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Reimbursement of HIV Pre-exposure Prophylaxis by health insurance

Is Switzerland finally PrEPared?

Am 29. November 2023 beschloss das Eidgenössische Departement des Innern, dass die Präexpositionsprophylaxe gegen HIV (PrEP) für Menschen mit erhöhtem Risiko ab dem 1. Juli 2024 von der obligatorischen Krankenkasse übernommen wird. In diesem Papier wird der rechtliche Rahmen für die Erstattung der PrEP untersucht und seine Auswirkungen auf die öffentliche Gesundheit erörtert. Die Verbesserung des Zugangs zu und der Inanspruchnahme von PrEP ist ein Fortschritt für die Prävention, aber es bleiben Fragen und Herausforderungen, insbesondere in Bezug auf die Risikowahrnehmung und potenzielle Stigmatisierung. Soweit wir wissen, ist dieses Papier die erste kritische juristische Überprüfung der öffentlichen Gesundheitspolitik zur PrEP in der Schweiz.

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Contents

1. Introduction
2. HIV in Switzerland: Public health context and the growing relevance of PrEP
 - 2.1. Prevalence of HIV and prevention legal framework
 - 2.2. Evolution of Pre-Exposure Prophylaxis access and uptake
3. PrEP covered by compulsory insurance: a significant milestone
 - 3.1. Introduction to the Swiss compulsory health insurance
 - 3.2. Legal framework of PrEP reimbursement
4. Incremental progress in HIV prevention: Remaining issues and the path forward for a less stigmatizing approach
 - 4.1. Better policies: Reimbursing prevention
 - 4.2. Pre and Post-Exposure Prophylaxis in perspective
 - 4.3. FOPH HIV risk analysis: from behaviour to specific groups
 - 4.4. Sex moralisation against public health progress
5. Conclusion

1. Introduction

[1] The fight against HIV (human immunodeficiency virus) has been a long and painful process from the first officially reported case in the United States in 1981 to the present day. The number of new HIV cases is declining steadily in most countries and the life expectancy of HIV-positive persons is «approaching that of the general population» thanks to the development of antiretroviral therapy.¹ The United Nations Sustainable Development Goal (SDG) 3.3 aims to eliminate the epidemic of AIDS by 2030. However, in 2022, WHO expressed concerns regarding undiagnosed HIV in the European region and reiterated that more efforts need to be done to facilitate the access to HIV services and care.²

[2] PrEP, or pre-exposure prophylaxis, is a preventive approach aimed at reducing the risk of HIV transmission in individuals who are not infected with the virus but are at high risk of infection.³ Functionally, PrEP is primarily based on the use of antiretroviral drugs that inhibit HIV replication. If a person is exposed to HIV, the antiretrovirals in their system can prevent the virus from becoming established and spreading. The drugs commonly used for PrEP are reverse transcriptase inhibitors, such as emtricitabine and tenofovir disoproxil fumarate.⁴ These active ingredients are usually combined in a single pill, which first came on the market with the commercial name of Truvada.⁵ Truvada was first authorized in Switzerland on the 1st of May 2007,

¹ ADAM TRICKEY *et alii*, «Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies», *The Lancet HIV*, vol. 4, n° 8 (2017), pp. e349-e356, [https://doi.org/10.1016/S2352-3018\(17\)30066-8](https://doi.org/10.1016/S2352-3018(17)30066-8) (accessed 22 December 2023).

² World Health Organization, WHO/Europe and ECDC report reveals increasing numbers living with undiagnosed HIV in the Region, <https://www.who.int/europe/news/item/30-11-2022-who-europe-and-ecdc-report-reveals-increasing-numbers-living-with-undiagnosed-hiv-in-the-region> (accessed 22 December 2023).

³ NOËLLIE GENRE/VANESSA CHRISTINET, «PrEP in French-speaking Switzerland: between anxiety and trust, antiretroviral use for HIV prevention.», *Revue Medicale Suisse* 19.842 (2023), pp. 1714–1717.

⁴ GREG L. PLOSKER, «Emtricitabine/tenofovir disoproxil fumarate: a review of its use in HIV-1 pre-exposure prophylaxis.» *Drugs* 73.3 (2013), pp. 279–291.

⁵ US Food and Drug Administration, «Drug approval package, Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets.» (2004); to facilitate reading, we will refer to the combination of emtricitabine and tenofovir as Truvada in the paper.

but without pre-exposure prophylaxis as an indication, only the management of HIV-1 infection in adults.⁶

[3] Since September 2015, the WHO has recommended PrEP as part of their global plan to reduce HIV transmission.⁷ It also figures in WHO model list of essential Medicines.⁸ PrEP is described as an «additional prevention choice, as part of comprehensive prevention», and as «highly effective at preventing HIV».⁹ In the case of Truvada, as early as 2012, analyses showed a 99% efficacy rate for users that show good adherence to the treatment¹⁰, and an overall efficacy rate of 86%¹¹. In order to eliminate HIV, UNAIDS wants «50% of people at very high risk of HIV acquisition and 5% of people at moderate risk of HIV acquisition» to be accessing PrEP by 2025.¹²

[4] In September 2023, the European Centre for Disease Prevention and Control (ECDC) published its evidence brief on the progress towards this SDG.¹³ In the European region, PrEP is available and reimbursed by the healthcare system in 23 countries out of 55. One of the key points from the ECDC brief is the slow progress regarding PrEP access and uptake. Even though there has been an increase of both metrics in many countries (including Switzerland), «there is room for significant improvement». To this end, the ECDC calls for renewed efforts of the public health authorities in Europe for greater access to and uptake of PrEP.¹⁴ In this context, many authors have called for improved implementation of PrEP in Switzerland.¹⁵ In reaction to this global consensus, Switzerland has announced that as of the 1st of July 2024, PrEP would be covered by the compulsory health insurance for people at increased risk.¹⁶

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- ⁶ Federal Office of Public Health, Reference documents related to the specialties list, <https://www.spezialitätenliste.ch/default.aspx> (accessed 22 December 2023).
- ⁷ World Health Organization, Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV (2015), <https://www.who.int/publications/i/item/9789241509565> (accessed 22 December 2023).
- ⁸ World Health Organization, Model List of Essential Medicines (2023), <https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf> (accessed 22 December 2023).
- ⁹ World Health Organization, Global HIV Programme, Pre-exposure prophylaxis (PrEP), <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis> (accessed 22 December 2023).
- ¹⁰ PETER L. ANDERSON *et alii*, «Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men», *Science Translational Medicine* (vol. 4, n° 151, 2012), p. 151ra125, <https://doi.org/10.1126/scitranslmed.3004006> (accessed 22 December 2023).
- ¹¹ DAVID I. DOLLING *et alii*, «An analysis of baseline data from the PROUD study: an open-label randomised trial of pre-exposure prophylaxis», *Trials* (vol. 17, 2016), p. 163, <https://doi.org/10.1186/s13063-016-1286-4> (accessed 22 December 2023).
- ¹² UNAIDS, Global Aids Strategy 2021–2026 End Inequalities. *End Aids*. (2021), p. 133, <https://www.unaids.org/en/Global-AIDS-Strategy-2021-2026> (accessed 22 December 2023).
- ¹³ European Centre for Disease Prevention and Control, Progress towards reaching the Sustainable Development Goals related to HIV in Europe and Central Asia, Monitoring the implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2021/22 (Stockholm 2023), <https://www.ecdc.europa.eu/en/publications-data/hiv-progress-towards-reaching-sustainable-development-goals> (accessed 22 December 2023).
- ¹⁴ *Ibid.* European Centre for Disease Prevention and Control, Pre-exposure Prophylaxis for HIV prevention in Europe and Central Asia, Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia – 2022 progress report (Stockholm 2023), <https://www.ecdc.europa.eu/en/publications-data/hiv-infection-prevention-pre-exposure-prophylaxis-monitoring-dublin> (accessed 22 December 2023).
- ¹⁵ MARC WEBER *et alii*, «HIV Prä-Expositionsprophylaxe (PrEP)», *Swiss Med Forum*, 2021, Vol. 21(37–38), pp. 632–36; PHILIPP TARR *et alii*, «HIV-Prä-Expositionsprophylaxe (PrEP)», *Swiss Med Forum*, 2017, Vol. 17(2627), pp. 579–82.
- ¹⁶ Federal Council, VIH et hépatites B et C objectif zéro nouvelle infection en Suisse d'ici à 2030 (2023), <https://www.admin.ch/gov/fr/accueil/documentation/communiqués.msg-id-99069.html> (accessed 22 December 2023).

