

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<sup>691</sup> Ibid.

<sup>692</sup> Bell, *Research for Health Policy*, 34–35.

<sup>693</sup> World Health Organization, 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection'.

are collected.<sup>694</sup> Unfortunately, the cancellation of the focus group meant a lost opportunity to engage with potential PrEP-users in a meaningful way. If there were higher levels of participation, the focus group could have provided unique insights from MSM and HIV experts to shape the policy. Involving input from multiple groups of key stakeholders could have further strengthened PrEPared Against HIV: 2.0.

## Conclusion

This chapter has presented PrEPared Against HIV: 2.0, a policy for the implementation of PrEP for MSM in New Zealand as a HIV prevention technique. This policy was informed by Weiss's problem-solving model, which utilises research to reduce uncertainty about a problem and inform the design of a policy recommendation. A Base Case was presented that highlighted that the current HIV prevention methods are not working based on increasing infections and record HIV diagnoses in 2016. As a result, PrEPared Against HIV: 2.0 calls for increased political action towards HIV prevention through the investment into a PrEP policy to prevent future infections. This policy is strategic, innovative and forward-thinking: it supports a new HIV prevention technique that has not been used in New Zealand before, and calls for greater funding for prevention rather than treatment. This policy goes beyond the typical evidence-based recommendation, as it factors in grassroots opinions from MSM in Canterbury, and "emotions and values" of HIV experts from various sectors.<sup>695</sup>

To summarise briefly, the policy will be led by the MOH, who are supported by the NZAF, DHBs, and PrEP providers. Clinical guidelines will determine the prescribing protocol, which may include techniques to improve adherence and enforce regular STI and HIV tests. This chapter presented nine different options for funding PrEP based on a monetary investment from the government and who could access the drug. It was recommended that the policy uses option B3, partial subsidisation of generic PrEP for high-risk MSM. This would allow an estimated 5,000 high-risk MSM to access partially funded PrEP. The government could be expected to pay between \$1.8-3 million annually for 5,000 prescriptions, and PrEP-users would pay \$360-600 for a year's worth of PrEP. This investment does not include the additional costs to the government, including funding the other components of this policy and increased strain on the healthcare system. PrEPared Against HIV: 2.0 also favours strong educational and promotional campaigns. These campaigns will help promote PrEP as an HIV prevention method, educate users about the drug, and provide current and potential users with resources to guide PrEP use. The promotional campaigns will also serve to remove any negative labels or stigma associated with PrEP and PrEP-users.

As with any policy, there are a number of limitations with PrEPared Against HIV: 2.0. Firstly, no risk analysis was completed for the policy. This would have identified potential risks and the suitable actions that could be taken to minimise these hazards. If the policy was developed further it would be essential to include a risk

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<sup>694</sup> Sherry R Arnstein, 'A Ladder of Citizen Participation', *Journal of the American Institute of Planners* 35, no. 4 (1969): 219.

<sup>695</sup> Bromell, *The Art and Craft of Policy Advising: A Practical Guide*, 100.

management strategy to ensure the implementation of PrEP is most effective. Secondly, PrEPared Against HIV: 2.0 is only designed for MSM, therefore excluding all other potentially at-risk groups and individuals. The funding option recommended for the policy also excluded any sort of subsidisation for non-MSM users. Given the scope of the research, it was not possible to create a policy for non-MSM users, but if interest in PrEP among other at-risk individuals was to increase, there is potential to expand PrEPared Against HIV: 2.0. Finally, the cancellation of the focus group meant there was a missed opportunity for community engagement for the policy. Consulting with the MSM and HIV experts in a focus group setting would have provided the policy with grassroots insights and offered information about HIV prevention that the researcher may not have thought of.

Regardless of the limitations, PrEPared Against HIV: 2.0 is an evidence-based policy that includes insights from potential PrEP-users and HIV experts through Weiss's problem-solving model. The primary data collected from the survey and interviews was complimented by document analysis. PrEPared Against HIV: 2.0 is not complete, but it highlights one way that PrEP could be implemented in New Zealand using the MOH and NZAF with support from other key stakeholders. While this policy is theoretical, there is potential that it could aid future PrEP policies that are established in New Zealand, such as the one currently being developed by the MOH. At the very least, PrEPared Against HIV: 2.0 proves that there is a very real need for a change in New Zealand's HIV prevention methods and PrEP is a worthwhile option. Change can be hard, particularly when it comes to promoting new ideas within the public health sector when people are set in their ways. However, not changing is also a risk,<sup>696</sup> and given the increasing diagnoses of HIV in New Zealand, it is time to take this risk and try something new. PrEPared Against HIV: 2.0 provides the health sector with a very real alternative to potentially stop new transmissions of HIV in New Zealand,<sup>697</sup> and change the course of the HIV epidemic forever.<sup>698</sup>

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<sup>696</sup> Bell, *Research for Health Policy*, 34.

<sup>697</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>698</sup> Newshub, 'Labour calls for Anti-HIV Drug Funding', *Newshub*, 16 July 2017, Online edition, sec. Health, <http://www.newshub.co.nz/home/health/2017/07/labour-calls-for-anti-hiv-drug-funding.html>.



## Chapter 6: The Beginning of a New Era

*Support for PrEP is obvious; PrEP is “an intervention that has clear individual benefit and therefore it’s important that we provide that.”<sup>699</sup> This chapter explores the future of this new biomedical era of HIV prevention.*

This concluding chapter discusses lessons that can be learned from this research, and explores that potential impact that this research and PrEP could have on academia and real-world policy.

