fNo311

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**IN THE SUPREME COURT OF INDIA**

**CIVIL ORIGINAL JURISDICTION**

**(Under Article 32 of the Constitution of India)**

**WRIT PETITION (CIVIL) NO. OF 2021**

**IN THE MATTER OF:**

THANGJAM SANTA SINGH
@ SANTA KHURAI ...PETITIONER

VERSUS

UNION OF INDIA & OTHERS ...RESPONDENTS

With

**IA NO. OF 2021 APPLICATION FOR INTERIM RELIEF**

**PAPER BOOK**
(FOR INDEX PLEASE SEE INSIDE)

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**PROFORMA FOR FIRST LISTING**

Section- X

Central Act: (Title) – N/A

Section: – N/A

Central Rule: (Title) : -N/A

Rule No (s) – N/A

State Act (Title) –N/A

Section: – N/A

State Rule (Title): – N/A

Rule No (s) : – N/A

Impugned Interim Order: (Date) –N/A

Impugned Final Order/Decree: (Date) N/A

High Court: (Name): N/A

Names of Judges: N/A

Tribunal/Authority : (Name) – N/A

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1. Nature of matter: **Civil**

2. (a) Petitioner/Appellant: Thangjam Santa Singh @ Santa Khurai

   **(b)** e-mail ID: – N/A

   (c) Mobile Phone Number: – N/A

3. (a) Respondent No.: Union of India & Ors.

   **(b)** e-mail ID: – N/A

   (c) Mobile Phone Number: – N/A

4. (a) Main category classification: 08

   **(b)** Sub classification :0812

5. Not to be listed before : – N/A

6. (a) Similar disposed of matter with citation, if any, & case details: –

No similar disposed off matter

(b) Similar pending matter with case details:- No similar pending matter

7. **Criminal Matters:**

(a) Whether accused/convict has surrendered: N/A

(b) FIR No. N/A

(c) Police Station : N/A

(d) Sentenced Awarded : – N/A

(e) Sentence Undergone: N/A

8. **Land Acquisition Matters: N/A**

(a) Date of Section 4 Notification: – N/A

(b) Date of Section 6 Notification: – N/A

(c) Date of Section 17 Notification: – N/A

9. **Tax Matters**: State the tax effect: – N/A

10. **Special Category** (first petitioner/appellant only– N/A

Senior Citizen>65 years SC/ST Women/child Disabled

Legal Aid case In custody

11. Vehicle Number (in case of Motor Accident Claim matters):

Date: 13.02.2021 AOR for petitioner(s)/appellant(s)

**ANINDITA PUJARI**
C.C. No. – **2087**
aninditapujari@gmail.com

## SYNOPSIS

The Petitioner is filing the present Writ Petition as a public interest litigation under Article 32 of the Constitution of India challenging the constitutional validity of the Guideline on Blood Donor Selection and Blood Donor Referral, 2017 issued on 11.10.2017 by the Respondents being the National Blood Transfusion Council and the National Aids Control Organization under the Ministry of Health and Family Welfare, Government of India. Clauses 12 and 51 of the general criteria under blood donor selection criteria of the impugned Guidelines to the extent it permanently defers/prohibits transgender persons, men having sex with men and female sex workers from donating blood and considers them to be a high-risk category as being HIV / AIDS infected. The said clauses are stated as follows:

| S.No. | General Criteria | Recommendations |
|---|---|---|
| 12 | Risk Behaviour | The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination.<br>The donor shall not be a person considered "**at risk**" for HIV, Hepatitis B or C infections (**Transgender, Men who have sex with men, female sex workers,** injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate |

| | | |
|---|---|---|
| | | blood). |
| 51 | *At risk for HIV infection* ***(Transgender, Men who have Sex with Men, Female Sex Workers,*** *injecting drug users, persons with multiple sex partners)* | *Permanently defer* |

The exclusion of transgender persons, men having sex with men and female sex workers from being blood donors and permanently prohibiting them from donating blood solely on the basis of their gender identity and sexual orientation is completely arbitrary, unreasonable and discriminatory and also unscientific.

In fact all blood units that are collected from donors are tested for infectious diseases including Hepatitis B, Hepatitis C, and HIV/AIDS and hence permanently excluding them from donating blood and categorising them as high-risk only on the basis of their gender identity and sexual orientation is violative of their right to be treated equally as other blood donors.The prohibition of transgender persons, men having sex with men and

female sex workers isdue to assumptions based on negative stereotypes which amounts to discrimination under Articles 14 and 15 of the Constitution and they are denied equal dignity under Article 14 as they are deemed less worthy and subordinate in social participation and healthcare.