[5] This development is the starting point of this paper. PrEP has been largely overlooked by the literature in public health and social insurance in Switzerland and has been examined mostly by activists and health professionals. Our aim is to fill this gap and contribute to the understanding of a prevention tool that remains rather niche in Switzerland. PrEP reimbursement is a step forward, and understanding the context around it provides insight into how the Swiss health insurance and prevention systems interact.

[6] The paper is structured as follows: we first provide an overview of the current situation in Switzerland regarding HIV and PrEP, then analyse the legal framework for PrEP reimbursement, and finally discuss the various key issues and challenges that lie ahead.

2. HIV in Switzerland: Public health context and the growing relevance of PrEP

2.1. Prevalence of HIV and prevention legal framework

[7] According to the Federal Office of Public Health (FOPH), «between 16600 and 17500 HIV-infected people live in Switzerland», and less than 300 people are infected with HIV each year since 2020.¹⁷ However, the FOPH statistics regarding the number of new diagnostics per year showed a slight increase of new cases per year in Switzerland. As of the 13th of December 2023, there had been 361 new reported cases in 2023, compared to 335 in 2022 and 331 in 2021.¹⁸ According to the FOPH, this relative increase can be explained by the fact that the years 2021 and 2022 deviated from the long-term trends due to the covid-19 pandemic. To illustrate this fact, in 2019, before the pandemic, there were 427 new diagnostics. This rise in 2023 is also interpreted by the FOPH as a consequence of the Russian-Ukrainian conflict, and its resulting displaced population.¹⁹

[8] Regarding the overall HIV legal framework in Switzerland, health is generally a cantonal prerogative. However, article 118 para. 1 of the Federal Constitution gives some power to the confederation to protect health. Article 118 para. 2 let. a and b states more specifically that the confederation shall legislate on «the use of therapeutic products», and on «the combating of communicable, widespread or particularly dangerous human and animal diseases».²⁰

[9] The Federal Act on Controlling Communicable Human Diseases (Epidemics Act, EpidA) is the relevant legislation providing the main legal framework for the control of communicable diseases in Switzerland. It gives the authorities the necessary powers to take public health measures to prevent and control epidemics. There is however no general federal law on health promotion and prevention that might apply specifically to HIV. The EpidA describes at its article 2 the purpose

¹⁷ Federal Office of Public Health, Statistiques et analyses concernant VIH/IST, <https://www.bag.admin.ch/bag/fr/home/zahlen-und-statistiken/zahlen-zu-infektionskrankheiten/hiv-sti-statistiken-analysen-trends.html> (accessed 22 December 2023); Federal Office of Public Health, AIDS, <https://www.bag.admin.ch/bag/fr/home/krankheiten/krankheiten-im-ueberblick/aids.html> (accessed 22 December 2023).

¹⁸ Federal Office of Public Health, Maladies infectieuses à déclaration obligatoire – Nombre de cas hebdomadaires, <https://www.bag.admin.ch/bag/fr/home/zahlen-und-statistiken/zahlen-zu-infektionskrankheiten/meldepflichtige-infektionskrankheiten---woechentliche-fallzahlen.html> (accessed 22 December 2023).

¹⁹ Federal Office of Public Health, OFSP-Bulletin 48/2023 (Bern 2023), pp. 12–29, <https://www.bag.admin.ch/bag/fr/home/das-bag/publikationen/periodika/bag-bulletin.html> (accessed 22 December 2023).

²⁰ Federal Constitution of 18 April 1999 of the Swiss Confederation (SR 101).

of the Act. Paragraph 1 states that it aims to «prevent and control» the spread of communicable diseases. Paragraph 2 let. a to f give several other precisions that are relevant to the PrEP, affirming for example that the act must enable «the dangers of the spread of communicable diseases to be avoided at an early stage», «the resources for protection against transmission to be ensured», and «the effects of communicable diseases on society and the persons affected to be reduced». This perspective is reiterated at the article 19 on general preventive measures, which states at its para. 1 that «the Confederation and the cantons shall take measures to control, reduce and eliminate the risks of disease transmission». Article 4 para. 1 of the EpidA states that the Federal Council and the cantons determine the «goals and strategies for detecting, monitoring, preventing and controlling communicable diseases». Article 4 para. 2 let. b and c specify that the goals and strategies must be informed by «international recommendations and guidelines» and the «current state of scientific knowledge».

[10] The only mention of HIV in the EpidA is at the article 5 para. 1. let. c regarding national programmes. The article gives power to the Federal Office of Public Health (FOPH) to «develop topic-specific national programmes for detecting, monitoring, preventing and controlling communicable diseases, in particular relation to: HIV and other sexually transmitted pathogens». Switzerland's first National Programme on HIV was launched in 1987. Since 2011, the National Programme on HIV and other Sexually Transmitted Infections (NPVI/NPHS) has aimed to «reduce the number of new infections and minimise the negative health consequences for those infected».²¹ The next version of the NPVI, in 2024, will be entitled «Stop HIV, hepatitis B and C viruses and sexually transmitted infections (NAPS)», and will have the same aim as the SDG 3.3 to eliminate any further transmission of these pathogens.²² Following this more ambitious goal, the Federal Department of Home Affairs declared that «As a first concrete step towards implementing the NAPS programme, (...) pre-exposure prophylaxis against HIV (PrEP) for people at increased risk will be covered by compulsory health insurance from 1 July 2024.»²³ With this decision, Switzerland finally catches up with most of western Europe and carries out a more inclusive strategy to improve PrEP access and uptake.²⁴

2.2. Evolution of Pre-Exposure Prophylaxis access and uptake

[11] The implementation of PrEP in Switzerland has not been straightforward. On the 25th of January 2016 the Swiss Federal Commission for Sexual Health (FCSH) gave the first public health recommendation regarding PrEP in Switzerland. This recommendation was quite restrictive and only recommended the use of PrEP «for limited periods and for a small group of persons at

²¹ Federal Council, Le Programme national VIH et autres infections sexuellement transmissibles est prolongé de deux ans (2021), <https://www.admin.ch/gov/fr/accueil/documentation/communiqués.msg-id-84826.html> (accessed 22 December 2023).

²² Supra note 16.

²³ Supra note 16.

²⁴ Federal Commission for Sexual Health, Recommendations of the Swiss Federal Commission for Sexual Health (FCSH) on pre-exposure prophylaxis (PrEP) for HIV prevention (2016), <https://www.bag.admin.ch/bag/en/home/das-bag/organisation/ausserparlamentarische-kommissionen/eidgenoessische-kommission-fuer-sexuelle-gesundheit-eksg.html> (accessed 22 December 2023).

substantial risk of acquiring HIV», when «consistent condom use is not a viable option».²⁵ In a 2017 study, Swiss healthcare professionals who prescribed PrEP to their patients described a rapidly growing demand for PrEP.²⁶ The same year, another study recommended the «urgent» creation of a national programme to facilitate access to medical care and provide PrEP.²⁷

[12] PrEP is first mentioned in the FOPH official communication in the 2017 HIV epidemiology report.²⁸ The following year, the FOPH officially recommends the use of PrEP for the first time in the 2018 edition of its HIV prevention strategy for MSM (Men who have Sex with Men) «Sex between men: towards better sexual health».²⁹ Information on access to PrEP, on the other hand, is the responsibility of the FOPH's partners, such as the Swiss AIDS Federation and SwissPrEPared.³⁰ The 2018 FOPH HIV epidemiology report also officially supports for the first time the use of PrEP.³¹ However, access to PrEP has proved difficult in Switzerland until recently. PrEP access and uptake faced two main hurdles: off-label use due to lack of regulatory approval, and access to generic medicines. In 2017, it was estimated that only around a hundred Swiss citizen used PrEP, far less than the conservative estimate of 1000 users by the FCSH.³²

[13] As mentioned in the introduction, Truvada was first approved on the Swiss market on the 1st of May 2007 with an indication for the management of HIV-1 infection in adults.³³ As early as July 2012, the US FDA approved the use of PrEP for reducing the risk of sexually acquired HIV infection.³⁴ It was almost 8 years later, in January 2020, that the combination of tenofovir/emtricitabine was granted an extension of indication in Switzerland for PrEP within the meaning of articles 4 and 10 of the Therapeutic Products Act, opening the door for a potential reimbursement.³⁵ Swissmedic now recognizes the following indication for PrEP: «PrEP is indicated as pre-exposure prophylaxis to reduce the risk of sexual HIV-1 infection in adults at high risk of

²⁵ Federal Commission for Sexual Health, Roadmap for eliminating HIV/AIDS and Hepatitis in Switzerland (2019), <https://www.bag.admin.ch/bag/en/home/das-bag/organisation/ausserparlamentarische-kommissionen/eidgenossische-kommission-fuer-sexuelle-gesundheit-eksg.html> (accessed 22 December 2023).