### Introduction

This research analysed PrEP as a new HIV prevention method. Chapter 1 introduced HIV as an illness, analysed trends of HIV infections in New Zealand among men who have sex with men (MSM), and introduced PrEP as a medication. Chapter 2 provided an in-depth literature review focusing on three key topics: the first-generation randomised controlled trials (RCTs) for PrEP, PrEP providers’ attitudes towards the new drug, and the opinions of MSM who could use PrEP. Chapters 1 and 2 clearly showed that while PrEP could have a positive impact on HIV prevention when taken correctly, the drug is not without its complications. For example, some complexities are potential antiretroviral resistance, side effects, cost, and adherence. The first two chapters provided the necessary background information for Chapter 3 where the research design, questions, and aims were all discussed. Chapter 3 also introduced Carol H. Weiss’s problem-solving model, which uses research to reduce uncertainty regarding a particular problem that subsequently informs a solution. This research asked if MSM from Canterbury felt that PrEP has a place in New Zealand’s public health system and Chapter 4 answered this question. 100% of participants from the online survey agreed that PrEP is a worthwhile HIV prevention method for MSM, and 100% agreed that PrEP is a good method to reduce the chance of HIV transmission. The research also questioned how an effective policy could be designed for PrEP that minimises the complexities linked to the medication cited in Chapters 1 and 2. Chapter 5 presented an evidence-based, grassroots policy for PrEP for MSM in New Zealand called PrEPared Against HIV: 2.0. This policy tackles issues such as PrEP providers, funding options, and the stigmatisation of PrEP.

Now we are at the beginning of a new era; we have the opportunity to implement a clearly effective, but complex, medication to reduce new HIV diagnoses in New Zealand. The future of HIV is uncertain, as PrEP and future biotechnologies that are not yet developed could eradicate HIV entirely. What was once one of the biggest “public health challenges of the twenty-first century” could soon become a disease of the past, just like the bubonic plague and smallpox.<sup>700</sup> This new era of HIV prevention

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<sup>699</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic, interview by Alice Hartley, Face-to-face, 23 September 2016.

<sup>700</sup> Theodore H. Tulchinsky and Elena Varavikova, ‘HIV/AIDS’, in *The New Public Health*, Third edition (San Diego: Academic Press, 2014), 225.



is important, which is why this final concluding chapter reflects on lessons learned and looks to the future of PrEP.

### **Reflections on this thesis**

This section explores what the researcher has learned throughout the thesis project. The researcher has chosen three key lessons:

- The politicisation of HIV,
- Interpreting health trends, and
- Researching a current topic comes with extra factors to consider.

### **Once political, always political?**

HIV is arguably just as politicised nowadays as it was in the 1980s. When the HIV virus was initially noticed, AIDS was drastically overrepresented in groups that were “politically disadvantaged, socially marginalized, and partially hidden.”<sup>701, 702</sup> Gay and bisexual men, injecting drug users (IDUs), and sex workers all faced severe discrimination. For many years after the virus was discovered, an HIV diagnosis was a death sentence, which often resulted in mental health issues and negatively impacted relationships.<sup>703</sup> While we now know far more about HIV, the virus is undoubtedly still politicised. The UNAIDS argues that stigmatisation and discrimination of HIV/AIDS can have real, negative impacts on prevention and treatment policies.<sup>704</sup>

HIV remains a tool of political leverage in New Zealand; various political parties have made claims about PrEP, and HIV prevention and treatment programmes leading up to the general election in September 2017. For example, the Labour party made the promise to fund PrEP in February and August 2017. Former Labour leader Andrew Little stated “spending this money now is actually saving us further down the track.”<sup>705</sup> MP David Clark, Labour’s health spokesperson, reinforced the economic value of PrEP in July 2017.<sup>706</sup> Furthermore, current Labour leader Jacinda Ardern said Labour “will fund access to PrEP.”<sup>707</sup> Similarly, the Green Party co-leader James Shaw said their party is “committed” to the New Zealand AIDS Foundation’s (NZAF) goal to eradicate

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<sup>701</sup> Peter Saxton et al., ‘Male Call / Waea Mai, Tane Ma: Report 7, Gay Community Involvement’ (Auckland, N.Z: New Zealand AIDS Foundation, April 1998), 1.

<sup>702</sup> Raymond A. Smith, ‘Government and Activism’, *Encyclopedia of AIDS: A Social, Political, Cultural, and Scientific Record of the HIV Epidemic* (Routledge, 27 August 1998).

<sup>703</sup> Heather Worth et al., ‘Male Call / Waea Mai, Tane Ma: Report 9, HIV Testing and Sero-Status’ (Auckland, N.Z: New Zealand AIDS Foundation, November 1999), 21.

<sup>704</sup> UNAIDS, ‘Reduction of HIV-Related Stigma and Discrimination | UNAIDS’ (UNAIDS, 2014), 2, <http://www.unaids.org/en/resources/documents/2014/ReductionofHIV-relatedstigmaanddiscrimination>.

<sup>705</sup> Breanna Barraclough, ‘Labour Promises to Fund HIV PrEP Pill’, *Newshub*, 12 February 2017, Online edition, sec. Politics, <http://www.newshub.co.nz/home/politics/2017/02/labour-promises-to-fund-hiv-prep-pill.html>.

<sup>706</sup> Newshub, ‘Labour Calls for Anti-HIV Drug Funding’, *Newshub*, 16 July 2017, Online edition, sec. Health, <http://www.newshub.co.nz/home/health/2017/07/labour-calls-for-anti-hiv-drug-funding.html>.

<sup>707</sup> Sarah Harris, ‘NZ Aids Foundation Say NZ Could Save Millions by Going HIV Free’, *NZ Herald*, 27 August 2017, Online edition, sec. New Zealand, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11909333](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11909333).

HIV by 2025, which includes the implementation of PrEP.<sup>708</sup> Prime Minister and National party leader Bill English has not made any open statements about PrEP, but was briefed about the demonstration project in Auckland while attending the Big Gay Out in February 2017. When asked about the National government's lack of prioritisation of HIV funding for treatment and prevention, English said, "If we saw some significant uplift in some of these debilitating health problems, then I would expect that the Minister of Health and the Ministry are answering questions about what action can be taken."<sup>709</sup> The researcher notes that after the Prime Minister made these comments, the AIDS Epidemiology Group confirmed that HIV rates are increasing and the Ministry of Health (MOH) has begun researching a policy for PrEP. In August 2017, the Minister of Health Dr Jonathan Coleman said that National supports an HIV-free New Zealand but the funding decision remains with PHARMAC.<sup>710</sup>

It is not surprising that the parties who are not in power currently (Labour and Green parties) would jump on this issue before a general election. It is always easy for parties in this situation to make bold statements about healthcare funding compared to what the current government budgeted. The support from the Labour and Green parties is further justified given the recent cuts to the Gay Auckland Periodic Sex Survey (GAPSS) and Gay men's Online Sex Survey (GOSS) under the National government. However, the promise of funding certain medication is not new to New Zealand politics, as these promises are used to potentially sway voters who have an interest in a health issue. In 2008, former Prime Minister John Key, who was the Leader of the Opposition at the time, made a promise to fund breast cancer treatment drug Herceptin. Key's decision went against the advice of PHARMAC and cancer experts<sup>711</sup> but was a clear example of politicising health as leverage to gain votes.