It is submitted that during the 1980s when the HIV/AIDS epidemic outbreak occurred, in many countries, such a similar lifetime ban on blood donations on transgender persons and men who had sex with men (MSM) was implemented. However, this was due to an outdated policy based on the stigma and stereotype associated with transgender persons and men having sex with men and sex workers. Now such complete bans have been removed in many countries, and now guidelines internationally on blood donation do not have such permanent bans based on identity. Many countries have revised their policies to not make deferrals identity based, but based on either a 3 month or 45-day deferral from the last high-risk sexual contact.

Blood is essential in healing patients in need and saving lives. Blood transfusions primarily are needed to take care of the injured in accidents or during surgeries involving high blood loss, and many serious diseases including malignant diseases which also have a good chance of being cured, however, the patient must receive blood products continuously during treatment. As blood supplies have come under pressure due to the coronavirus pandemic, there is more need for blood and plasma donations. Given the COVID-19 crisis, where blood transfusions are needed more than ever for emergency and elective surgeries and treatments, it is more critical than ever for

members of the transgender community to rely on the generosity of their family and community members to meet the demands for getting life-saving blood to those affected by the pandemic. Due to the virus, many members of the community who needed blood were unable to get it from their trans relatives and loved ones due to the Guidelines. Transgender persons and gay and bisexual men who have been requesting to donate blood during the pandemic when their community and family members needed blood for emergency medical treatment were refused due to the permanent deferral under the Impugned Guidelines. Persons who are barred are not even able to donate plasma for research for COVID, due to this prohibition.

It is submitted that blood donor guidelines need to be based on an individualized system for all donors based on actual and not perceived risk and not based on identities. The present impugned Guidelines are stigmatizing as they are not based on how HIV transmission actually works, nor are they based on the actual risks involved in specific activities but are based only on the identities of donors such as, whether they are transgender, gay or bisexual men or female sex workers. A large number of transgender persons are sex workers, and hence they are covered under both exclusions of being transgender as well as being female sex workers and permanently prohibited from being donors.

The said restriction in the impugned Guidelines is arbitrary, illegal and violative of the fundamental rights of the transgender persons under Articles 14, 15 and 21 of the Constitution. Excluding transgender persons, men having sex

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with men and female sex workers from donating blood solely on the basis of their identity violates their rights to equality and non-discrimination under Articles 14 and 15 and 21 and which is also in violation of the settled position of law that discrimination cannot be made on the basis of gender identity and sexual orientation as held by this Hon'ble Court in ***NALSA v. Union of India***, (2014) 5 SCC 438 and ***Navtej Singh Johar v. Union of India***, (2018) 10 SCC 1.Hence the present Writ Petition.

## LIST OF DATES

| | |
|---|---|
| Nil | That the Petitioner is a transgender activist from the State of Manipur. She belongs to a Manipuri indigenous transgender community called as "Nupi Maanbi". She is a writer, poet, artist and a gender rights advocate. The Petitioner herein is a well-known transgender activist. Her work for the betterment and welfare of the trans community has gained acknowledgment in the entire region of North East India. She has contributed to the field of transgender rights especially for their legal rights. The petitioner has helped transgender persons to get gender recognition documents, helping them to self-identify their chosen gender. During the COVID 19 pandemic she has been active in organizing relief work for the transgender community in Manipur and distributed rations to close to 2000 trans persons including trans men and women. The |

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Petitioner is also the Secretary of the State level Apex body for queer persons known as the "All Manipur Nupi Maanbi Association" (AMANA). The petitioner is the first person to set up a trans beauty salon in Manipur which is run and managed by transgender persons. She has also worked immensely in providing better employment and livelihood opportunities for the transgender persons. The Petitioner was also invited to be a part of the Universal Periodic Review, a working group session of the United Nations Human Rights Initiative held in Delhi. She has been working on connecting mental health professionals with transgender persons so that members of the community who need counselling and treatment have access to professionals. Her work has created a wide visibility for the transgender community in the North east region.