²⁶ RAPHAËL BIZE *et alii*, «État des lieux sur la prescription de PrEP auprès d'un échantillon de médecins en Suisse», (Lausanne 2017), 10.16908/issn.1660-7104/280 (accessed 22 December 2023).

²⁷ BENJAMIN HAMPEL *et alii*, «Assessing the need for a preexposure prophylaxis programme using the social media app Grindr®.», *HIV medicine*, Vol.18(10), 2017, pp. 772–776.

²⁸ Federal Office of Public Health, OFSP-Bulletin 47/2018 (Bern 2018), pp. 10–19, <https://www.bag.admin.ch/bag/fr/home/das-bag/publikationen/periodika/bag-bulletin.html> (accessed 22 December 2023).

²⁹ Federal Office of Public Health, Stratégie de prévention VIH, «Le sexe entre hommes: vers une meilleure santé sexuelle» (2018), https://shop.sante-sexuelle.ch/img/A{~}1627{~}2/10/1627-02_Strategie-sa.pdf?xet=1624966968302 (accessed 22 December 2023).

³⁰ BARRILE, «La prophylaxie préexposition contre le VIH constitue aujourd'hui un volet important de la prévention», Interpellation 17.4109, <https://www.parlament.ch/fr/ratsbetrieb/suche-curia-vista/geschaef?AffairId=20174109> (accessed 22 December 2023).

³¹ Federal Office of Public Health, OFSP-Bulletin 41/2019 (Bern 2019), pp. 10–20, <https://www.bag.admin.ch/bag/fr/home/das-bag/publikationen/periodika/bag-bulletin.html> (accessed 22 December 2023).

³² STEPHEN MOSSAZ, «La Prep, cette pilule «anti-VIH» efficace, mais peu utilisée en Suisse», *Rts.ch* (December 1st, 2017), <https://www.rts.ch/info/sciences-tech/medecine/9133952-la-prep-cette-pilule-antivih-efficace-mais-peu-utilisee-en-suisse.html> (accessed 22 December 2023); *supra* note 24, <https://www.rts.ch/info/sciences-tech/medecine/9133952-la-prep-cette-pilule-antivih-efficace-mais-peu-utilisee-en-suisse.html> (accessed 22 December 2023); *supra* note 24.

³³ *Supra* note 7.

³⁴ «FDA approves first drug for reducing the risk of sexually acquired HIV infection», *HIV.gov* (July 16, 2012), <https://www.hiv.gov/blog/fda-approves-first-drug-for-reducing-the-risk-of-sexually-acquired-hiv-infection/> (accessed 22 December 2023).

³⁵ Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21).

HIV infection, in combination with safer sex practices.»³⁶ In terms of dosage, the recommended dose for pre-exposure prophylaxis is «one film-coated tablet once daily. The efficacy and safety of a non-daily (on-demand) regimen is not recommended».³⁷

[14] In the meantime, PrEP was only prescribed as an «off-label» drug by physicians, who could be held responsible for any side effects PrEP may cause.³⁸ Furthermore, since the prophylactic indication of PrEP was not approved, reimbursement by the Swiss Health insurance was not an option.³⁹ The lack of reimbursement had a direct impact on uptake.⁴⁰ Until April 2021 the price of Truvada in Switzerland was CHF 899.30 for a box of thirty pills, about a month worth of treatment.⁴¹ In Switzerland, Gilead's patent on Truvada was extended by the Swiss Federal Institute of Intellectual Property and upheld by the Swiss Federal Patent Court in several decisions.⁴² On 25 July 2017, the patent on Truvada came to an end in many European countries, allowing affordable access to PrEP with generic medicines.⁴³ In France, PrEP cost less than EUR 180 for 30 tablets, in Germany less than EUR 80 and could be ordered online for EUR 40. This led physicians to recommend that their patients import the drugs themselves.⁴⁴ A petition called for the possibility of importing three months' treatment instead of one month as is determined by the article 49 al. 1 of the Ordinance on Licensing in the Medicinal Products Sector and the case law.⁴⁵ Finally, as of the 1st of April 2021, generic medicines of PrEP are allowed in Switzerland, leading to a significant reduction in costs. For the Swiss AIDS Federation, «the umbrella organisation for Switzerland's 8 regional AIDS organisations», PrEP has helped to reduce the number of new HIV diagnoses each year and hopes that generic medicines «will contribute to the wider deployment of PrEP, particularly outside the major urban centres».⁴⁶ As of December 2023, generic drugs are now available for CHF 65 for thirty tablets, compared with a revised CHF 593.50 for Truvada.⁴⁷ In addition to the cost of the drug, one must also take into account the cost of the medical follow-up recommended by the FOPH, which costs an extra CHF 1800 per year.⁴⁸

[15] In this context, access to PrEP in Switzerland has mainly been enabled by the SwissPrEPared project. This national research program was created in April 2019 and is directed by the Institute

³⁶ Swissmedic, Truvada®, Gilead Sciences Switzerland Sàrl, <https://www.swissmedicinfo.ch> (accessed 22 December 2023).

³⁷ *Ibid.*

³⁸ Art. 3 TPA «Due diligence» and art. 26 TPA «Principles of prescription, dispensing and application».

³⁹ Art. 71a al. 1 let. b OAMal/KVV (Ordinance of June 27, 1995, on Health Insurance; SR 832.102); supra note 30.

⁴⁰ SABINE VOGLER *et alii*, «How can pricing and reimbursement policies improve affordable access to medicines? Lessons learned from European countries.», *Applied health economics and health policy*, Vol. 15 (2017), pp. 307–321.

⁴¹ Federal Office of Public Health, Specialties List, Truvada, last change of price on the 1 April 2021, <https://www.spezialitätenliste.ch/default.aspx> (accessed 22 December 2023).

⁴² Judgment of the Federal Patent Court O2017_001 of 3 October 2017; Judgment of the Federal Court 4A_576/2017 of 11 June 2018; Judgment of the Federal Patent Court O2017_023 of 3 May 2019.

⁴³ Judgement of the CJEU, Case n° C-121/17, *Teva UK Ltd e.a. v. Gilead Sciences Inc*, 25 July 2018.

⁴⁴ KATY ROMY, «Pourquoi la pilule «anti-VIH» est si difficile d'accès en Suisse», *SWI swissinfo.ch* (November 30th, 2018), https://www.swissinfo.ch/fre/politique/sant%C3%A9-sexuelle_pourquoi-la-pilule-anti-vih-est-si-difficile-d-acc%C3%A8s-en-suisse-/44581076 (accessed 22 December 2023).

⁴⁵ «Une pétition demande un accès facilité à la PrEP», *profa.ch* (21 June 2022), <https://www.profa.ch/prep> (accessed 22 December 2023); CAROLE-ANNE BAUD, *L'accès aux médicaments compassionnel*, Geneva 2022, pp. 97–114 and 115–130.

⁴⁶ FRANÇOIS TOUZAIN, «PrEP: enfin des génériques en Suisse», *360°* (25 March 2021), <https://360.ch/sante/61165-prep-enfin-des-generiques-en-suisse/> (accessed 22 December 2023).

⁴⁷ Supra note 6.

⁴⁸ Supra note 32.

of Epidemiology, Biostatistics and Prevention at the University of Zurich, and supported by the Swiss HIV Cohort Study and the FOPH.⁴⁹ SwissPrEPared consists of two complementary parts: on the one hand, it is a national programme that guarantees quality standards and intends to «improve medical care for PrEP users»⁵⁰, on the other hand, it is a «multicentre, observational cohort to study the characteristics of individuals asking for pre-exposure prophylaxis (PrEP) and the incidence of HIV»⁵¹. Within this framework, PrEP has been available at low cost: CHF 40 for 30 pills since October 2020, subject to participation in the study.⁵² The FOPH is confident that the SwissPrEPared programme has heavily contributed to the access and uptake of PrEP.⁵³ By the end of 2022, at least 4,500 people had used PrEP to protect themselves, almost exclusively MSM, and the number of new diagnoses had fallen more sharply among MSM than in any other group.⁵⁴

[16] The decision to cover PrEP with the compulsory health insurance is in line with this progress and operates within a complex legal framework.

3. PrEP covered by compulsory insurance: a significant milestone

[17] The Swiss legal framework for compulsory health insurance is notoriously difficult to navigate. To better understand the context in which PrEP is reimbursed, we need to set the scene and provide some background.

