



Summary report questionnaire MSM policy and PrEP/PEP

25 October 2023

Blood donation eligibility policies for men who have sex with men (MSM) have evolved since they were found to be at increased (disproportionate to other population groups) risk of HIV infection. Starting with a permanent (lifetime) deferral, the policy has shifted to a temporary deferral with a trend of shortening the deferral period. In recent years, the screening method for determining the presence of such behavioural risk in blood donors has also changed from specific questions about sexual contact with MSM to universal questions for individual risk-based assessment regardless sex and sexual orientation of the donor.

In 2019 and 2021, the EBA EID Monitor Working group performed surveys on MSM policy and pre-and post-exposure prophylaxis (PrEP and PEP) groups among its members. During these years countries shifted gradually to more relaxed the MSM rules or to a non-MSM specific individual risk assessment approach.

A new survey was sent to members of the EID Monitor Working group on March 30th 2023 to follow up on the current donor selection strategies or expected changes concerning MSM, PrEP and PEP for HIV.

Till June 5th 2023, 25 responses from 23 countries (including 3 non-European countries) were received. Three blood operators ARC, OneBlood and Impact Life from the US sent separate responses. Updates in policy received after the survey till Oct 16th are included in the report.

Question 1. Do you have a specific question for MSM contact on the Donor History Questionnaire (DHQ)?

Ten countries ask donors for MSM contact directly via the DHQ. The number of countries that abandoned the specific MSM questions increased from 3 countries (Italy, Portugal and Spain) in 2021 to 12 countries in 2023. One country, Croatia, does not raise a question for MSM contact. A list is provided on the first page of the questionnaire with risk behaviours for acquiring blood-borne infection, which includes MSM contact. All donors are asked if they recognise themselves in any of the listed groups of people at increased risk or if they had sexual contact with such a person.

In Luxembourg, in addition to the specific question for MSM, all donors are asked if they had a new sexual partner or multiple sexual partners in the past 4 months and if, to their knowledge their partner had another sexual partner in the past 4 months. The deferral period is 4 months.

Questions 2. If yes, what are the donor consequences for MSM? What is the length of deferral, deferral for all MSM and donation types?



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The deferral period for MSM ranges from 3, 4, 6, and 12 months to lifetime deferral. The deferral periods for MSM in countries are summarized in Table 1 for the years 2019, 2021 and 2023.

The deferral criteria apply to all donation types, including donations of plasma for fractionation for the preparation of medicinal products, in all participating countries except Luxembourg. In Luxembourg, MSM donors are allowed to donate plasma for fractionation. The plasma is then quarantined and released if all serological tests are negative on another donation after 4 months.

In the Netherlands, donors are deferred for 4 months after sexual contact with MSM, if it was not in a monogamous relationship. A monogamous relationship is defined as a relationship with one partner of at least 12 months and who have sex only with each other. For the remaining 10 countries the same deferral rules are in place for all MSM.

Table 1. MSM deferral periods

Country	Deferral period 2019 (months)	Deferral period 2021 (months)	Deferral period 2023 (months)
Australia	12	3	3
Austria	lifetime	12	individual risk
Belgium	12	12	4 (as of July 1 st)
Canada	3	3	individual risk
Croatia	-	lifetime	lifetime
Denmark	lifetime	4	4
Estonia	-	12 (lifetime PF*)	4
Finland	12 (lifetime PF*)	4 (lifetime PF*)	4
France	12	4	individual risk
Germany	12	-	individual risk (as of July)
Ireland	12	12	individual risk
Italy	individual risk	individual risk	individual risk
Luxembourg	-	12	12**
Malta	12	12	individual risk
Netherlands	4 (lifetime PF*)	4	4, accepting monogamous MSM
Norway	-	-	12
Portugal	-	individual risk	individual risk
Slovenia	lifetime	lifetime	individual risk
Spain	individual risk	individual risk	individual risk
Sweden	12 (lifetime PF*)	6	6
Switzerland	12	12	individual risk (as of Nov 1 st)
UK	3	3	individual risk
USA	12 (some manufacturers require lifetime PF*)	3 (OneBlood lifetime PF*)	3 (individual risk implemented by blood operators during 2023)

* PF plasma donations for fractionation



** No deferral for plasma for fractionation; plasma is put in quarantine and released if all serological tests are negative on another donation after 4 months

Question 3. If no specific MSM question is raised, what are the questions and/or criteria to identify donors with sexual risk behaviour?

Twelve countries that have an individual risk assessment approach ask each donor questions about sexual contact with a new sexual partner and/ or more than one sexual partner (Table 2). Five countries added the criteria of anal sex if the donor had new or multiple sexual partners.