1980's

That during the 1980s when the HIV/AIDS epidemic outbreak occurred, in many countries, a lifetime ban on blood donations on transgender persons and men who had sex with men (MSM) was imposed. That it was due to the stigma and false stereotypes associated with transgender persons, men having sex with men and sex workers that they are carriers of HIV/AIDS. That another reason for a lifetime ban was due to lack of

testing facilities for HIV/AIDS and the negative stereotypical beliefs held in general that such category of persons were high risk, as they were thought to be promiscuous, engaging in unsafe sex and having multiple partners.

15.04.2014 That this Hon'ble Court in *National Legal Services Authority v. Union of India* (2014) 5 SCC 438 for the first time recognised that transgender persons have the right to self-determine their gender identity and held that no one can be discriminated on the basis of their gender identity and positive directions were issued to the Centre and State governments to ensure their social participation through affirmative action, social welfare schemes etc. This Hon'ble Court held that the discrimination on the ground of 'sex' under Articles 15 and 16, would also includes discrimination on the ground of gender identity.

18.07.2017 That a news article titled, 'No blood from you, you're LGBTQ' was published in DNA on 18.07.2017.

21.07.2017 That on 21.07.2017 ScoopWhoop published news article titled, "India's LGBTQ Can't Donate Blood For The Most Bizarre Reason, According To An RTI Reply".

| | |
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| 2017 | That Department of Health and Social Care, United Kingdom published the Expert Summary of the Donor selection Criteria Report by the Advisory Committee on the safety of Blood, Tissues and Organs wherein it recommended a 3-month deferral for blood and plasma donation after sex between men or sex with a person who has received money or drugs for sex and no deferral or ban for transgender persons. That many countries have reformed their outdated and discriminatory policies on blood donation and moved away from such permanent bans considering the new data available and in light of the United Kingdom Report. |
| 11.10.2017 | Despite the judgement of this Hon'ble Court in NALSA, on 11.10.2017 vide Letter no. S-12016/5/2016-NACO(NBTC) issued by the Respondents No. 2 and 3 being the National Aids Control Organization (NACO) and the National Blood Transfusion Council (NBTC) under the Ministry of Health and Family Welfare issued Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 wherein as per point/clause 12 and 51 of the general criteria under blood donor selection criteria transgender persons, men having sex with men and female sex workers are permanently deferred/ prohibited from being eligible as donors for Blood Donation. |

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The relevant clauses are reproduced below:

| S.No. | General Criteria | Recommendations |
|---|---|---|
| 12 | Risk Behaviour | The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination.<br>The donor shall not be a person considered "**at risk**" for HIV, Hepatitis B or C infections (**Transgender, Men who have sex with men**, **female sex workers**, injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood). |
| *51* | *At risk for HIV infection (**Transgender, Men who have Sex with Men, Female Sex Workers**, injecting drug users, persons with* | *Permanently defer* |

| | | |
|---|---|---|
| | *multiple sex partners)* | |

Due to these impugned guidelines, transgender persons, female sex workers and gay men who would fall under the category of men having sex with men are permanently prohibited from being donors for blood or plasma. The Guidelines as they are issued by the Respondents, are sent to all State Blood Transfusion Councils, blood banks and public and private hospitals which follow them scrupulously. Due to these Guidelines which prohibit transgender persons, female sex workers and gay / bisexual men from donating blood, they are barred from donating blood and are unable to do so, even when their family members, relatives, loved ones and community members need blood to save their life and their blood group is matching and are denied this ability to do this.

This has been reported widely, as many transgender persons, female sex workers and gay and trans men have repeatedly sought for the opportunity to donate blood to their loved ones and have been refused as is evident from the news items mentioned herein above.

*guaranteed by Part III of the Constitution. Even though the LGBT constitute a sexual minority, members of the LGBT community are citizens of this country who are equally entitled to the enforcement of their fundamental rights guaranteed by Articles 14, 15, 19, and 21."*

This Hon'ble Court further went on to hold that discrimination on the basis of 'sex' under Article 15 would include discrimination on the basis of sex based stereotypes, gender identity and sexual orientation.

| | |
|---|---|
| 26.09.2018 | That on 26.09.2018 news article titled, "Blood not needed if you're gay: The stigma attached to Mumbai blood banks" was published in the Business Standard. |
| 26.09.2018 | That on 26.09.2018 news article titled, "Pride and Prejudice: SC gives equality, but blood banks don't want 'gay donors' was published in Times Now. |
| 10.05.2020 | That on 10.05.2020 news article titled, "Brazilian Court lifts Restrictions on gay and Bisexual Men Giving Blood" was published in the Reuters in Rio de Janeiro |
| August 2020 | That the Food and Drug Administration ("FDA"), United States revised its recommendations for blood donors and issued guidelines for the Industry. The Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus |

*guaranteed by Part III of the Constitution. Even though the LGBT constitute a sexual minority, members of the LGBT community are citizens of this country who are equally entitled to the enforcement of their fundamental rights guaranteed by Articles 14, 15, 19, and 21."*

This Hon'ble Court further went on to hold that discrimination on the basis of 'sex' under Article 15 would include discrimination on the basis of sex based stereotypes, gender identity and sexual orientation.

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|---|---|
| 26.09.2018 | That on 26.09.2018 news article titled, "Blood not needed if you're gay: The stigma attached to Mumbai blood banks" was published in the Business Standard. |
| 26.09.2018 | That on 26.09.2018 news article titled, "Pride and Prejudice: SC gives equality, but blood banks don't want 'gay donors' was published in Times Now. |
| 02.05.2020 | That on 02.05.2020 news article titled, "Brazilian Court lifts Restrictions on gay and Bisexual Men Giving Blood" was published in the Reuters in Rio de Janeiro |
| August 2020 | That the Food and Drug Administration ("FDA"), United States revised its recommendations for blood donors and issued guidelines for the Industry. The Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus |

Transmission by Blood and Blood Products have no prohibition on transgender persons from being blood donors, and have a 3-month blood donor referral for men having sex with men since their last MSM contact and 3-month deferral for commercial sex works since their last sexual contact.

In other countries there is now an individual approach taken for the potential donor. There is no blanket prohibition based on gender identity or sexual orientation. Heterosexual men who have had multiple sexual partners and unprotected sex, are also considered as "high risk" candidates. Such individual assessment is not discriminatory and can assess potential donors regardless of their gender identity and sexual orientation and strictly based on what is described as "risky sexual behavior" and short deferral period such as 3 months or 45 days from the last contact are imposed, if required.

2020 That with the ongoing COVID 19 pandemic, blood supplies have come under pressure and there is more need for blood and plasma donations. Given the COVID-19 crisis, where blood transfusions are needed more than ever for emergency and elective surgeries and treatments, it is more critical than ever for

members of the transgender community to rely on the generosity of their family and community members to meet the demands for getting life-saving blood to those affected by the pandemic. Due to the virus, many members of the community who needed blood were unable to get it from their trans relatives and loved ones due to the Guidelines. Transgender persons, gay and bisexual men who have been requesting to donate blood during the pandemic when their community and family members needed blood for emergency medical treatment were refused due to the permanent deferral under the Impugned Guidelines. Persons who are barred are not even able to donate plasma for research for COVID 19, due to this prohibition.

Such exclusion and blanket prohibition banning transgender persons, men having sex with men and female sex workers from being able to donate blood, is completely based on their gender identity, sexual orientation, the false and negative stereotypes and assumptions associated with them. The same is not based on any scientific basis or any real assessment of risk. Such an exclusion prohibiting them as eligible blood donors discriminates against them on the basis of

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|---|---|
| | their sex, gender identity and sexual orientation, denies them the dignity and equal worth as equal citizens and denies them the opportunity and autonomy of equal participation and right to access to health, thus violating their right to equality and life under Articles 14, 15 and 21 of the Constitution. |
| 01.09.2020 | That on 01.09.2020 article, titled "Rescuing traditional queerness: An interview with Santa Khurai" was published in Heinrich Boll Stiftung |
| 26.12.2020 | That on 26.12.2020 article titled, "Santa Khurai's Efforts towards the Manipur queer community" was published in The Sentinel |
| 9.2.2021 | That Clauses 12 and 51 of the Guideline on Blood Donor Selection and Blood Donor Referral, 2017 issued by the Respondents namely NBTC and NACO is violative of Article 14, 15 and 21 of the Constitution of India. Hence, in view of the discriminatory nature of the said guideline towards particular persons i.e. transgender persons, men having sex with men and female sex workers by permanently deferring them from donating blood, the Petitioner is filing the present public interest litigation under Article 32 of the Constitution of India. Hence, the present petition. |

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION (CIVIL) NO. _____ OF 2021

(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)

**IN THE MATTER OF:**

1. Thangjam Santa Singh
   Also known as Santa Khurai
   Khurai Thoidingjam Leikai
   P.O, P.S - Porompat, Imphal East,
   Manipur – 795010 ...Petitioner

Vs.