3.1. Introduction to the Swiss compulsory health insurance

[18] Health insurance is an element of the Swiss healthcare system, providing universal coverage to all persons residing in the national territory. Article 117 of the Swiss Constitution grants the confederation extensive power to regulate health insurance. This power is not limited to establishing principles but also allows the confederation to set detailed rules in this area⁵⁵. Using this power, the confederation can create comprehensive regulations for health insurance, and as it develops these regulations, the cantons lose their competence in this area.⁵⁶ The confederation has exercised this competence by adopting, among others, the Swiss Federal Law on Health Insurance (LAMal/KVG).⁵⁷ It establishes the principles of mandatory health care insurance and

⁴⁹ «Imprint – SwissPrEPared», <https://www.swissprepared.ch/en/imprint/> (accessed 22 December 2023).

⁵⁰ «Frequently Asked Questions – SwissPrEPared», <https://www.swissprepared.ch/en/faq/> (accessed 22 December 2023).

⁵¹ University of Zürich, Epidemiology, Biostatistics and Prevention Institute, «A multicenter, observational cohort to study the characteristics of individuals asking for pre-exposure prophylaxis (PrEP) and the incidence of HIV and STIs: «The Swiss PrEPared Study».», https://www.ebpi.uzh.ch/en/translational_research/chronic_conditions_health/prepared.html (accessed 22 December 2023).

⁵² MARC WEBER *et alii*, «HIV-Prä-Expositionsprophylaxe in der Schweiz», *Swiss Medical Forum Schweizerisches Medizin-Forum* 21(37–38), Zurich 2021, pp. 632–636.

⁵³ *Supra* note 19.

⁵⁴ *Supra* note 19.

⁵⁵ ATF/BGE 140 I 218, c. 5.6; CR Cst.-HUMMER KAHIL-WOLFF, art. 117, N 7.

⁵⁶ ATF/BGE 140 I 218, c. 5.6; CR Cst.-HUMMER KAHIL-WOLFF, art. 117, N 7.

⁵⁷ Swiss Federal Law of March 18, 1994 on Health Insurance (LAMal/KVG; SR 832.10); CR Cst.-HUMMER KAHIL-WOLFF, art. 117, N 7.

ensures uniform access to healthcare. It is completed by several other laws and ordinances. The Federal Law on the General Part of Insurance Law (LPGA/ATSG) provides the fundamental principles and general framework for social insurance laws.⁵⁸ Ordinances such as the Ordinance on Health Insurance (OAMal/KVV)⁵⁹ and the Ordinance on Benefits in Mandatory Health Care Insurance in Case of Illness (OPAS/KLV)⁶⁰ provide details on the practical implementation of LAMal/KVG, including the calculation of premiums and covered provisions.

[19] The Swiss health insurance system is characterized by its compulsory aspect, ensuring that every person residing in Switzerland is covered against the risk of illness.⁶¹ It requires individual and proactive enrolment (art. 3 para. 1 KVG/LAMal)⁶², with specific exceptions and penalties for non-compliance (art. 5 para. 2 and art. 92 KVG/LAMal).⁶³ The coverage ends when the conditions are no longer met (art. 5 para. 3 KVG/LAMal).⁶⁴

[20] The compulsory health insurance coverage is managed with two sections. The first component of the system concerns healthcare services, as defined by article 3 and subsequent LAMal/KVG.⁶⁵ It covers illness, including congenital disabilities (art. 3 para. 2 LPGA/ATSG)⁶⁶, accidents not covered by accident insurance (art. 4 LPGA/ATSG)⁶⁷ and maternity (art. 5 LPGA/ATSG)⁶⁸, which includes pregnancy, childbirth and convalescence. The second component, based on article 67 and subsequent LAMal/KVG⁶⁹, provides daily allowances to compensate for income loss in case of incapacity to work. The coverage of care is governed by the LAMal/KVG and is designed to be comprehensive, including a wide range of medical services. Another key element of the system is the freedom of choice given to policyholders, who can choose their healthcare providers and their insurer.⁷⁰ Moreover, the system allows for an easy transition between different insurance policies.⁷¹

[21] Regarding financing, premiums are calculated individually, based on the overall costs of healthcare. The Swiss health insurance system follows the principle of solidarity, where contributions are not dependent on individual risk factors, but rather on the collective healthcare

⁵⁸ Federal Law of October 6, 2000, on the General Part of Insurance Law (LPGA/ATSG; SR 830.1).

⁵⁹ Ordinance of June 27, 1995, on Health Insurance (SR 832.102).

⁶⁰ Ordinance of the Federal Department of Home Affairs of September 29, 1995, on Benefits in Mandatory Health Care Insurance in Case of Illness (OPAS/KLV; SR 832.112.31).

⁶¹ Art. 3 LAMal/KVG.

⁶² Supra note 65, pp. 29–55; GUY LONGCHAMP, «L'affiliation à l'assurance-maladie sociale en Suisse (articles 3 et suivants LAMal)», *Cahiers genevois et romands de sécurité sociale* 32/33 (2004), pp. 36–55; BSK KVG-EUGSTER, Art. 5 KVG; supra note 65, pp. 45–47.

⁶³ BSK KVG-EUGSTER, Art. 5 KVG; supra note 65, pp. 5 KVG; supra note 65, pp. 46–47.

⁶⁴ BSK KVG-EUGSTER, Art. 5 KVG; supra note 65, pp. 5 KVG; supra note 65, pp. 47–48.

⁶⁵ BETTINA KAHIL-WOLFF/STÉPHANIE PERRENOUD/GHISLAINE FRÉSARD-FELLAY, *Droit suisse de la sécurité*, vol. 2, Bern 2015, pp. 23–27.

⁶⁶ BSK ATSG-TRAUB, Art. 3; supra note 65, pp. 58–84; GUY LONGCHAMP, *Conditions et étendue du droit aux prestations de l'assurance-maladie sociale en cas de séjour à l'hôpital, en établissement médico-social et/ou en cas de soins à domicile* (Berne 2004); Judgment of the Federal Administrative Court K 92/06 of 17 April 2007, c. 2.2; Judgment of the Federal Administrative Court K 92/05 of 3 November 2005, c. 2.4.

⁶⁷ BSK ATSG-HOFER, Art. 4; supra note 65, pp. 93–94.

⁶⁸ BSK ATSG-HOFER, Art. 5; supra note 65, pp. 84–91.

⁶⁹ *Ibid.*

⁷⁰ BSK KVG-EUGSTER, Art. 4 KVG.

⁷¹ Art. 7 LAMal/KVG.

costs.⁷² This means that the system is designed to distribute the financial burden across all insured individuals, regardless of their personal health risk, ensuring equitable access to healthcare for everyone covered.

[22] The coverage of healthcare, under the health insurance framework, is subject to three conditions for a treatment or service to be covered. The standard that establishes these conditions is article 24 LAMal/KVG, which refers to the articles 25 to 31 for benefits and to articles 32 to 34 for the specific conditions to be met:⁷³

1. Inclusion in the complete list of benefits defined by the articles 25 to 31 LAMal/KVG.⁷⁴
2. Effectiveness, appropriateness, and economy (art. 32 para. 1 LAMal/KVG).⁷⁵
3. Provision by an approved care provider (art. 35 to 40 LAMal/KVG).⁷⁶

[23] To ensure that the provisions reimbursed by the Compulsory Health Insurance (CHI) are effective, economical, and adequate, the Federal Department of the Home Affairs (FDHA), by delegation from the Federal Council (cf. art. 33 para. 5 LAMal/KVG and art. 33 OAMal/KVV), follows the procedure for designating benefits as provided in article 33 LAMal/KVG. It must do so by adhering to the principle of the list prescribed by the legislator in article 34 LAMal/KVG.

[24] Now that the general framework for healthcare reimbursement has been established, we will take a closer look at the legal mechanism planned for the PrEP coverage on the 1st of July 2024.

3.2. Legal framework of PrEP reimbursement

[25] It is important to note that outside of the lists issued by the FDHA, there is no obligation for coverage.⁷⁷ The designation of the provisions can be made based regarding the healthcare providers, the nature of the services, or by combining the two elements. In the second case (art. 33 para. 2 LAMal/KVG and art. 33 let. b and d OAMal/KVV), the FDHA also designates some preventive measures in the sense of article 26 LAMal/KVG. In this context, the corresponding list can be found in article 12 to 12e OPAS/KLV.⁷⁸

[26] In the former law on health insurance, there was no mention of reimbursement for preventive measures. When the law was amended in 1991, the Federal Council deemed that this aspect should be reimbursed.⁷⁹ Based on this provision and the will to prevent an HIV pandemic according to the EPiDA, the Federal Department of the Home Affairs developed the positive lists of articles 12 to 12e OPAS. Upon examination, it is clear that the coverage of the costs of these

⁷² DYLAN HOFMANN/MÉLANIE LEVY, «Solidarité et santé publique», *Rev Med Suisse* (vol. 790, 2022), pp. 1395–1397.

