World Health Organization

GUIDELINES ON

LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION

WEB ANNEX A. DECLARATIONS OF INTEREST FOR THE GUIDELINE DEVELOPMENT GROUP AND EXTERNAL PEER REVIEWERS

Guidelines on long-acting injectable cabotegravir for HIV prevention. Web Annex A. Declarations of interest for the Guidelines Development Group and external peer reviewers

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Guideline Development Group members (*n* = 22)

Gender identity	Percentage	Region	Percentage
Cis men	**41%**	AFRO	27%
Cis women	**50%**	AMRO	27%
Trans men	**5%**	EURO	9%
Trans women	**5%**	EMRO	14%
		SEARO	5%
		WPRO	18%

Name	1.Consulting & technical advisory boards	2.Research support	3. Investments & business interests	4. Intellectual property	5. Public statements and positions	6. Additional information	7.Tobacco products	Conflicts management plan
Max Appenroth, Global Action for Trans Equality (GATE), Germany	1b) Consulting for trans inclusion in one of their trials, Merck, 600€	0	0	0	0	0	0	Full participation.
Connie Celum, International Clinical Research Center, University of Washington, United States of America	1b) Scientific advisor, Merck, no, US$ 3000, collaborator, IMPOWER islatravir for HIV prevention 1b) Scientific advisor, Gilead Sciences, no, US$ 2000, none	0	0	0	5a) Expert opinion for federal patent case, Gilead Sciences, Feb–June 2022	0	0	Financial, not significant. Full participation.
Mohamed Chakroun, University Hospital Monastir, Tunisia	0	0	0	0	0	0	0	Full participation.
Thato Chidarikire, National Department of Health, Pretoria, South Africa	0	0	0	0	0	0	0	Full participation.

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Olga Denisiuk, Alliance for Public Health, Ukraine	0	0	0	0	0	0	0	Full participation.
Daouda Diouf, Enda Santé, Senegal	0	0	0	0	0	0	0	Full participation.
Inês Dourado, Instituto de Saúde Coletiva, Federal University of Bahia, Brazil	0	0	0	0	0	0	0	Full participation.
Andrew Grulich, Kirby Institute, University of New South Wales, Australia	1b) Consulting, member of global forum on HPV, MSD, me, AU$ 1500, current.	0	2a) Research support grant on preparation for injectable PrEP, Viiv, AU$ 125 000, current. 2a) Research support, other (in-kind support provision of Truvada), Gilead, employer, in-kind support Truvada, 2000 person years, ceased 2018.	0	0	5b) Membership of NSW HIV strategy implementation committee, I have been advocating for increased PrEP uptake, NSW Ministry of Health, employer, zero value to me, current. Additional information sought by email.[1]	0	Financial, not significant. Full participation.

[1] Researchers at the Kirby Institute (Sydney), and Monash University (Melbourne), are conducting pilot research on injectable PrEP feasibility. I am leading the Sydney arm of the study with my colleague Dr Ben Bavinton, and Viiv have part-funded the study. This includes the following activities: 1. Literature review including CAB-LA pre-clinical and clinical trials, injectable PrEP acceptability, values, and preferences; 2. Key informant/stakeholder interviews on the role of and strategies for implementing injectable PrEP and future PrEP technologies in Australia, policy makers, researchers, community organizations, Australian Society of HIV Medicine (ASHM), pharmacists; 3. A survey on PrEP values and preferences and the role of injectable PrEP with gay and bisexual men; 4. User experience consultation workshops (co-design approach), with groups of interest, current PrEP users, previous PrEP users, non-PrEP-users, and people from populations known to be at risk of HIV who may not yet have accessed PrEP; 5. Clinical service-provider consultation workshops with specialist (100) and non-specialist GPs, sexual health physicians, outreach workers, community HIV testing site peer workers, HIV specialists, nurses, pharmacists, with the aim of using a co-design approach to inform the development of clinical models of CAB-LA administration; 6. Drafting of CAB-LA implementation research concept plan for consultation, including primary research questions, proposed study design/methods, summary of findings of the above data collection, initial ideas on potential supports for CAB-LA users and service providers (e.g. digital app), and initial ideas on information materials; 7. Consultation meetings on the concept plan with implementation research and community stakeholders, three meetings (face-to-face/online/hybrid); 8. Drafting of full proposal and research protocol; and 9. Submission of either: a) National Health and Medical Research Council (NHMRC) Partnership Grant or b) ViiV investigator-initiated grant if NHMRC Partnership Grant is not feasible.