Yet once an issue gains traction politically and is prioritised by politicians, it is very hard for other topics to receive coverage. There is no doubt that HIV is not given priority in New Zealand compared to other health problems, based on the removal of the GAPSS/GOSS studies, the absence of a national HIV strategy since 2003,<sup>712</sup> and until very recently, the CD4 threshold for antiretroviral therapy (ART) for HIV-positive people. Mark Fisher, the Director of Body Positive, argues that HIV has limited exposure in the media and from the ministries, which has led to an attitude that HIV is "normalised" and a "non-issue."<sup>713</sup> It is highly likely that HIV will remain politicised in the short-term future, despite the experience of living with HIV nowadays is so

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<sup>708</sup> New Zealand Herald, 'Prime Minister Bill English's First Big Gay Out', *New Zealand Herald*, 12 February 2017, Online edition, sec. New Zealand, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11799367](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11799367).

<sup>709</sup> Ibid.

<sup>710</sup> Harris, 'NZ Aids Foundation Say NZ Could Save Millions by Going HIV Free'.

<sup>711</sup> Radio New Zealand, 'Herceptin Funded for 12-Month Course under National', *Radio New Zealand*, 23 October 2008, Online edition, sec. Election 2008, <http://www.radionz.co.nz/news/election-2008/86490/herceptin-funded-for-12-month-course-under-national>.

<sup>712</sup> Mark Fisher, Interview with Mark Fisher, Director of Body Positive, interview by Alice Hartley, Skype, 20 September 2016.

<sup>713</sup> Ibid.

different compared to the 1980s and 1990s.<sup>714</sup> Those working against HIV will face a losing battle to eradicate HIV unless PrEP or other HIV prevention methods are given priority by politicians and healthcare officials. Whether this occurs depends on many stakeholders and key factors: the results of the 2017 general election; the MOH's upcoming PrEP policy; PHARMAC's decision regarding subsidisation of PrEP; and the success of PrEP policies overseas. At this stage, it seems that HIV prevention and treatment will remain politicised, just as it has always been.

### Each to their own interpretation

When it comes to incidences of infection, the data cannot be taken at face value.<sup>715</sup> While incidences of HIV have been increasing steadily in New Zealand since 2011, it was not until 2017 that the AIDS Epidemiology Group confirmed a "true rise" in HIV infections.<sup>716</sup> However, before this confirmation in May 2017, the interpretation of HIV diagnoses greatly differed among the interviewees. The NZAF's Sean Kelly denied that HIV infections were increasing but argued that the increased testing meant it was inevitable that there would be more positive results from individuals who had not been tested before.<sup>717</sup> Kelly said that the increased testing would uncover a large number of infections quickly and then plateau out because HIV rates were not increasing overall. However, an HIV researcher argued that Kelly's prediction of a plateau of infections is not the only reason for the increase in diagnoses. In 2016, nearly 50% of the 244 new infections had a CD4 cell count of over 500, which confirms that these infections are "newly acquired."<sup>718</sup> The researcher also states that condom use is lower than it was a decade ago, which will have also contributed to the increase in HIV infections.<sup>719</sup> Infectious disease doctor Nigel Raymond agreed with the HIV researcher, stating that the increase in infection rates is a combination of increased testing uncovering old infections and lower condom use contributing to new infections.<sup>720</sup> Similarly, the Director of Body Positive attributed the increased incidence of HIV to new infections based on high CD4 cell counts reported when the virus was diagnosed.<sup>721</sup> These five HIV experts who come from very different backgrounds all had differing interpretations of HIV trends in New Zealand. This has uncovered how inferring data on a graph can vary based on who is looking at the

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<sup>714</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher, interview by Alice Hartley, Skype, 6 September 2016.

<sup>715</sup> Nigel Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group, interview by Alice Hartley, Skype, 7 September 2016.

<sup>716</sup> AIDS Epidemiology Group, 'AIDS - New Zealand', Newsletter (Dunedin, New Zealand: AIDS Epidemiology Group, Dunedin School of Medicine, University of Otago, May 2017), <http://dnmeds.otago.ac.nz/departments/psm/research/aids/newsletters.html>.

<sup>717</sup> Sean Kelly and Akira Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office, interview by Alice Hartley, Face-to-face, 24 August 2016.

<sup>718</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

<sup>719</sup> Ibid.

<sup>720</sup> Nigel Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital, Skype, 19 March 2017.

<sup>721</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

results and their experience of the topic. By talking to multiple interviewees from different sectors, the researcher was able to gain a better understanding of how different interpretations of the same data can be. Furthermore, it shows how data must be treated carefully and how certain one must be before making bold claims about trends.

### **Current events can cause a headache**

While it has been exciting to study an innovative and new biomedical HIV prevention method, it has not been easy keeping up with all of the new developments regarding PrEP nationally and internationally. Since the beginning of this research, huge progress has been made overseas regarding funding battles for PrEP, the implementation of numerous PrEP policies, and multiple demonstration projects and pilot studies. For example, HIV infections among gay and bisexual men have dropped by 25% in London and 17% in England overall in one year.<sup>722</sup> While the cause of “this first downturn of the HIV epidemic in gay men” is yet to be fully understood, experts believe it is linked to increased PrEP use, more frequent HIV testing, and quick access of ART for HIV-positive individuals.<sup>723</sup>

Meanwhile in New Zealand, the researcher was aware of the NZAF’s PrEP demonstration project that was to be held in late-2016. The wheels were quickly put into motion for PrEP implementation throughout the country, with Medsafe’s approval of Truvada and two generic versions of PrEP, as well as multiple community forums hosted by the NZAF to discuss PrEP. Furthermore, the researcher was made aware that the MOH was formulating a policy for PrEP in late-March 2017. PrEP was constantly evolving, both nationally and internationally, which left the researcher with the never-ending task of trying to keep up with new developments while completing this research. This thesis has shown that while it is exciting to focus on topical subjects, it can be hard, as the work must be constantly updated to reflect new changes. The next section will discuss implications of PrEP in the future.