⁷³ BSK KVG-VOKINGER, Art. 24 KVG; supra note 65, pp. 95–185 and 187.

⁷⁴ Supra note 65, pp. 97–185. For more details on the benefits, see: BSK KVG-OLAH, Art. 25 KVG; BSK KVG-LANDOLT, Art. 25a KVG; BSK KVG-VOKINGER/GUTZWILLER, Art. 26 KVG; BSK KVG-LANDOLT, Art. 27 KVG; BSK KVG-OLAH, Art. 28 KVG; BSK KVG-M. GAUTSCHI, Art. 29 KVG; BSK KVG-M. GAUTSCHI, Art. 30 KVG; BSK KVG-WEBER/GASSMANN, Art. 31 KVG.

⁷⁵ Supra note 65, pp. 187–196 and cited judgments; BSK KVG-OGGIER/VOKINGER, Art. 32 KVG.

⁷⁶ Supra note 65, pp. 204–220; BSK KVG-VASELLA, Art. 35 KVG; TOMAS POLEDNA, *Arzt und Krankenversicherung*, in: W. KUHN MORITZ et al., *Arztrecht in der Praxis*, Zurich/Basel/Geneva 2007, pp. 293–419.

⁷⁷ Judgment of the Federal Court 9C_912/2010 of 31 october 2011, c. 3.3; supra note 65, pp. 197–201.

⁷⁸ Supra note 65, pp. 198–199.

⁷⁹ FF 1992 I 77, pp. 135–136; BSK KVG-VOKINGER/GUTZWILLER, Art. 26 KVG.

preventive measures is fundamentally linked to certain conditions.⁸⁰ Finally, it should be noted that the services listed in these lists are presumed to be economical, effective, and adequate.⁸¹ Regarding the reimbursement of pre-exposure prophylaxis against HIV, it is through this article 26 LAMal/KVG that the Federal Department of the Home Affairs included it in article 12b let. i OPAS/KLV. Therefore, the coverage of this preventive measure is subject to four conditions:

1. «As part of the SwissPrEPared program»;
2. «Indications according to the Federal Office of Public Health (FOPH) reference document on Pre-Exposure Prophylaxis against HIV (HIV-PrEP) dated October 31, 2023. Coverage includes the medication as well as the necessary medical consultations and laboratory analyses according to the FOPH reference document on Pre-Exposure Prophylaxis against HIV (HIV-PrEP) dated October 31, 2023»;
3. «Microbiological laboratory analyses must be reimbursed as lump sums»;
4. «The obligation to provide coverage is subject to an evaluation requirement».

[27] These conditions tightly frame the reimbursement of PrEP (pre-exposure prophylaxis) by the Compulsory Health Insurance. Furthermore, they are complemented by a reference document that specifies which groups of people are concerned, the type of medication to be prescribed, the accepted modes of PrEP use, other conditions or requirements related to follow-up visits, and the reimbursement modalities for side effects.⁸² This document is based on a certain perception of «at risk» groups and «at risk» behaviours regarding HIV transmission. Therefore, coverage will only be valid if prescribed by a doctor participating in the SwissPrEPared program and only if all the conditions mentioned in the reference document are met.⁸³

[28] PrEP reimbursement is embedded in a wider public health and social context. Reimbursement for prevention in the Swiss statutory compulsory insurance, which was previously very limited, is gradually being expanded. However, due to the inertia of policies, there are still issues to be addressed, which we will address here.

4. Incremental progress in HIV prevention: Remaining issues and the path forward for a less stigmatizing approach

4.1. Better policies: Reimbursing prevention

[29] As mentioned above, compulsory health insurance was not originally designed to cover preventive treatments and measures. When the law was completely revised in 1991, the Federal

⁸⁰ BSK KVG-VOKINGER/GUTZWILLER, Art. 26 KVG.

⁸¹ Supra note 65, pp. 197–201.

⁸² Federal Office of Public Health, Reference document «Prophylaxie pré-exposition contre VIH (HIV-PrEP)» (Version of 31 October 2023).

⁸³ BENJAMIN HAMPEL *et alii*, «Medical Guidance». Recommendations Regarding PrEP Use – The «SwissPrEPared Guidance» Version 3.0. (13 January 2023), <https://www.swissprepared.ch/fr/medical-guidance-3/> (accessed 22 December 2023); RECHSTEINER, «Le sexe aux frais de l'assurance-maladie. Jusqu'où irons-nous?», Question 23.7799, <https://www.parlament.ch/fr/ratsbetrieb/suche-curia-vista/geschaefte?AffairId=20237799> (accessed 22 December 2023); CHRISTINE TALOS, «Le remboursement de la PrEP est rentable», *affiche* Berne, 20 minutes (12 December 2023), <https://www.20min.ch/fr/story/sante-sexuelle-le-remboursement-de-la-prep-est-rentable-selon-berne-965977656164> (accessed 22 December 2023).

Council accepted that prevention should gradually be included in the catalogue of covered services, in order to control costs and match the practices of certain health insurers at the time. This amendment recognized the importance of disease prevention measures, but only incorporated them into the law to a limited extent.⁸⁴

[30] Then, we need to ask whether the reimbursement of preventive measures is a health promotion measure and encourages prevention. As things stand, there is little literature that makes a direct link between the funding of preventive measures by social insurance and the accessibility of these same measures. By analogy with the financing of healthcare services, the financial barrier is often a reason for not seeking care. In fact, two FSO studies, dating from 2013⁸⁵ and 2014⁸⁶, have highlighted a link between not seeking healthcare and a difficult financial situation. People with financial difficulties are 2.5 times more likely to forego medical or dental services. A study in Geneva also found a rate of 3.7% for high-income earners and almost 40% for low-income earners.⁸⁷ From the point of view of eliminating barriers to access and uptake of preventive measures⁸⁸, it would not be excessive to admit that wider reimbursement of these measures under the compulsory health insurance scheme would have a positive impact on access to prevention. Furthermore, improving the situation in this area would encourage the early detection of illnesses, reduce the financial burden associated with the care of acute and chronic illnesses, place the emphasis on proactive medicine and improve public health by reducing the prevalence of certain pathologies.⁸⁹

[31] In the revision of the OPAS/KLV, which will come into force on 1st of July 2024, the FOPH has also included other preventive measures in the catalogue of services under article 12a to 12e. These include another important preventive measure: coverage for prophylactic mastectomy and/or adnexectomy. This service is available to women with an increased genetic risk of breast or ovarian cancer. Genetic counselling (art. 12d let. f OPAS/KLV) is required prior to the operation. Factors taken into consideration include the patient's age and family history of cancer. Lastly, reimbursement is based on a decision taken in accordance with the FOPH's Reference Document on greatly increased family risk of breast or ovarian cancer of 2nd of November 2023.⁹⁰ It is interesting to note that this reimbursement also targets an «at-risk» population, but due to genetic factors. The Cancer Ligue has also criticised this reimbursement, since not all genetic mutations are considered. According to the Cancer Ligue, this situation means that «some people

⁸⁴ FF 1992 I 77, pp. 80, 101, 135–136.

⁸⁵ Federal Office of Statistics, *Etat de santé, renoncement aux soins et pauvreté, Enquête sur les revenus et les conditions de vie (SILC) 2011 (Neuchâtel 2013)*, <https://www.bfs.admin.ch/bfs/fr/home/statistiques/sante/determinants/situation-sociale.assetdetail.350809.html> (accessed 22 December 2023).

⁸⁶ Federal Office of Statistics, *Statistiques de la santé 2014 (Neuchâtel 2014)*, <https://www.bfs.admin.ch/bfs/fr/home/statistiques/sante.assetdetail.349485.html> (accessed 22 December 2023).

⁸⁷ IDIRS GUESSOUS *et alii*, «High prevalence of forgoing healthcare for economic reasons in Switzerland: a population-based study in a region with universal health insurance coverage», *Preventive Medicine* (vol. 55, n° 5, 2012), pp. 521527, <https://doi.org/10.1016/j.ypmed.2012.08.005> (accessed 22 December 2023).