1. Union of India
   Ministry of Health and Family Welfare
   Nirman Bhawan, Maulana Azad Road,
   New Delhi, Delhi—110108
   Represented by its Secretary ...Respondent No.1

2. National Blood Transfusion Council
   ("NBTC") 9th Floor, Chanderlok Building
   36, Janpath, New Delhi – 110001
   Represented by its President
   and Chairperson ...Respondent No.2

3. National Aids Control Organisation
   9th Floor, Chanderlok Building
   36, Janpath, New Delhi – 110001

Represented by its Secretary ...Respondent No.3

**A PUBLIC INTEREST LITIGATION FILED UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA FOR ENFORCEMENT OF THE FUNDAMENTAL RIGHTS OF THE PETITIONER FOR ISSUANCE OF WRIT/ WRITS, ORDER, DIRECTION, WRIT BEING IN THE NATURE OF DECLARATION, DECLARING CLAUSE 12 OF GENERAL CRITERIA UNDER BLOOD DONOR SELECTION CRITERIA OF THE GUIDELINES FOR BLOOD DONOR SELECTION AND BLOOD DONOR REFERRAL, 2017 DATED 11.10.2017 TO THE EXTENT IT EXCLUDES TRANSGENDER PERSONS, MEN HAVING SEX WITH MEN AND FEMALE SEX WORKERS FROM BEING DONORS, AS BEING UNCONSTITUTIONAL AND IN VIOLATION OF ARTICLES 14, 15 AND 21 OF THE CONSTITUTION; AND FOR ISSUANCE OF WRIT/ WRITS, ORDER, DIRECTION, WRIT BEING IN THE NATURE OF DECLARATION, DECLARING CLAUSE 51 OF GENERAL CRITERIA UNDER BLOOD DONOR SELECTION CRITERIA OF THE GUIDELINES FOR BLOOD DONOR SELECTION AND BLOOD DONOR REFERRAL, 2017 DATED 11.10.2017 TO THE EXTENT IT PERMANENTLY DEFERS TRANSGENDER PERSONS, MEN HAVING SEX WITH MEN AND FEMALE SEX WORKERS FROM BEING DONORS ON ACCOUNT OF BEING AT RISK OF HIV INFECTION AS BEING**

**UNCONSTITUTIONAL AND IN VIOLATION OF ARTICLES 14, 15 AND 21 OF THE CONSTITUTION**

TO,

THE HON'BLE CHIEF JUSTICE OF INDIA AND
HIS COMPANION JUSTICES OF THE HON'BLE
SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE
ETITIONERS ABOVE NAMED

**MOST RESPECTFULLY SHOWETH:**

1. The Petitioner, who is a member of the transgender community, is filing the present Writ Petition in public interest, on behalf of all transgender persons, challenging constitutional validity of the Guidelines on Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10 2017 issued by the National Blood Transfusion Council ( NBTC) and National Aids Control Organization ( NACO), Ministry of Health and Family Welfare, Government of India which permanently defers transgender persons, female sex workers and men having sex with men, from donating blood and being blood donors. Such a prohibition is a violation of the right to equality, dignity and life under Articles 14, 15 and 21 of the Constitution. Hence, the Petitioner is filing the present public interest litigation praying for issuance of writ/ writs, order, direction, writ being in the nature of declaration, declaring clause 12 of general criteria under Blood Donor Selection Criteria of the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10.2017 to the extent it

permanently excludes transgender persons, men having sex with men and female sex workers from being donors, as being unconstitutional and in violation of Articles 14, 15 and 21 of the Constitution; and also for issuance of writ/ writs, order, direction, writ being in the nature of declaration, declaring clause 51 of general criteria under Blood Donor Selection Criteria of the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10.2017 to the extent it permanently defers transgender persons, men having sex with men and female sex workers from being donors on account of being at risk of HIV infection as being unconstitutional and in violation of Articles 14, 15 and 21 of the Constitution.