### **Implications of PrEP in the future**

There is no doubt that there will be implications associated with using PrEP in the future if it has a real impact on HIV infections worldwide. The researcher has identified three key implications:

- What will happen to PrEP-users if there is no policy in place,
- The impact on third-world nations, and
- The importance of promoting PrEP and HIV prevention in sexual education curricula in schools.

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<sup>722</sup> Sarah Boseley, ‘Fall in HIV among Gay Men Could Spell End for Britain’s Epidemic, Say Experts’, *The Guardian*, 22 June 2017, Online edition, sec. Society, <http://www.theguardian.com/society/2017/jun/22/fall-in-hiv-among-gay-men-could-spell-end-for-britains-epidemic-say-experts>.

<sup>723</sup> Ibid.

### Impact of PrEP without a policy

If the MOH or another stakeholder implements a policy for PrEP in New Zealand, the implications that PrEP could have on the future are well-known. Most obviously, there is a very high chance that PrEP will prevent future HIV infections (PrEP's efficacy cannot be assumed totally effective, given the lack of success seen in the FEM-PrEP and VOICE RCTs<sup>724, 725</sup>). Furthermore, the healthcare sector will be required to cope with the extra demands this medication creates. However, if a decision is made that a policy for PrEP is not in the best interests of the government/MOH/other key stakeholders, the responsibility for PrEP is likely to rest on PrEP-users, doctors, and the NZAF. Any at-risk individuals who wish to use PrEP without an official health policy will be required to parallel import the medication regularly. While this is what current PrEP-users are doing, as PrEP gains more attention, there is potential for considerable numbers of at-risk individuals to use this method. Parallel importing is legal, though there is no guarantee that the medication sent from overseas is safe, which is a risk for both doctors who authorise the prescription and PrEP-users.<sup>726</sup> In addition, doctors may be required to provide adequate healthcare for PrEP importers without clinical guidelines that would be required for a PrEP policy. Without ministry support for PrEP, healthcare professionals may be put under unnecessary pressure, which could negatively impact the PrEP-users. Furthermore, the NZAF and other similar community groups are likely to face an increase in their work. These groups may be required to pick up the slack of the MOH if a policy is not implemented because PrEP-users will need specialised support. This will be even harder for the NZAF and other groups if they are not given extra funding for this increase in work. The MOH should be wary of what impact not having a PrEP policy could have on PrEP-users, not-for-profit organisations, and the health sector.

### Impact on HIV in third-world countries

While PrEP has proven efficacy in RCTs, there is a level of caution regarding how PrEP will perform in a real-world situation free from the control of a trial.<sup>727, 728, 729</sup> This is known as the efficacy-effectiveness gap, which was discussed in Chapter 2. However, if the current pilot studies and demonstration projects show PrEP reduces HIV acquisition without the controlled circumstances of trials, PrEP should become available in all countries. There will be a particular need for PrEP in developing nations with high rates of HIV. For example, sub-Saharan African nations make up 69%

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<sup>724</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>725</sup> Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital.

<sup>726</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>727</sup> Douglas Krakower et al., 'HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings: A Qualitative Study', *AIDS and Behavior* 18, no. 9 (26 June 2014): 1712–21.

<sup>728</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

<sup>729</sup> Raymond, Interview with Dr Nigel Raymond, Infectious Disease Specialist at Wellington Hospital.

of new HIV infections<sup>730</sup> and HIV affects more than 15% of the total population in Swaziland, Botswana, Lesotho, South Africa, Zimbabwe, and Namibia.<sup>731</sup> PrEP could have a significant impact on the HIV epidemic in third-world countries. This impression could be especially noticeable in nations where condom use is low, as individuals will have a layer of protection that was not available before. Furthermore, serodiscordant couples in third-world nations could access support for conceiving while using PrEP to ensure the HIV infection is not passed on.

It is likely that these developing nations will require tailored PrEP policies that take into consideration geographic, cultural and demographic barriers of each country. Developing countries may require support to implement PrEP from outside parties such as UNAIDS or other nations with current PrEP policies in action. However, if PrEP is not made readily available and easily accessible, less developed nations with already disproportionate incidences of HIV will be hugely disadvantaged. Access to PrEP may also become an essential human right for all those who are at-risk of contracting HIV. Therefore, if the efficacy-effectiveness gap has limited influence on PrEP, there is a very real chance that PrEP may have clear implications for the future of the HIV epidemic, chiefly in developing nations.

#### Promotion of PrEP in sexual education

It is imperative that sexual education is updated if PrEP becomes a key tool in the HIV prevention kit. When interviewed, Sean Kelly and Akira Le Fevre said sex education that incorporates HIV and LGBTI topics is currently limited in New Zealand. Many “principals and school board members” do not want to include HIV and LGBTI subjects as part of their sexual education classes.<sup>732</sup> These decisions may encourage stigmatisation of HIV and can negatively impact students who would benefit from HIV education. Without teaching future generations about safe sex and HIV prevention, many teenagers may make unwise decisions or be under the impression that HIV is not an issue anymore.<sup>733</sup> It is recommended that if PrEP becomes a mainstream HIV prevention method it is added to the curriculum for sexual health classes in schools, just as condoms and oral contraceptive methods currently are. This will help ensure that young, impressionable New Zealanders have the knowledge to make the right decisions based on their behaviour. Having correct information about PrEP, HIV prevention, and safe sex instead of relying on out-dated material or rumours will positively benefit everyone. The final section will discuss recommendations for future research regarding PrEP.

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<sup>730</sup> United Nations Human Rights: Office of the High Commissioner, ‘HIV/AIDS and Human Rights’, *United Nations Human Rights: Office of the High Commissioner*, n.d., <http://www.ohchr.org/EN/Issues/HIV/Pages/HIVIndex.aspx>.