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ Federal Office of Public Health, «Document de référence risque familial fortement accru de cancer du sein ou des ovaires de l'OFSP du 2 novembre 2023», <https://www.bag.admin.ch/bag/fr/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-versicherungen/gesetzgebung-krankenversicherung/kvg/referenzdokumente-zur-klv-und-deren-anhaenge.html> (accessed 22 December 2023).

forgo preventive surgery for financial reasons».⁹¹ This second example highlights the FOPH's desire to move towards the reimbursement of preventive measures, through the conditions governing the reimbursement of PrEP. However, when the reference documents were being drawn up, the authorities came up against a major obstacle in trying to identify the criteria that would determine whether a person fell into the «at risk» category. As a result, there will still be people who do not meet the criteria and who will not be eligible for reimbursement for these preventive measures, which, from a public health point of view, can be described as a missed opportunity.

[32] The inclusion of PrEP in the list of preventive measures and in the programme to fight against sexually transmitted infections has brought the issue of reimbursement for condoms by compulsory health insurance back to the fore. In Switzerland, the idea of reimbursement has been raised several times in Parliament. However, it has always been rejected, either because of the excessive costs that reimbursement would entail, or because of the individual responsibility of each person to protect themselves against the risks of unwanted pregnancy or sexually transmitted infections.⁹² Today, this position seems difficult to support from a public health perspective. Indeed, the reimbursement of PrEP does not concern such a vast population as in a context of financial coverage of condoms. As we mentioned previously, FOPH latest national program (NAPS) aims to eliminate all new HIV and Hepatitis B and C infections by 2030 and significantly reduce other cases of sexually transmitted infections.⁹³ Unfortunately, it should be noted that despite 24 occurrences of the term «condoms»⁹⁴, there is no mention of accessibility or possible reimbursement to improve their use among all population groups. Yet the FOPH insists on recognizing the importance and effectiveness of condom use in the fight against all sexually transmitted infections.⁹⁵

[33] On the other hand, another prevention tool – post-exposure prophylaxis – has been reimbursed in Switzerland for a long time, despite its many similarities to PrEP.

4.2. Pre and Post-Exposure Prophylaxis in perspective

[34] Post-exposure prophylaxis (PEP) is another HIV prevention strategies, but it differs with PrEP in terms of when and how they are used. In the case of HIV prevention in the context of sexual intercourse, the FOPH recommends PEP use after unprotected anal or vaginal sexual intercourse with a partner whose HIV status is either unknown or who is HIV-positive without an

⁹¹ THIBAUT NIEUWE WEME, «Ablation des seins ou des ovaires – Face aux assurances, les femmes ne sont pas toutes égales», *24 heures* (28 October 2023), <https://www.24heures.ch/ablation-des-seins-ou-des-ovaires-face-aux-assurances-les-femmes-ne-sont-pas-toutes-egales-133935215480> (accessed 22 December 2023).

⁹² MARTI, Motion 19.3660; GILLI, Interpellation 10.3104; SEYDOUX, Interpellation 10.3765; STUMP, Motion 10.3306 and 10.4119; (HODGERS) GILLI, Motion 13.3494; FERI YVONNE, Postulat 18.4228. All those references are available online at: <https://www.parlament.ch/fr/> (accessed 22 December 2023).

⁹³ Federal Office of Public Health, Programme national (NAPS), Stop au VIH, aux virus des hépatites B et C et aux infections sexuellement transmissibles (13 December 2023), <https://www.bag.admin.ch/bag/en/home/strategie-und-politik/nationale-gesundheitsstrategien/nationales-programm-hiv-hep-sti-naps.html> (accessed 22 December 2023).

⁹⁴ *Ibid.*

⁹⁵ *Ibid.*

antiretroviral treatment. If a partner whose HIV status is either unknown or who is HIV-positive has ejaculated in the mouth, then PEP prescription must be considered.⁹⁶

[35] It involves a short-term course of antiretroviral medications initiated as soon as possible and is highly effective when initiated within 72 hours after exposure. It typically involves a 28-day course of antiretroviral medications.⁹⁷

[36] PEP has been recommended by WHO guidelines since 2005.⁹⁸ Since the 1st of July 2009, it figures in the positive lists for disease prevention measures of the OPAS/KLV at article 12b let. c. In Switzerland, the Federal Commission for Sexual Health (FCSH) recommends a treatment of emtricitabine and tenofovir once a day (Truvada, the same molecules used for PrEP) combined with raltegravir (Isentress) twice a day.⁹⁹ In contrast to PrEP, Swissmedic does not explicitly recognise a PEP indication for these two drugs. However, both Truvada and Isentress mention the «treatment of HIV-1 infection», which could suggest that the treatment is indicated to avoid infection by the HIV.¹⁰⁰ The FOPH's data regarding the cost of the treatment is outdated now that generic medicines for Truvada are available. With the available data on the specialties list, it should cost CHF 700¹⁰¹, which would be equivalent to around 11 months of PrEP.

[37] The decision to reimburse PEP since 2009 and to wait 15 years to reimburse PrEP can be seen as paradoxical given both the cost of the treatment and their similarity. Two compatible hypotheses can help understand this situation. First, PEP can be seen as a therapeutic rather than a preventive endeavour, which, as we have already shown in the previous section, is easier to implement. Second, the FOPH identified two additional target groups for PEP, which are very different from those for PrEP. When the partner's serology is not known, the first situation mentioned by the FOPH is that of HIV exposure following a rape. Then, in its document on «care of healthcare personnel following accidents involving exposure to blood or other biological fluids» the FOPH recommends the use of PEP in several cases with a high risk of infection.¹⁰² In both of these cases, no steps could have been taken beforehand to reduce the risk of HIV exposure, which might explain why PEP was reimbursed so early compared to PrEP.

[38] These considerations about risk management are at the heart of discussions about health insurance, and we can see it again in the case of PrEP.

⁹⁶ Federal Office of Public Health, Reference document «Urgence en cas d'exposition au VIH: la PEP peut être la bonne réponse» (Version of 8 December 2022), <https://www.bag.admin.ch/dam/bag/fr/dokumente/kuv-leistungen/referenzdokumente-klv/art.12b-hiv-postexpositionsprophylaxe-empfehlungen-des-bag-vom-24.11.2014.pdf.download.pdf> (accessed 22 December 2023).

⁹⁷ NASTASJA WASSILEW *et alii*, «La prophylaxie post-exposition dans tous ses états», *Rev Med Suisse* (vol. 383, 2013), pp. 872–878.

⁹⁸ World Health Organization, «Post-exposure prophylaxis to prevent hiv infection Joint WHO/ILO guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection», Geneva September 2005, https://iris.who.int/bitstream/handle/10665/43838/9789241596374_eng.pdf?sequence=1 (accessed 22 December 2023).

⁹⁹ *Supra* note 19.

¹⁰⁰ *Supra* note 36; Isentress® MSD Merck Sharp & Dohme AG, <https://www.swissmedicin.ch> (accessed 22 December 2023).

¹⁰¹ Federal Office of Public Health, Specialties List, <https://www.spezialitätenliste.ch/default.aspx> (accessed 22 December 2023). Price for a month worth of treatment: Emtricitabin-Tenofovir: CHF 65; Raltegravir: CHF 634,80.

¹⁰² Federal Office of Public Health, OFSP-Bulletin 31/2007 (Bern 2007), pp. 543–555, <https://www.bag.admin.ch/bag/fr/home/das-bag/publikationen/periodika/bag-bulletin.html> (accessed 22 December 2023).

4.3. FOPH HIV risk analysis: from behaviour to specific groups

[39] When it comes to sexually transmitted infections, and more specifically HIV, there is often mention of risk groups or risk behaviours. It therefore seems appropriate to look at which groups have been identified as being particularly at risk of HIV, and to see whether these criteria correspond to the people targeted by the OPAS/KVV for reimbursement of PrEP and to the populations that are most affected by this disease.

[40] A preliminary remark should be made about the notion of «at-risk» groups or behaviour. This is not a new concept in public health, and can refer to factors, situations, conditions, or populations.¹⁰³ This risk-based approach is adopted for prevention on a targeted aspect of a public health issue. In the case of HIV, this approach has long contributed to confusion about the origin of the risk: is it a group of people who is particularly at risk, or the behaviours that create the risk?¹⁰⁴ This difference is even more marked between the heterosexual and LGBTQ+ populations when it comes to education and awareness of sexually transmitted diseases more generally. Heterosexuals are less likely to be tested and less concerned about their health than LGBTQ+ people.¹⁰⁵

[41] In Switzerland, the FOPH keeps statistics on HIV cases. In 2022, 70% of new HIV infections were among men, compared with 30% among women. No cases were recorded among trans men or women, nor among intersex people. In terms of incidence, the FOPH notes an increase in cases from 1.8 to 2.5 per 100,000 people among women, and from 5.6 to 5.9 per 100,000 people among men, between 2021 and 2022.¹⁰⁶

[42] In terms of identified routes of infection, among men, 45% of new HIV cases came from sexual relations with other men, followed by 26% from heterosexual relations, and 3% from contaminated needles. The source of infection remained unknown in 26% of cases. For women, 58% of HIV cases were due to heterosexual transmission, with one case linked to injecting drug use, and 39% of cases with no identified source of infection. No infections were recorded through sex between women.¹⁰⁷

[43] In terms of type of relationship, in cases of heterosexual contamination, 33.3% of women were infected by a known partner and 6.7% by prostitution. Among men, known partners accounted for 19.3% of infections, anonymous partners for 14.0%, and prostitution for 12.3%. Among men who have sex with men, 18.2% were infected by a known partner and 27.3% by an anonymous partner. The reliability of these data is limited by the high number of cases where the source of infection was not identified¹⁰⁸.