**PARTICULARS OF THE PETITIONER**

2. The Petitioner is a transgender activist from the State of Manipur. She belongs to a Manipuri indigenous transgender community called as "Nupi Maanbi". She is a writer, poet, artist and a gender rights advocate. The Petitioner herein is a well-known transgender activist. Her work for the betterment and welfare of the trans community has gained acknowledgment in the entire region of North East India. She has contributed to the field of transgender rights especially for their legal rights. The petitioner has helped transgender persons to get gender recognition documents, helping them to self-identify their chosen gender. During the COVID 19 pandemic she has been active in organizing relief work for the transgender community in Manipur and distributed rations to close to 2000 trans persons including trans men and women. The Petitioner is also the Secretary of the State level Apex

body for queer persons known as the "All Manipur Nupi Maanbi Association" (AMANA). The Petitioner is the first person to set up a trans beauty salon in Manipur which is run and managed by transgender persons. She has also worked immensely in providing better employment and livelihood opportunities for the transgender persons. The Petitioner was also invited to be a part of the Universal Periodic Review, a working group session of the United Nations Human Rights Initiative held in Delhi. She has been working on connecting mental health professionals with transgender persons so that members of the community who need counselling and treatment have access to professionals. Her work has created a wide visibility for the transgender community in the North east region.

That the complete name and address of the Petitioner is as mentioned herein above. The email address of the Petitioner is santakhurai888@gmail.com. That the PAN Card No. of the Petitioner is FPLPS3592N and that she has income of approximately Rs. 300000 per annum. **That the phone no.** of the Petitioner is +91 84159 25251.

That the Petitioner is filing the present public interest litigation under Article 32 of the Constitution of India for the larger interest of the Trans community and female sex workers and she does not have any personal interest, private motive or oblique reason in filing the present Petition.

That there are no civil, criminal or revenue litigation involving the petitioner which has or could have a nexus with the issues involved in the PIL.

The Petitioner submits that since she is challenging the constitutional validity of a guideline i.e. Guidelines on Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10 2017 issued by the National Blood Transfusion Council ( NBTC) and National Aids Control Organisation( NACO), Ministry of Health and Family Welfare, Government of India no representation to any authority is warranted before invoking the powers of this Hon'ble Court under the provisions of Article 32 of the Constitution of India.

A copy of the article titled, "Santa Khurai's Efforts towards the Manipur queer community" dated 26.12.2020 published in The Sentinel is annexed herein and is marked as **ANNEXURE – P/1 ( Pages .28to29 )**

A copy of the article, titled "Rescuing traditional queerness: An interview with Santa Khurai" dated 1.9.2020 published in Heinrich Boll Stiftung is annexed herein and is marked as **ANNEXURE – P/2 ( Pages .30 To 37... )**

A copy of the article titled, "Manipur's foremost transgender activist Santa Khurai looks back at the movement she helped shape" dated 30.11.2017 published in The Sentinel is annexed herein and is marked as **ANNEXURE – P/3 ( Pages .38 To41 ..... )**

3. That the Respondents are various departments and agencies of the Union of India and fall within the ambit of "State" under Article 12 of the Constitution and are amendable to the writ jurisdiction of this Hon'ble Court under Article 32 of the Constitution of India.

**BRIEF FACTS**

4. The brief facts and background giving rise to the filing of this petition are narrated below:

i. That during the 1980s when the HIV/AIDS epidemic outbreak occurred, in many countries, a lifetime ban on blood donations on transgender persons and men who had sex with men (MSM) was implemented. However, this was due to an outdated policy based on the stigma and stereotype associated with transgender persons and men having sex with men and sex workers. This was also due to there not being enough facilities for testing for HIV/AIDS and the negative stereotypes that these categories of persons are high risk, as they were thought to be promiscuous, engaging in unsafe sex and having multiple partners.

ii. That on 11.10.2017 the Respondents No. 2 and 3 being the National Blood Transfusion Services and the National Aids Control Organization under the Ministry of Health and Family Welfare issued guidelines for Blood Donor Selection & Blood Donor Referral (hereinafter, referred as the "Guidelines"). The donor selection criteria as elaborated in the guidelines would be applicable to all the donors who wish to donate their blood, red cells, platelets and plasma. These Guidelines under the "Blood Donor Selection Criteria" state in Serial No. 12 that a donor shall not be among others, transgender persons, men who have sex with men and female sex workers, as they are considered 'at risk' for HIV and are permanently deferred or prohibited from being eligible as donors for blood or plasma. The relevant

clauses in the "Blood Donor Selection Criteria" of the Guidelines are as follows:

| S.No. | General Criteria | Recommendations |
|---|---|---|
| 12 | Risk Behaviour | The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination.<br>The donor shall not be a person considered "**at risk**" for HIV, Hepatitis B or C infections (**Transgender, Men who have sex with men**, **female sex workers**, injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood). |

| S.No. | HIV Infection/AIDS | Recommendations |
|---|---|---|
| 51. | At risk for HIV infection (**Transgender, Men who have Sex with Men**, **Female Sex Workers**, injecting drug users, persons with multiple sex partners) | Permanently defer |