<sup>731</sup> Central Intelligence Agency, ‘HIV/AIDS - Adult Prevalence Rate’, *The World Factbook — Central Intelligence Agency*, 2014, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2155rank.html>.

<sup>732</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>733</sup> Ibid.



### Directions for future research

Research on PrEP is only just beginning, as academics, scientists, and policymakers alike have the opportunity to explore the impact of this new biomedical technology. This thesis has only skimmed the surface in terms of PrEP-related topics, particularly regarding attitudes towards the medication and its potential as a health policy in New Zealand. Therefore, the researcher has identified three directions for future research that may be worthwhile in New Zealand:

- Further exploration of PrEP and biomedicalisation,
- The need for an in-depth understanding of non-MSM PrEP-users, and
- Case study policies.

### Biomedicalisation

In order to understand biomedicalisation, it is essential to have a basic knowledge of medicalisation, a sociological theory that was a key process prior to biomedicalisation. Medicalisation emerged slowly in the 1940s as a political-sociological phenomenon influenced by psychiatry and public health.<sup>734</sup> Medicalisation, as an exploratory framework, explains the expansion of medicine where problems that were once considered “moral, social, or legal” became medicalised.<sup>735</sup> Since 1985, medicalisation shifted into biomedicalisation. This transition was greatly influenced by the launch of the Human Genome Project in 1990, which aimed to map the genetic make-up of human beings. Biomedicalisation theorises the use of technology and science in the spheres of health and medicine to improve the current and future lives of humans.<sup>736</sup> Examples of biomedicalisation include plastic and cosmetic surgery, personalised medicine, anti-love medicine to cure ‘bad’ loves,<sup>737</sup> and identifying health risks at the gene, molecule, and protein level. Thus, biomedicalisation provides a scientific, technological, and medical tool that can correct what is ‘wrong’ or not good enough.

PrEP fits within the lens of biomedicalisation, as it uses a prophylactic to reduce the risk of HIV acquisition, thus improving the users’ lives. However, the biomedicalisation of HIV prevention has been continually cited as a problem with PrEP, as some doctors believe that non-biomedical HIV prevention methods are more effective and safer than PrEP.<sup>738, 739</sup> Furthermore, many doctors agreed that giving medication to otherwise healthy individuals is not recommended.<sup>740, 741, 742, 743, 744, 745</sup>

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<sup>734</sup> Irving Kenneth Zola, ‘Medicine as an Institution of Social Control’, *The Sociological Review* 20, no. 4 (1 November 1972): 487.

<sup>735</sup> Ibid.

<sup>736</sup> Adele E. Clarke et al., ‘Biomedicalization: A Theoretical and Substantive Introduction’, in *Biomedicalization: Technoscience, Health and Illness in the U.S.*, ed. Adele E. Clarke et al. (Durham, NC: Duke University Press, 2010), 2.

<sup>737</sup> Brian D. Earp et al., ‘If I Could Just Stop Loving You: Anti-Love Biotechnology and the Ethics of a Chemical Breakup’, *The American Journal of Bioethics* 13, no. 11 (1 November 2013): 3–17.

<sup>738</sup> Puro et al., ‘Attitude towards Antiretroviral Pre-Exposure Prophylaxis (PrEP) Prescription among HIV Specialists’.

<sup>739</sup> Senn et al., ‘Knowledge of and Opinions on HIV Preexposure Prophylaxis among Front-Line Service Providers at Canadian AIDS Service Organizations’.

<sup>740</sup> Tripathi et al., ‘Preexposure Prophylaxis for HIV Infection’.

Similarly, some of the interviewees also argued against biomedicalisation. Sean Kelly from the NZAF echoes the argument that providing MSM with highly “toxic” drugs is unnecessary,<sup>746</sup> and Associate Professor and epidemiologist Nigel Dickson questions if medicalising sex is an issue because it is “a recreational activity.”<sup>747</sup> Yet the prevention of unwanted health problems have been medicalised long before PrEP. Dickson’s argument is invalid, given that the oral contraceptive pill for women is a clear example of medicalised sex that enables healthy women to take a medication to prevent an unwanted pregnancy. Another example of medicalised prevention are antimalarials; an individual has two choices to prevent malaria: wear long sleeved tops and pants to cover their skin as much as possible, or pay for antimalarials for medical protection.<sup>748</sup> This is the same for MSM having sex – they can choose to wear condoms, which is like wearing long sleeves,<sup>749</sup> or pay to use PrEP, a biomedical prevention method. Furthermore, the argument against prescribing healthy individuals with toxic drugs can also be compared to antimalarials, as doxycycline is also a strong medication with potentially long-term side effects.<sup>750</sup> The decision to use biomedicalised prevention interventions is weighed against the option to take drugs rather than contract a nasty illness,<sup>751</sup> and in the case of HIV, a permanent infection.

There is no doubt that the arguments against biomedicalisation of HIV prevention have merit, but it cannot be said that PrEP is the first drug to medicalise sex or be given to healthy individuals. Due to the empirical focus of this research driven by Weiss’s problem-solving model there was little room to use biomedicalisation to examine PrEP, although it is clear that PrEP fits within this academic theory. Furthermore, theories are useful for explaining why things have happened in the past, discussing current trends, and making assumptions about the future. Consequently, it is recommended that future research on PrEP places more importance on this topic in relation to biomedicalisation and other relevant academic theories.

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<sup>741</sup> Tellalian et al., ‘Pre-Exposure Prophylaxis (PrEP) for HIV Infection’.

<sup>742</sup> Karris et al., ‘Are We Prepped for Preexposure Prophylaxis (PrEP)?’

<sup>743</sup> Krakower et al., ‘HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings’, 26 June 2014.

<sup>744</sup> Blumenthal et al., ‘Knowledge Is Power! Increased Provider Knowledge Scores Regarding Pre-Exposure Prophylaxis (PrEP) Are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP’.

<sup>745</sup> Krakower et al., ‘Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention’.

<sup>746</sup> Kelly and Le Fevre, Interview with Sean Kelly and Akira Le Fevre: New Zealand AIDS Foundation, Christchurch office.

<sup>747</sup> Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group.

<sup>748</sup> Dickson, Interview with Associate Professor Nigel Dickson, Epidemiologist at the University of Otago and former Director of the AIDS Epidemiology Group.