[44] It is interesting to compare the above data with the criteria specified by the FOPH in its reference document «Pre-exposure prophylaxis against HIV (HIV-PrEP)» to see if the statistics mentioned above matched to the selected criteria for the PrEP coverage. In the high HIV prevalence

¹⁰³ RAYMOND MASSÉ, «Le risque en santé publique: pistes pour un élargissement de la théorie sociale», *Sociologie et sociétés* (vol. 39, n°1, Les Presses de l'Université de Montréal, 2007), pp. 1327.

¹⁰⁴ *Ibid.*

¹⁰⁵ BRIDGET M. KUEHN, «PrEP Awareness Is Low Among Heterosexual People», *JAMA* (vol. 327, n° 2, 2022).

¹⁰⁶ *Supra* note 19; AXEL JEREMIAS SCHMIDT/EKKEHARDT ALTPETER, «The Denominator problem: estimating the size of local populations of men-who-have-sex-with-men and rates of HIV and other STIs in Switzerland», *Sexually Transmitted Infections* (vol. 95, n° 4, 2019) pp. 285291.

¹⁰⁷ *Supra* note 19.

¹⁰⁸ *Supra* note 19.

groups, the FOPH document mentions cisgender and transgender men who have sex with men, as well as transgender women who have sex with men. Specific criteria include anal intercourse without consistent condom use, recent sexually transmitted infections, use of stimulant drugs in a sexual context, a stable partner living with HIV with detectable viremia or poor adherence to treatment, and use of HIV post-exposure prophylaxis.¹⁰⁹ For those with low HIV prevalence, the FOPH mentions cisgender heterosexual men and women, and transgender heterosexual men, specifically those having unprotected sex with a stable partner living with HIV and presenting detectable viremia, or with people belonging to groups with increased HIV prevalence.¹¹⁰ The reference document covers a large proportion of the high-risk situations identified in the statistics. However, there are no specific criteria for some less common situations, such as the use of contaminated syringes.

[45] Historically, these discussions on risk have been linked to moral considerations, particularly where HIV is concerned. Risk was famously defined by Lupton as «moral danger».¹¹¹

4.4. Sex moralisation against public health progress

[46] The global fight against HIV has witnessed diverse approaches of variable efficiency, but the influence of sex moralization on prevention efforts cannot be overstated. From criticism regarding lack of abstinence and fidelity,¹¹² then regarding the use of condoms from the pope himself,¹¹³ then regarding PrEP.¹¹⁴ Every new step in the fight against HIV has been treated with initial distrust and has required considerable activism to gain public acceptance.

[47] For JAMES A. MORONE, the «myth of a liberal society» hides the true impact and influence of morality on public health policies, which are «shaped by images of vice and virtue». For him, «apparent efforts to improve public health often turn into ways of sorting out the moral *us* from the threatening *them*».¹¹⁵ This moralization of sexually transmitted diseases intersects with various social factors, such as gender, race, socioeconomic status, and sexual orientation and identity.¹¹⁶

[48] HIV in particular has been heavily linked to the «menace» that homosexuality represents for the traditional family and values.¹¹⁷

¹⁰⁹ *Supra* note 82.

¹¹⁰ *Ibid.*

¹¹¹ DEBORAH LUPTON, «Risk as moral danger: the social and political functions of risk discourse in public health.», *International journal of health services* 23.3 (1993); pp. 425–435.

¹¹² KENT BUSE/MIKAELA HILDEBRAND/SARAH HAWKES, «A farewell to abstinence and fidelity?», *The Lancet Global Health* (vol.4(9), 2016), pp. e599–e600.

¹¹³ GIUSEPPE BENAGIANO *et alii*, «Condoms, HIV and the roman catholic church», *Reproductive BioMedicine Online* (vol. 22, n° 7, 2011), pp. 701–709.

¹¹⁴ SARIT A. GOLUB, «PrEP stigma: implicit and explicit drivers of disparity», *Current HIV/AIDS Reports* (vol. 15, 2018), pp. 190–197.

¹¹⁵ JAMES A. MORONE, «Enemies of the people: the moral dimension to public health.», *Journal of Health Politics, Policy and Law* (vol.22(4), 1997), pp. 993–1020.

¹¹⁶ ALLAN M. BRANDT, *No magic bullet: A social history of venereal disease in the United States since 1880*, Oxford 2020, p. 6.

¹¹⁷ JUDITH STACEY, *In the name of the family: Rethinking family values in the postmodern age*, Boston 1997.

[49] Historically, you can see the opposition between the two approaches that framed HIV prevention. In the 1990s, «Abstinence, Be faithful, use a Condom», also known as the ABC strategy, was steeped in moral values and did not prove very effective for high-risk groups.¹¹⁸

[50] In contrast, the «Condoms, Needles, and Negotiation», known as the CNN strategy, adopted a more evidence-based perspective and contributed to reducing the transmission rates of HIV.¹¹⁹

[51] This reactionary moral influence still plays a significant role in shaping attitudes towards sex and, consequently, influence HIV prevention efforts. In 2009, Pope Benedict XVI asserted that the extensive use of condoms could make the HIV crisis worse, a claim widely regarded as unscientific.¹²⁰ In 2014, the secretary general of the Swiss Evangelical Network argued that HIV prevention focused on the use of condoms was «an issue, as it promoted only one lifestyle» and would rather focus on «faithfulness».¹²¹ «Concerned parents» further asked the FOPH to stop the 2014 HIV prevention campaign and appealed to the federal court to censor the campaign.¹²² These intersecting factors contribute to disparities in HIV prevalence and access to prevention resources, often framing discussions around safe sex practices, abstinence, and stigmatization of individuals who are at risk for or living with HIV. Moral judgments and misconceptions perpetuate stigma and hinder effective prevention and support initiatives.

[52] PrEP is no exception, and criticisms were swiftly voiced when the Swiss AIDS Federation started a campaign advocating against discrimination of HIV-Positive people and for better national implementation of PrEP in 2018.¹²³ Despite renewed evidence that the use of PrEP was a net positive for HIV prevention,¹²⁴ the *Tages-Anzeiger* released an article which denounced the supposed «contradictory» messaging of the Swiss AIDS Federation. The article claimed that the key message was that one «no longer needs condoms when having sex with HIV-positive people» and argued that this new tool «played down» AIDS and rendered «obsolete» the tried and tested «Ohne Dings kein Bums»¹²⁵ campaign.¹²⁶ The news of the reimbursement of PrEP has further aggravated these reactions. Some politicians at the National Council reiterated this binary opposition between condom and PrEP, while even a supporter of this measure implied that PrEP users

¹¹⁸ JOHN STOVER AND TENG YU, «The impact of condom use on the HIV epidemic», *Gates Open Research* (vol. 5, 2021).

¹¹⁹ STEVEN W. SINDING, «Does CNN (condoms, needles and negotiation) work better than ABC (abstinence, being faithful and condom use) in attacking the AIDS epidemic?», *International Family Planning Perspectives* (vol. 31(1), 2005), pp. 38–40.

¹²⁰ *Supra* note 113.

¹²¹ Radio Télévision Suisse, «La campagne contre le Sida «Love Life» continue de faire polémique», at 2:30 (7 August 2014), <https://www.rts.ch/play/tv/19h30/video/la-campagne-contre-le-sida-love-life-continue-de-faire-polemique?urn=urn:rt:video:6050599> (accessed 22 December 2023).

¹²² «Pas de censure immédiate de la campagne contre le sida Love Life», *Letemps.ch* (9 October 2019, <https://www.letemps.ch/suisse/censure-immEDIATE-campagne-contre-sida-love-life> (accessed 22 December 2023); ATF/BGE 144 II 233.