A true copy of the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10.2017 is

annexed hereto and marked as **ANNEXURE – P/4** ( Pages 42 To 72 )

iii. That due to the above mentioned impugned guidelines, transgender persons, female sex workers and gay men who would fall under the category of men having sex with men are permanently prohibited from being donors for blood or plasma. The Guidelines as they are issued by the Respondents, are sent to all State Blood Transfusion Councils, blood banks and public and private hospitals which follow them scrupulously. Due to these Guidelines which prohibit transgender persons, female sex workers and gay men from donating blood, they are barred from donating blood and are unable to do so, even when their family members, relatives, loved ones and community members need blood to save their life and their blood group is matching and are denied this ability to do this.

iv. This has been reported widely, as many transgender persons, female sex workers and gay and trans men have repeatedly sought for the opportunity to donate blood to their loved ones and have been refused.

A copy of the news article titled, 'No blood from you, you're LGBTQ' dated 18.7.2017 published in DNA is annexed herein and is marked as **ANNEXURE – P/5** ( Pages 73 To 75 .... ).

A copy of the news article titled, "India's LGBTQ Can't Donate Blood For The Most Bizarre Reason, According To An RTI Reply" dated 21.7.2017 in ScoopWhoop is annexed

herein and is marked as **ANNEXURE – P/6** ( Pages .76 To 78 .... )

A copy of the news article titled, "Blood not needed if you're gay: The stigma attached to Mumbai blood banks" dated 26.9.2018 published in the Business Standard is annexed herein and is marked as **ANNEXURE – P/7**( Pages ..79 To 81 .... )

A copy of the news article titled, "Pride and Prejudice: SC gives equality, but blood banks don't want 'gay donors' dated 26.9.2018 in Times Now is annexed herein and is marked as **ANNEXURE – P/8**( Pages . 82 To 83. )

v. It is submitted that all blood donated by all donors is screened for infections such as HIV, Hepatitis and other transmittable diseases infections irrespective of donors and units that are found to be unsuitable for transfusion are discarded. Hence, prohibiting/ permanently deferring certain categories of persons from being blood donors is completely arbitrary and violative of their constitutional rights.

**BLOOD DONOR GUIDELINES REVISED IN OTHER COUNTRIES**

vi. Many countries, considering the new data available, have reformed their policies and moved away from such bans.

vii. In the United Kingdom, in July 2017, the Advisory Committee on the safety of Blood, Tissues and Organs

published its Donor selection Criteria Report. This Report recommended a 3-month deferral for blood and plasma donation after sex between men or sex with a person who has received money or drugs for sex and no deferral or ban for transgender persons.

A copy of the Expert Summary of the Donor selection Criteria Report by the Advisory Committee on the safety of Blood, Tissues and Organs dated July 2017 is annexed herein and is marked as **ANNEXURE – P/9** ( Pages ..84To 90. )

viii. In the United States, the Food and Drug Administration ("FDA") has revised its recommendations for blood donors. As per the FDA's 1992 recommendations, there was a lifetime deferral for men having sex with men and sex workers. Based on its new data available, the new FDA recommendations have no prohibition on transgender persons from being blood donors, and have a 3-month blood donor referral for men having sex with men since their last MSM contact and 3-month deferral for commercial sex works since their last sexual contact.

A copy of the "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products- Guidance for Industry" issued by the US department for Health and Human Services, Food and Drug Administration dated August 2020 is annexed herein and is marked as **ANNEXURE – P/10** ( Pages. 91 To .111)

ix. Like the United States, many other countries around the world are reviewing restrictions on blood donations by

gay and bisexual men imposed during the 1980s HIV/AIDS crisis, with some removing blanket bans and others reducing waiting periods. Denmark and Northern Ireland have also cut their deferral periods for blood donation by gay men.

x. It is submitted that Brazil's Supreme Court ruled recently in May 2020 has held that a 12-month deferral period for gay and bisexual men to give blood is unconstitutional and discriminatory given modern blood-screening technology and Brazil's government will have to treat gay and bisexual men the same as heterosexual men when donating blood.