Other questions raised were about: chemsex; a sexual partner infected with HIV, HBV, HCV, HTLV who had a sexually transmitted disease or mpox; a sexual partner from a region where AIDS (Sub-Saharan Africa) is common; having a sexually transmitted disease or mpox; a sexual partner with other sexual partner(s); a sexual partner who has a bleeding disorder; injecting drugs, non-prescribed/ recreational drugs; sex in exchange for money or drugs. In Italy, a personalised interview is performed to identify risk factors. The period after the last sexual contact (new or multiple partners) at risk varies from at least 4 weeks, to 3 months or 4 months.

Table 2. Deferral criteria for individual risk assessment

Country	New sexual partner	More than one sexual partner
Austria	Last 4 weeks (except "safe sex")	Last 3 months (more than 3 partners)
Portugal	Last 3 months	Last 3 months
Canada, UK, USA	Last 3 months and anal sex	Last 3 months and anal sex
France	-	Last 4 months (or a partner with another partner)
Italy, Malta, Spain	Last 4 months	Last 4 months
Germany, Ireland, Slovenia	Last 4 months and anal sex	Last 4 months and anal sex
Switzerland	Last 4 months	Last 12 months (more than 2 partners)

Question 4. Do you expect a change in your MSM policy?

In 11 countries new strategies are under consideration or a new strategy will be implemented soon or has been recently.

Australia has submitted a request to its regulator (Therapeutics Goods Administration) to remove all sexual activity deferrals for donating plasma for fractionation which has been approved and allows all donors, regardless of sexual activity, to donate plasma for

fractionation without a deferral period. This approval must still be approved by the Australian government and the plasma fractionator.

Belgium (Flanders) changed from a 12-month deferral to 4 months as of July 1st 2023. Under the same law from 2022, MSM should be able to donate quarantine plasma by apheresis without deferral, whereby the plasma should be kept long enough in quarantine to bridge the window periods for HIV, HBV, HCV and HTLV. However, it is not specified in the law which testing method should be used for HTLV testing and what window period to consider. Additionally, approval of the fractionator (CSL) is needed to accept the quarantined plasma.

In Denmark an individualized risk assessment is considered. The timeframe is not known.

Estonia changed from a 12-month to a 4-month deferral in April 2022. Depending on the epidemiological situation changes could be considered in future.

Finland expects a change in the near future where they might ask all donors a neutral question about new sexual partners during the last 4 months. They are waiting for approval from the authority (Fimea, Finnish Medicine Agency) to proceed with the plan to change the questions to be neutral and identical for everyone.

In Germany, the transfusion law and the directive of the Bundesärztekammer have been updated this year. They changed from a 4-month deferral for all MSM to a no gender-specific individual risk assessment in July 2023.

In the Netherlands, Sanquin blood bank is working to further improve the equal treatment of all donors by introducing a universal assessment of sexual risk behaviour. It is expected this change will be implemented as of January 2024.

In Norway, the Norwegian Directorate of Health is currently working on a risk assessment.

In Sweden, the National Board of Health and Welfare and the Public Health Agency are reviewing the criteria for MSM, but no decision has yet been made.

In Switzerland Swiss transfusion submitted a change request to the competent regulation authority Swissmedic, the change was accepted in July 2023. As of November 1st 2023, all donors are deferred for 4 months after sexual contact with a new partner and 12 months after sexual contact with multiple partners. MSM and heterosexual donors have the same criteria.

In the US gender-inclusive, individual risk-based questions relevant to HIV risk, will be implemented according to the recommendation in the U.S. Food and Drug Administration guidance "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based



Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products” that has been finalised in May 2023. As of October 2023, most US blood centers have implemented gender-inclusive, individual risk-based questions relevant to HIV risk.

Question 5. Do you have a specific question about HIV antiretrovirals on the DHQ?

If yes, please specify the question.

In 14 of the 23 countries, a specific question for HIV antiretrovirals is raised through the DHQ. The questions are listed in Table 3. Two respondents indicated questions will be implemented (Spain, US Impact Life). For countries not asking direct question to donors who are taking antiretrovirals may be identified by the general question on medication. Portugal had in their previous version of the DHQ a question mentioning PREP and PEP. They updated the question with more generic and understandable wording, referring to prophylaxis or treatment for infectious disease ("Did or do you do any prophylaxis or treatment for infectious disease?").

Question 6. What is the deferral period for PrEP or PEP?