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Diane Havlir, University of California San Francisco, United States of America		2b) Donation of PrEP to a research study, Gilead, donation goes through university contract, no income, ongoing, Gilead provides non-financial support to NIH- funded research study through a contract with UCSF.					0	Full participation.
Phan Thi Thu Huong, Viet Nam Authority of HIV/AIDS Control, Viet Nam	0	0	0	0	0	0	0	Full participation.
Elizabeth Irungu, Jhpiego, Kenya	0	0	0	0	0	0	0	Full participation.
Rena Janamnuaysook, Institute of HIV Research and Innovation and Tangerine Clinic, Thailand	0	0	0	0	0	0	0	Full participation.

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Julie Fox, King's College London, United Kingdom	0	2a) Research grant to conduct pharmacokinetic studies of drug-drug-drug interaction between gender-affirming hormone and tenofovir alafenamide (F/TAF) used as PrEP among transgender men and transgender women, Gilead Sciences, my organization, around US$ 500 000, ongoing.	0	0	0	0	0	Full participation.
Mehdi Karkouri, Association de Lutte Contra la Sida/ Centre Hospitalier Universitaire Ibn, Morocco	0	0	0	0	0	0	0	Full participation.

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Geoffroy Liegeon, University of Paris Diderot, France	0	2a) We are going to implement this year a study aiming to assess the acceptability of long-acting injectable cabotegravir for PrEP among MSM in Paris region. This study is a partnership between ViiV and the ANRS. Viiv provides the drugs for the study but no financial support.	0	0	0	0	0	Full participation.
Imelda Mahaka, Pangaea Zimbabwe AIDS Trust, Zimbabwe	0	0	0	0	0	0	0	Full participation.
Kenneth Mayer, Fenway Health Center, United States of America	1b) Scientific Advisory Board. 1b) Merck, me, US$ 3500, current. 1b) Gilead Sciences, me, US$ 3000, current.	2a) Research grant, Merck, employer, US$ 300 000, current. 2a) Research grant, Gilead Sciences, employer, US$ 350 000, current, research on pre-exposure prophylaxis product preference.	0	0	0	Additional information was sought by email.[2]	0	Financial, not significant. Full participation.

[2] The Merck grant on product preference involves focus groups and web surveys of American MSM to assess knowledge and attitudes about current and potential future HIV prevention approaches. It is product agnostic. The Gilead grant was to conduct a study of Bictegravir-TAF-FTC for post-exposure prophylaxis. The study is completed and a manuscript has been e-published in JAIDS. Fenway Health is an HPTN site, and enrolled participants in HPTN 083. Our funding to conduct our work in that trial came directly from NIH-NIAID and not from ViiV.

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Getrude Ncube, Minister of Health and Child Care, Zimbabwe	0	0	0	0	0	0	0	Full participation.
Urvi Parikh, University of Pittsburgh, United States of America	0	0	0	0	0	0	0	Full participation.
Danvic Rosadiño, LoveYourself, Philippines	0	0	0	0	0	0	0	Full participation.
François Venter, University of the Witwatersrand, South Africa	ViiV Healthcare, me, varies, but generally around US$ 1000 per meeting, I do not know the cost of the drug donation. I have been on advisory boards for ViiV for several years, for treatment, as well as for PrEP. In addition, Viiv donated drug (DTG) and provided monetary support for a sub study for a treatment study I lead.		0	0	0	0	0	Full participation.
Mitchell Warren, AVAC, United States of America	0	0	0	0	0	0	0	Full participation.

HPV: human papillomavirus; **MSD:** Merck & Co., Inc. (in the US and Canada); **AU$:** Australian dollars; **NSW:** New South Wales; **NIH:** National Institutes of Health; **UCSF:** University of California, San Francisco; **MSM:** men who have sex with men; **ANRS:** French National Agency for Research on AIDS; **DTG:** dolutegravir.

External peer reviewers (*n* = 22)

Conflicts management: The steering group assessed comments for validity on a case-by-case basis, in the context of the reviewer's conflicts of interest.

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Carolyn Amole, Clinton Health Access Initiative, USA	0	0	0		0	0	0
Iskandar Azwa, University of Malaya, Malaysia	0	0	0		0	0	0
Linda-Gail Bekker, Desmond Tutu HIV Centre, South Africa	1b) Gilead Sciences, Janssen and Merck for advisory work, belongs to me, between US$ 5000–7000 in total, past 12 months.	0	0		5a) Current Board Member: AVAC, IAVI, APHA.	0	0
Ngauv Bora, NCHADS, Cambodia	1a) Employment	0	0		0	0	0

[3] Two individuals were contacted to participate in the peer review process from the WHO Eastern Mediterranean Region but did not respond.