¹²³ FLORIAN DELAFOI, «Les messages contradictoires de l'Aide suisse contre le sida», *Le Temps* (12 November 2018), <https://www.letemps.ch/opinions/messages-contradictaires-laide-suisse-contre-sida> (accessed 22 December 2023).

¹²⁴ VIRGINIA A. FONNER *et alii*, «Effectiveness and safety of oral HIV preexposure prophylaxis for all populations.», *AIDS* (vol.30(12)), London 2016, p. 1973.

¹²⁵ Roughly translated as: «No sex without a condom».

¹²⁶ BENI GAFNER/STEFAN HÄNE, «Ohne Gummi: Aids-Kampagne weckt Ängste», *Tages-Anzeiger*, 10 November 2018, <https://www.tagesanzeiger.ch/ohne-gummi-aids-kampagne-weckt-aengste-153829210801> (accessed 22 December 2023).

were not ready to «bear the responsibility» of not using a condom.¹²⁷ This binary idea that the use of PrEP completely replaces condom use in the context of HIV is naïve at best and disingenuous at worst. The Federal Council had to step in and remind that despite this new tool: «Condoms are and remain the main means of HIV prevention.»¹²⁸ This is all the more demonstrated by the indication for Truvada and its generic, which states that it must be used «as part of overall strategy to prevent HIV-1 infection, including the use of other HIV-1 prevention methods (e.g. correct and systematic use of condoms, knowledge of HIV-1 serological status, screening every 3 months for other sexually transmitted infections)».¹²⁹

[53] Another common concern raised about PrEP and the reduction in condom use is the potential increase in other sexually transmitted infections. However, the scientific data on the matter is unanimous and shows a stability in other STI transmission, while HIV transmission decreases significantly. These results can be explained by the heavy medical monitoring that is mandatory with PrEP use.¹³⁰

[54] The news of the reimbursement of PrEP further illustrated the role of morality in these matters and raised important questions regarding solidarity in health insurance. The idea that some populations might not deserve to see their healthcare costs covered is apparent. The first article in the wake of this news was in the *Neue Zürcher Zeitung* was titled «Sex at the expense of health insurance». It starts with the following: «The health insurance fund must now pay for a drug for prostitutes and homosexuals that protects against HIV», incidentally focusing on two groups that have been heavily discriminated against in various ways. They chose to focus on a given group instead of focusing on the risky behaviour targeted, which can be stigmatising. After various questionable understatement regarding MSM that do not use condoms, the article sarcastically remarks that someone can charge their insurer before going «to a brothel and insist on having sex without a condom».¹³¹

[55] This posturing conveniently seems to forget that preventing HIV transmission is in the interests of society as a whole, and that PrEP is expected to be cost-effective. In the same article, the deputy director of the health insurance umbrella organization *Santésuisse* heavily criticized the decision to cover the costs of PrEP. He once again resorts to a binary discourse opposing the «expensive» PrEP and the cheap and responsible condom. For him, the general public should not be responsible for the «funding of PrEP», when everyone «can actually protect themselves.»¹³² However, this discourse is overall at odds with science, and the cost-effectiveness of PrEP has been well documented.¹³³ The Federal Council dismisses the cost argument and states that «after

¹²⁷ DANIEL GRAF/ADRIEL MONOSTORI, «Santé sexuelle: Polémique sur la pilule anti-VIH remboursée par les caisses», *20 minutes* (5 December 2023), <https://www.20min.ch/fr/story/sante-sexuelle-polemique-sur-la-pilule-anti-vih-remboursee-par-les-caisses-495602914823> (accessed 22 December 2023).

¹²⁸ CHRISTINE TALOS, «Le remboursement de la PrEP est rentable», *affirme Berne*, *20 minutes* (12 December 2023), <https://www.20min.ch/fr/story/sante-sexuelle-le-remboursement-de-la-prep-est-rentable-selon-berne-965977656164> (accessed 22 December 2023).

¹²⁹ *Supra* note 36.

¹³⁰ KENNETH H. MAYER *et alii*, «Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multi-centre, active-controlled, phase 3, non-inferiority trial.», *The Lancet* 396.10246 (2020), pp. 239–254.

¹³¹ *Neue Zürcher Zeitung* am Sonntag, «Sex auf Kosten der Krankenkasse» (3 December 2023), p. 12.

¹³² *Ibid.*

¹³³ For example: In the UK: VALENTINA CAMBIANO *et alii*, «Cost-effectiveness of pre-exposure prophylaxis for HIV prevention in men who have sex with men in the UK: a modelling study and health economic evaluation», *The Lancet infectious diseases* (vol. 18, n° 1, 2018), pp. 85–94. In Ireland: EAMON O. MURCHU *et alii*, «Cost-effectiveness analysis

5 to 10 years, [PrEP] will generate savings in compulsory health insurance, because it will make it possible to avoid the costs of treating HIV infections». ¹³⁴ Both the Swiss AIDS Federation and Procore, the Swiss national network defending the interests of sex workers, are convinced of the cost-effectiveness of the decision. They estimate the number of users in Switzerland at between 5,000 and 8,000, with a monthly pack costing around CHF 65. With 8,000 users, this comes to a cost of around CHF 6 million per year. According to Procore, only six cases of contamination avoided are enough to make PrEP cost effective. ¹³⁵

[56] Overall, this perspective on the moral aspect of HIV prevention is summed up best by the managing director of the gay umbrella organization Pink Cross: «Good prevention is based on reality. It is the task of politics to bring about good public health – and not to judge people’s sexual behavior with a moral cudgel.» ¹³⁶ As we have described in this paper, in this case reality is clear: based on current scientific evidence, PrEP reimbursement is undoubtedly a step forward in the fight against HIV.

5. Conclusion

[57] In the context of slowly rising HIV transmission in Switzerland, the reimbursement of pre-exposure prophylaxis represents a significant step forward to fight the spread of HIV. Switzerland’s conservative approach to reimbursement for prevention tools has resulted in rather slow progress in PrEP access and uptake, especially compared to its European neighbours. ¹³⁷ Even though prices have dropped significantly in the last two years, costs still represented a non-negligible hurdle for potential users.

[58] The positive impact of PrEP reimbursement extends beyond individual health benefits to broader societal advantages, including an expected reduction of health costs associated with HIV prevention and treatment, and a decrease in the transmission and overall prevalence of HIV. By further integrating PrEP into the national healthcare system, Switzerland aligns its national programmes against HIV with global efforts to achieve the UNAIDS targets of ending the AIDS epidemic by 2030.

[59] PrEP coverage by the compulsory health insurance reflects the progress made in promoting evidence-based decision-making and follows in the efforts from the FOPH to improve HIV prevention and reduce stigmatisation of at-risk groups. However, this paper has also highlighted the challenges that remain with the approach chosen by the Swiss authorities. The FOPH has created additional obstacles by limiting reimbursement to at-risk groups rather than adopting a more comprehensive approach. This leads to a focus and stigma on at-risk groups and limits access and awareness for heterosexual people.

of a national pre-exposure prophylaxis (PrEP) program in Ireland.», *Value in Health* (vol. 24(7), 2021), pp. 948–956.
In France: YOUSSEUEA OUSSEINE/NATHALIE LYDIÉ/ANNIE VELTER, «Pre-exposure prophylaxis in France: How many MSM are eligible and how much will it cost?», *Plos one* (vol. 17(12), 2022).

¹³⁴ Supra note 128.

¹³⁵ Supra note 131 and note 127.

¹³⁶ Supra note 131.

¹³⁷ Supra note 13.

[60] These challenges are a direct consequence of the framework for reimbursement of prevention tools by Swiss compulsory health insurance. The example of insurance coverage for condoms shows the way forward for HIV prevention in Switzerland. As an example, in France, since the 14th of February 2018, condoms are partially reimbursed by the French national insurance.¹³⁸ Since the 1st of January 2023, condoms are reimbursed at 100% without prescription for people under 26, or at 60% with a doctor's prescription for people over 26.¹³⁹

[61] Reimbursement of PrEP in Switzerland is a progressive and commendable initiative and should be celebrated as a public health success. We can only hope that this trend towards reimbursement of prevention tools will continue in Switzerland, and that the reimbursement of PrEP is just another step towards the goal of truly comprehensive HIV prevention.

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¹³⁸ France, Health Ministry, «Arrêté du 14 février 2019 portant inscription du préservatif masculin lubrifié SORTEZ COUVERTS ! du laboratoire POLIDIS au titre I de la liste des produits et prestations remboursables prévue à l'article L. 165-1 du code de la sécurité sociale», 14 February 2019.

¹³⁹ France, Assemblée Nationale, Article 18 du Projet de Loi de Financement de la Sécurité Sociale n°1682 pour 2024, 27 September 2023.