<sup>749</sup> Ibid.

<sup>750</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>751</sup> Ibid.



### Non-MSM PrEP-users

Due to the scope of this thesis, the researcher focused solely on PrEP for MSM. While MSM are disproportionately represented in the HIV epidemic nationally and internationally, there are many at-risk groups and individuals that do not fit within this category that could benefit from PrEP. Due to the focus on MSM, little was discovered about the proportion of other at-risk individuals, but it is important that future research looks at non-MSM cohorts. These non-MSM users will be a minority within an already small group of New Zealanders that are deemed at-risk of HIV, so it is important that they are not treated as a homogenous group. Therefore, this research will ensure that all high-risk individuals are able to benefit from the added protection of PrEP against HIV. Furthermore, if non-MSM use PrEP, they may need to receive different types of healthcare when they visit their doctor. Similarly, non-MSM individuals will need to be targeted differently: they will require directed education resources based on their risky behaviours and a different advertising approach. Thus, it is recommended that further research be completed about potential non-MSM PrEP-users to uncover attitudes towards the medication, appropriate methods of education and promotion, and ways to improve healthcare for these individuals. If the non-MSM are able to use PrEP for HIV prevention, the stakeholders will need to design parts of an overall PrEP policy that are unique to these non-MSM. Future research into these minority groups of non-MSM PrEP-users will also enable targeted prevention programmes that aim to reduce their overall risk of HIV using multiple methods, not just PrEP.

### Case study policies

Case studies are a research method that consists of a comprehensive study of a topic, such as “a policy, programme, intervention site, [and] and implementation process.”<sup>752</sup> Policy case studies allow the researcher to become an expert on a policy topic. The information gathered in a policy case study can encourage discussion and be used to help make decisions for the future policies in development.<sup>753</sup> For example, case studies may be used to explore why a policy was so successful. As a contrast, failed policies can also be analysed by extracting valuable lessons because policies that do not succeed are often just as helpful for policymakers. It is important that the MOH and other key stakeholders monitor the current and future PrEP demonstration projects, pilot studies, and health policies worldwide. Observing what methods are used overseas to effectively implement PrEP, particularly health policies, will be a useful way for decision-makers to take successful recommendations and make them relevant to PrEP-users in New Zealand. For example, the Auckland PrEP demonstration project organised by the NZAF was based on similar PrEP projects undertaken in Australia.<sup>754</sup> Undertaking case studies of PrEP policies may help the MOH and other key

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<sup>752</sup> Delwyn Goodrick, ‘Comparative Case Studies’, Methodological Briefs: Impact Evaluation No. 9 (Florence: Unicef, 2014), 1, <https://www.unicef-irc.org/publications/754/>.

<sup>753</sup> Robert K. Yin, *Case Study Research: Design and Methods*, Fifth edition (Los Angeles: SAGE, 2014), 14, 113.

<sup>754</sup> Fisher, Interview with Mark Fisher, Director of Body Positive.

stakeholders to ensure that the PrEP policy in New Zealand is as effective as possible, based on evidence from overseas.

### Conclusion

PrEP is a complex medication that spans both the public health sphere and the private, intimate behaviour of individuals. The medical evidence of PrEP's efficacy is clear: when taken once daily, PrEP is 92% effective of preventing HIV transmission. However, the social, economic, and emotional aspects of PrEP are more complicated. Branded PrEP, Truvada, is currently too expensive at around \$900-1,200 per month,<sup>755, 756, 757</sup> while generic PrEP costs between \$60-100 per month, which is significantly cheaper. If PrEP-users do not take the medication every day, the amount of active drugs in their body will decrease which can lead to seroconversion. If PrEP is taken while an individual seroconverts, there is a chance that their virus will become resistant to the active components in PrEP. PrEP-users are required to have regular HIV and STIs tests, as well as monitoring of their kidney function and bone density, which may be a hassle. Unlike condoms, PrEP does not prevent against STIs, so there is a chance that STI rates may increase among PrEP-users if they do not continue to use condoms. Furthermore, PrEP-users currently face stigmatisation for using the drug and are often labelled as promiscuous.

Given the complexities associated with PrEP, and slow uptake of the drug overseas, this thesis used Weiss's problem-solving model to answer the following questions: do MSM from Canterbury feel that PrEP has a place in New Zealand's public health system, and how could a policy be developed to minimise the difficulties faced overseas? It was important that the first research question was answered before the second because if Canterbury MSM did not see a role for PrEP in HIV prevention then there might have been no need for a policy. However, the results from the attitude scaling survey of Canterbury MSM found undeniable support for PrEP. While attitudes towards certain aspects of PrEP varied, all of the participants believe that PrEP is a worthwhile HIV prevention method and a good way to reduce the likelihood of HIV infection. With the level of support for PrEP clear, Chapter 5 analysed the need for a new HIV prevention policy using a Base Case. It is impossible to ignore the increasing rates of HIV infection since 2011, including the highest number of diagnoses in 2016 since records began. Therefore, PrEPared Against HIV: 2.0 calls for higher prioritisation of HIV prevention over treatment by allowing high-risk MSM to access subsidised PrEP. It is recommended that the government and PHARMAC choose a 50-50 split of the cost of PrEP prescriptions. The policy also acknowledged the need for adequate clinical guidelines, education material and promotional campaigns, and strategies to minimise risk compensation and stigma while encouraging adherence.

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<sup>755</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>756</sup> New Zealand AIDS Foundation, 'Pre-Exposure Prophylaxis (PrEP) Factsheet' (New Zealand Aids Foundation, n.d.), 1.

<sup>757</sup> Shriya Chitale, 'Cost of PrEP and HIV Treatment', 9 March 2017.