The deferral period for PrEP and PEP are summarised in Table 4. As the MSM deferral the deferral period between countries varies from 3 months to a lifetime deferral or deferral period based on risk behaviour. In the US the deferral is 3 months and 4 months in Canada for oral PrEP or PEP and 2 years for injectable PrEP/PEP (cabotegravir).

Table 3. Specific question for HIV antiretrovirals

Country	Question(s)
Australia	Since your last donation, have you – or if you’re a new donor, have you in the last 12 months – taken or used any medication, including: <ul style="list-style-type: none"> • Regular or clinical trial medication? • Acne or other skin condition medications? • PrEP (pre-exposure prophylaxis) to prevent HIV infection? • Injectable medications?
Austria	Did you use medication to prevent an HIV infection during the last 12 months?
Belgium (Flanders)	Have you ever used medication to prevent HIV infection (pre-exposure or post-exposure prophylaxis, PrEP/PEP)? If so, when and why?
Canada	In the last 4 months have you taken any medication by mouth to prevent an HIV infection such as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP). In the last 2 years have you received an injection or shot to prevent an HIV infection, such as pre-exposure prophylaxis (PrEP)?
Croatia	Have you ever taken or are you taking these medications: PrEP/PEP?
France	Did you take a medication to prevent HIV infection such as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) in the last 4 months?
Germany	Have you taken an anti-HIV medication (PrEP) in the last 4 months?



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Ireland	In the past 4 months have you taken medication to prevent HIV infection (pre/post exposure prophylaxis, PrEP/PEP)?
Malta	Have you ever used medication to prevent HIV infection (PrEP/PEP, pre/post-exposure prophylaxis for HIV)?
Netherlands	In the last 12 months: have you taken any medication to prevent HIV infection, such as PrEP or PEP?
Slovenia	In the last 12 months did you take drugs for prevention of HIV infection before risk exposure or after risk exposure?
Switzerland	During the past 4 months, have you taken antiretroviral therapy /PEP/PrEP (e.g. Truvada®, Isentress® Prezista® or Norvir®)?
UK	In the past 3 months have you taken Pre- or Post-Exposure Prophylaxis (PrEP/PEP) to prevent HIV infection?"
USA	In the past 3 months have you taken Pre- or Post-Exposure Prophylaxis (PrEP/PEP) to prevent HIV infection?"; In the past 2 years, have you received an injection or shot to prevent an HIV infection?; Have you EVER taken any medication to treat an HIV infection? Or Have you taken any medications to prevent HIV either by mouth or injection?

Table 4 PrEP/PEP deferral

Country	Deferral period PrEP (months)	Deferral period PEP (months)
Australia	12 months (3 months for plasma for fractionation donors only)	4 needle stick, 3 sexual risk
Austria	12	12
Belgium (Flanders)	Based on risk behaviour	Based on risk evaluation
Canada	4 months oral; 2 years injectable	4 (oral)
Croatia	Lifetime	Lifetime
Denmark	4	4
Estonia	4 (based on risk behaviour)	4 (based on risk behaviour)
Finland	4	4
France	4	4
Germany	4	4
Ireland	4	4
Italy	Based on risk behaviour	Based on risk behaviour
Luxembourg	4	4
Malta	4	4
Netherlands	12	4
Norway	6	6
Portugal	3	3
Slovenia	12	12
Spain	4	4
Sweden	4	Based on risk behaviour
Switzerland	4	4
UK	3	3 or 4



USA	3 months oral; 2 years injectable	3 months oral; 2 years injectable
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Question 7. Do you expect a change in your policy for PrEP use?

In Australia, a submission to the regulator (Therapeutics Goods Administration) was done to accept PrEP use for plasma for fractionation donations which has been approved but waiting on further approvals on the 'plasma pathway' before implementation. The 12-month deferral for fresh components will remain. In September 2023, Canada added a question about long-acting PrEP in the last 2 years with a 2-year deferral since the last use. Canadian Blood Services also consulted with Canadian treatment/prophylaxis experts who suggested that long-acting injectables would not likely be used for PEP in Canada. In other countries, the situation is under evaluation, especially for long-acting antiretrovirals.

Question 8. Other information/ concerns expressed.

Lifeblood will undertake a research program to determine an individual risk assessment approach which is safe and appropriate for blood donations in Australia. The research program will include issues such as calculating the likely impact of the donor panel – from newly eligible donors, and from losing currently eligible donors; assessing the community's attitude towards the risk of HIV infection through a blood transfusion and assessing the acceptability of asking all blood donors more detailed questions about their sexual activity.

Canada continues to study PREP/PEP use in their donor population and investigate HIV - positive donations with follow-up with the donor and additional laboratory testing.