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Esteban Burrone, Medicines Patent Pool, Switzerland	1a) Employment: I work for the Medicines Patent Pool, a public health non-profit organization in official relations with WHO, that has publicly indicated that it has prioritized cabotegravir for in-licensing in order to support affordable access to this prevention tool in LMICs.	0	0		0	0	0
Judy Chang, International Network of People who Use Drugs, Italy	1a) Employment, INPUD, INPUD is a network representing the interests of people who use drugs. We receive money to advocate for equitable access to HIV and hepatitis C prevention, care and treatment services. Employees of the organization are salaried to work towards fulfilling the above objective. £54 106 annually, 2021.	0	0		In 2021, the WHO Department for Global HIV, Hepatitis and STI Programmes (HHS) will update the 2016 Consolidated guidelines for HIV prevention, diagnosis, treatment and care for key populations. Part of the requirements for the GDG to consider making recommendations are the values and preferences of key populations related to behavioural and structural interventions, service delivery, hepatitis C testing and treatment, and STI screening. The principal investigators will be senior staff and consultants from four global key populations networks representing gay and bisexual men (MPACT), people who use drugs (INPUD), sex workers (NSWP) and trans communities (GATE). Additionally, key population members' values and preferences will be assessed related to: Key populationled responses (i.e. services and programmes run and managed by peers); Face-to-face interventions compared with digital interventions; Effect of criminalization of drug use, sexual orientation, gender identity and sex work on uptake of prevention, testing, linkage to treatment and treatment retention; Enabling interventions to address structural barriers to accessing health services and Effect of stigma and discrimination on uptake of prevention, testing, linkage to treatment and treatment retention.	0	0

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Teddy Cook, ACON, Australia	1a) Employment, ACON Health Limited, employer, AU$ 145 000 per year, current.	0	0		0	0	0
Siobhan Crowley, The Global Fund, Switzerland	1a) Employment, The Global Fund, salary, current. 1a) Employed as head of HIV at the Global Fund - we are major supplier for all HIV products to LMICs.	0	0		0	0	0
Mario Gomez Zepeda, Ministry of Health, Mexico	0	0	0		0	0	0
Kimberly Green, PATH, Vietnam	1a) I am employed by PATH and in my role, I oversee research, implementation and documentation related to HIV testing. At times, when I attend a WHO meeting, PATH will contribute to the costs of travel.	0	0		0	0	0
Micheal Ighodaro, AVAC, Nigeria	0	0	0		0	0	0
Stephane Wen-Wei Ku, HIV Education and Research, The Republic of China	ViiV, myself, US$ 350, 2021, Gilead, US$ 350, 2021, MSD, US$ 350, 2021	0	0		0	0	0
Ioannis Mameletzis, independent consultant, Greece	0	0	0		0	0	0

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Frank Mugisha, Sexual Minorities Uganda, Uganda	0	0	0		0	0	0
Saiqa Mullick, Wits Reproductive Health and HIV Institute (RHI), South Africa	0	2a) Research support. Wits RHI receives grant funding support from ViiV.	0		0	0	0
José Carlos Quiñónez, Asociación PASMO, Guatemala	0	0	0		0	0	0
Kaushal Ranasinghe, The PACT, Sri Lanka	0	0	0		0	0	0
Sushena Reza Paul, University of Manitoba, India	0	0	0		0	0	0
Anna Shapiro, Global Network of Sex Work Projects, United Kingdom	0	0	0		0	0	0
Valdilea Veloso, Fundação Oswaldo Cruz, Brazil	0	0	0		0	0	0

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Edwina Wright, Alfred Health and Monash University, Australia	0	2a) I have recently received funding to undertake research to evaluate the interest and acceptability of injectable PrEP in Australia, ViiV, AU$ 125 000.	0	0	5b) I am Chair of the PrEP Guidelines of the Australasian Society of HIV, Blood Borne Viruses and Sexual Health Medicine and hence I am in a position to influence the prescribing practices of Australian clinicians. We have not yet included any injectable PrEP in our current guidelines.	0	0
Rebecca Zash, Botswana Harvard AIDS Institute Partnership, Botswana, USA	0	2a) Research support, NIH/NICHD, me, I currently have a K23 research grant from NICHD which supports my research and salary, NICHD also funds the study which led to results that I will speak about at this meeting. Total budget for my K23 is Y2 Budget US$ 163 335, of which US$ 100 000 supports salary. 2b) Received coverage of hotel and honorarium for being a speaker on a panel at HIV/Hepatitis 2019, PAHO, me, US$ 1250 -- research support, ViiV, me, supplying the product for a research study that is funded by NIH/NICHD, cost of the product (unknown).	0		0	0	0

NCHADS: National Center for HIV/AIDS, Dermatology and STD (Cambodia); **LMIC:** low- and middle-income country; **NIH:** National Institutes of Health; **NICHD:** National Institute of Child Health and Human Development

For more information, contact:

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