Therefore, it can be seen that both research questions were answered in this thesis through the multiple, mixed-methods design: MSM from Canterbury do support the use of PrEP for HIV prevention, and a policy can be developed that attempts to minimise the issues faced overseas with other PrEP programmes. Whether the government and MOH decide to also support PrEP is up to them, and as discussed earlier in the chapter, it is very possible that this decision will be impacted by the politicisation of HIV. However, it is important to put politics aside and look at the bigger picture: PrEP, when implemented correctly and successfully, can offer extremely high levels of protection against HIV. As one sexual health doctor argues,

It's an intervention that has clear individual benefit and therefore it's important that we provide [PrEP]... And it's verging on unethical not to – I don't want to be on the side of history saying, 'why did you wait so long?' frankly.<sup>758</sup>

It is time to take a risk by trying something new<sup>759</sup> and embrace an innovative, strategic, and forward-thinking policy for HIV prevention. PrEP is undoubtedly an investment for the future, which could help eradicate all future HIV diagnoses within New Zealand.<sup>760</sup> While further research may need to be conducted, at this stage we have nothing to lose from trying PrEP and everything to gain.

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<sup>758</sup> Sexual Health Doctor, Interview with Sexual Health Doctor, Christchurch Sexual Health Clinic.

<sup>759</sup> Erica Bell, *Research for Health Policy* (Oxford ; New York: Oxford University Press, 2010), 34.

<sup>760</sup> HIV/AIDS researcher, Interview with HIV/AIDS researcher.

## Appendices

### Appendix 1: List of AIDS defining conditions

The New Zealand Ministry of Health (MOH) lists the following as AIDS defining conditions:<sup>761</sup>

- “Candidiasis of bronchi, trachea, or lungs
- Candidiasis, oesophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcus, extrapulmonary
- Cytomegalovirus disease (other than liver, spleen or nodes)
- Cytomegalovirus retinitis (with impairment of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) >1 month’s duration; or bronchitis, pneumonitis, or oesophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month’s duration)
- Kaposi’s sarcoma
- Lymphoma, Burkitt’s (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Pneumonia, recurrent bacterial
- Progressive multifocal leukoencephalopathy
- Salmonella septicaemia, recurrent
- Toxoplasmosis, cerebral
- Wasting syndrome due to HIV.”

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<sup>761</sup> Ministry of Health and AIDS Medical and Technical Advisory Committee (AMTAC), ‘Management Guidelines: HIV/AIDS’, Fact sheet (Ministry of Health: Ministry of Health, December 1995), 3–4.

## Appendix 2: Facebook and email advertisement for online survey

### **Male Participants Wanted**

Pre-exposure prophylaxis (PrEP) is a once-daily, oral pill taken by HIV-negative individuals to reduce their risk of infection. When taken consistently, PrEP has been shown to reduce the chance of HIV infection by more than 90 percent. PrEP is not currently available in New Zealand, but this research aims to design a policy where it can be offered to those who are at high risk of HIV.

PrEP is an additional HIV prevention method for gay and bisexual males/men who have sex with men who have a high risk of HIV.

I am looking for gay and bisexual males/men who have sex with men to complete an anonymous online survey about attitudes towards condom use and PrEP.

Please follow the link to learn more and take the survey. <link inserted here.>

### Appendix 3: Anonymous attitude scaling survey of Canterbury MSM

#### **Anonymous survey about pre-exposure prophylaxis (PrEP) for tertiary MSM/gay and bisexual men in New Zealand**

Pre-exposure prophylaxis (PrEP) is a drug given to individuals that are HIV-negative but are at a high risk of contracting HIV. PrEP is a once-daily, oral pill and when taken consistently (everyday) it can reduce the chances of HIV infection in high-risk individuals by up to 92 percent (Grant et al. 2012).

PrEP is recommended for use by sexually active men who have anal intercourse with other men (MSM)/gay and bisexual males. It has also been recommended for serodiscordant couples (where one partner is HIV-negative and one partner is HIV-positive).

PrEP has been associated with some side effects, particularly in the first few months of use. These side effects can include headaches, nausea, loss of appetite, and weight loss. PrEP can also be expensive – branded PrEP called Truvada (Gilead Sciences) costs an estimated NZD \$1,200 per month per person.

In June 2015, PHARMAC and the Ministry of Health granted the District Health Boards and New Zealand AIDS Foundation permission to trial PrEP in New Zealand for high-risk individuals. For further information on PrEP, see [here](#). Please note: PrEP is different to PEP (post-exposure prophylaxis).

This anonymous survey has two key sections:

1. General questions about HIV and condom use
2. Attitudes towards using PrEP to prevent HIV infection

The survey is an attitude scaling survey. You will be presented with a statement and are required to indicate your answer by picking the box that best represents you. For example: “I feel comfortable using condoms for anal intercourse with my partner”

☐- Strongly agree   ☐- Agree   ☐- Disagree   ☐- Strongly disagree   You are not required to explain or justify your answer. There is no right or wrong answer.

The results from this survey are anonymous, but will be used for data analysis in a University of Canterbury Master's thesis. Once you have submitted your answers to this survey, you cannot remove your results. If you wish to stop the survey at any point, you can exit using the tab on your Internet browser and your answers will not be collected. I consent to taking part in this survey and understand that my participation and answers will remain anonymous

☐ Yes

☐ No

If No Is Selected, Then Skip To End of Survey

Age

- ☐ Under 18
- ☐ 18 - 24
- ☐ 25 - 34
- ☐ 35 - 44
- ☐ 45 - 54
- ☐ 55 - 64
- ☐ 65 - 74
- ☐ 75 - 84
- ☐ 85 or older

Gender

- ☐ Male
- ☐ Female
- ☐ Other/prefer not to answer

Ethnicity (optional)

Sexual orientation (optional)

I know my current HIV status

- ☐ Yes
- ☐ No

I believe that it is important to get regular HIV tests

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

HIV is not a serious issue for MSM/gay and bisexual men

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

It is important to tell my sexual partners about my HIV status

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I don't care about the HIV status of my sexual partners

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I have engaged in anal sexual intercourse with another male with a condom in the last 12 months

- ☐ Yes
- ☐ No

I have engaged in anal sexual intercourse with another male without a condom in the last 12 months

- ☐ Yes
- ☐ No

I feel comfortable asking my partner (regular sexual partner) to use a condom for anal sexual intercourse

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I feel comfortable asking an irregular partner (one night stand/friend with benefits/new sexual partner) to use a condom for anal sexual intercourse

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

If a partner refused to wear a condom, I would not engage in anal sexual intercourse (insertive or receptive)

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

Condoms are not necessary for safe anal sexual intercourse between two men

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

If I do not have condoms handy I will still have anal sexual intercourse

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

*(New page)*



Taking PrEP is a good way to reduce my chances of HIV infection

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I feel comfortable talking to my doctor about my sexual orientation

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I would feel comfortable asking my doctor for PrEP

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

Remembering to take PrEP everyday would be too hard

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

Taking PrEP means I don't need to use condoms for anal sexual intercourse

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

People who take PrEP do it so they can have sex with lots of men

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

If I took PrEP, I would be less likely to use condoms

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

I would be embarrassed if people knew I took PrEP

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

PrEP should be subsidised for MSM/gay and bisexual men in NZ

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

PrEP is a worthwhile HIV prevention method for MSM/gay and bisexual men

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

The requirement for regular HIV tests while using PrEP would be a hassle

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

*(END OF SURVEY, LINK TO FOCUS GROUP DETAILS)*

### **Collection of focus group details**

If you are interested in participating in the Christchurch focus group about PrEP in New Zealand for MSM/gay and bisexual men, feel free to leave your contact details here. Your inquiry will remain confidential and you are welcome to refuse to participate at any point.

Name

Email address

Cell phone

If you have any questions, comments or suggestions regarding this survey, pre-exposure prophylaxis or my overall research, please email the researcher here. Your questions and comments will remain confidential and your answers to the survey will remain anonymous. This research project has been approved by the Human Ethics Committee of the University of Canterbury. You are also welcome to contact my supervisor, Dr. Amy Fletcher, if you have any questions or concerns about this research. Her phone number is +64 03 356-2987 ext. 8675 and her email is amy.fletcher@canterbury.ac.nz.

## Appendix 4: Information sheet and consent form for interviews

Alice Hartley  
University of Canterbury  
Department: Political Science  
Telephone: 027 327 0555  
Email: [alice.hartley@pg.canterbury.ac.nz](mailto:alice.hartley@pg.canterbury.ac.nz)

**To whom it may concern,**

**RE: Invitation to Participate**

**HIV in the 21<sup>st</sup> century: Pandemic or apathetic? MSM tertiary students, HIV, and pre-exposure prophylaxis (PrEP)**

Tēnā koe,

I am a Master's thesis student studying Political Science at the University of Canterbury. Currently I am conducting research into pre-exposure prophylaxis (PrEP), a once-daily pill given to individuals that are at a high risk of contracting HIV. As you may be aware, men who have sex with men (MSM)/gay and bisexual men are one of the recommended groups that use PrEP to decrease their chances of an HIV infection. My research is policy-based, as I would like to provide a policy recommendation for how PrEP could be implemented for MSM/gay and bisexual men in New Zealand.

I am seeking participants for my research for one-on-one interviews; I wish to speak with you along side other experts in the HIV/AIDS field in New Zealand. I have three main aims for these interviews:

- To gain an understanding of the history of HIV/AIDS in New Zealand;
- To get more context regarding current HIV/AIDS rates in New Zealand;
- And to hear opinions about how PrEP could be effectively implemented for gay and bisexual men/MSM in New Zealand.

If you chose to take part in this study, your involvement in the project will be an interview conducted in Christchurch or Wellington, or over the phone or on Skype. The interviews should take between twenty and sixty minutes. Interviews will be audio recorded and participants will be provided with an interview transcription within five days of the interview to approve.

Participation in the interview is voluntary and you have the right to withdraw at any stage without penalty. You are welcome to interview on or off the record, but the presumption is that all identities will remain confidential unless a request is made for the participant to be identified. Following the interview, you continue to own the data generated from our interaction. You may choose to withdraw your raw data at any time, without penalty. Please be assured that all raw data collected from the interview will be kept on a password-protected private laptop and the University Server. If you wish any record of your involvement to be deleted, or immediately returned to you, this will always be possible. However, after the researcher has analysed all the data to draw conclusions and the Master's thesis is published on the University of Canterbury Library website and made public, the researcher's use of the data will be impossible to withdraw.

This project is being carried out as a requirement for the Master's of Arts in Political Science under the supervision of Dr. Amy Fletcher. Amy can be contacted on

[amy.fletcher@canterbury.ac.nz](mailto:amy.fletcher@canterbury.ac.nz) and will be happy to discuss any concerns you may have about the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch ([human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz)).

If you are willing to be interviewed please complete the consent form attached and return to [alice.hartley@pg.canterbury.ac.nz](mailto:alice.hartley@pg.canterbury.ac.nz) or send to

Alice Hartley c/o Department of Political Science and International Relations  
College of Arts  
University of Canterbury  
Christchurch 8041

I look forward to hearing from you.

Kind regards,

Alice Hartley

Alice Hartley  
University of Canterbury  
Department: Political Science  
Telephone: 027 327 0555  
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**RE: Project Consent Form**

**HIV in the 21<sup>st</sup> century: Epidemic or endemic? MSM tertiary students, HIV, and pre-exposure prophylaxis (PrEP)**

I have read and understood the description of the above-named project. On this basis I agree to participate as a subject in the project.

I understood that my participation remains confidential to protect my identity unless I request to be identifiable.

I consent to the publication of the results of the project with the understanding that if requested the information will remain confidential and my anonymity will be preserved.

I understand that I may at any time withdraw from the project, including withdrawal of any information I have provided, without penalty. Withdrawal of participation will include the withdrawal of any information I have provided should this remain practically achievable.

I understand that all data collected for the study will be kept in locked and secure facilities and /or in password protected electronic form and will be destroyed after five years.

I understand that the interviews will be audio recorded, which I will be given the opportunity to review and revise within five days from the interview date.

I understand that I can contact the researcher or Amy Fletcher ([amy.fletcher@canterbury.ac.nz](mailto:amy.fletcher@canterbury.ac.nz)) for further information.

Please tick one or more of the following

☐ ***I agree that I am to be identified and my notes of this interview will be on the record \_\_\_\_\_ (signature required)***

☐ ***I am authorised to speak on behalf of my institution \_\_\_\_\_ (signature required)***

Please tick one or more of the following

☐ ***After 5 years, I would like the raw data destroyed***

☐ ***I would like a summary of any output produced from this research.***  
(email \_\_\_\_\_)

NAME (please print): .....

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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