A copy of the news article titled, "Brazilian Court lifts Restrictions on gay and Bisexual Men Giving Blood" dated 10.05.2020 in Reuters in Rio de Janeiro is annexed herein and is marked as **ANNEXURE – P/11** ( Pages 112 To 114)

xi. In other countries there is an individual approach taken to the potential donor. Heterosexual men who have had multiple sexual partners and unprotected sex during the last month, are also considered as "high risk" candidates. This individual assessment policy is not discriminatory and can assess potential donors regardless of their gender identity and sexual orientation and strictly based on what is described as "risky sexual behavior".

**COVID PANDEMIC AND THE NEED FOR BLOOD AND PLASMA DONORS**

xii. As blood supplies have come under pressure due to the coronavirus pandemic, there is more need for blood and plasma donations. Given the COVID-19 crisis, where blood transfusions are needed more than ever for emergency and elective surgeries and treatments, it is more critical than ever for members of the transgender community to rely on the generosity of their family and community members to meet the demands for getting life-saving blood to those affected by the pandemic. Due to the virus, many members of the community who needed blood were unable to get it from their trans relatives and loved ones due to the Guidelines. Transgender persons who have been requesting to donate blood during the pandemic when their community and family members needed blood for emergency medical treatment were refused due to the permanent deferral under the Impugned Guidelines. Persons who are barred are not even able to donate plasma for research for COVID 19, due to this prohibition.

xiii. It is submitted that blood donor guidelines need to be based on an individualized system for all donors based on actual and not perceived risk and it should not be based on identities. The present impugned Guidelines are stigmatizing as they are not based on how HIV transmission actually works, nor are they based on the actual risks specific activities but are based only on the

identities of donors such as whether they are transgender, gay or bisexual men or female sex workers. A large number of transgender persons are sex workers, and hence they are covered under both exclusions of being transgender as well as being female sex workers and permanently prohibited from being donors.

**QUESTION OF LAW**

5. That the present writ petition involves the following substantial questions of law:

A. **WHETHER** imposing a prohibition on transgender persons, men having sex with men and female sex workers from being blood donors in the impugned Guidelines violates the rights to equality and non-discrimination under Articles 14 of the Constitution because such prohibition is only on the basis of their gender identity and sexual orientation and not based on any intelligible differentia which would disqualify them from being eligible as donors?

B. **WHETHER** the prohibition on transgender persons, men having sex with men and female sex workers from being blood donors in the impugned Guidelines amounts to discrimination under Article 15 of the Constitution on the basis of sex, as they are excluded from being blood

donors, solely on the basis of their gender identity, sexual orientation and on the basis of their sex and hence deserves to be set aside?

C. **WHETHER** the impugned Guidelines are in violation of the Article 15 as held by this Hon'ble Court in *NALSA v. Union of India*, (2014) 5 SCC 438, that discrimination on the ground of sex under Articles 15 and 16, therefore, includes discrimination on the ground of gender identity and that the expression "sex" used in Article 15 is not just limited to biological sex of male or female but intended to include people who consider themselves to be neither male nor female" and hence excluding transgender persons and rendering them ineligible for blood transfusion solely on account of their gender identity violates Articles 14 and 15 of the Constitution?

D. **WHETHER** the exclusion of persons on the basis of their gender identity and sexual orientation is arbitrary, and unreasonable when all blood units are tested for infectious diseases including Hepatitis B, Hepatitis C, and HIV/AIDS and hence, permanently excluding them from donating blood and categorising them as high-risk only on the basis of their gender identity and sexual orientation is violative of their right to be treated equally as other blood donors?

E. **WHETHER** assumptions based on stereotypes which lead to discrimination and subordination can be permitted to continue and that by excluding and prohibiting transgender

persons, men having sex with men and female sex workers, from donating blood under the impugned Guidelines, they are denied equal dignity under Article 14 as they are deemed less worthy and subordinate in social participation and healthcare?

F. **WHETHER** such subordination is particularly pronounced given that the Respondents do not presume that heterosexual persons are also as likely to have HIV and would be high – risk regardless of how many sexual partners they may have had or whether they have engaged in unprotected oral, anal, or vaginal sex and hence such exclusion in the impugned Guidelines is discriminatory and violative of Article 14 of the constitution?

G. **WHETHER** the exclusion in the impugned Guidelines are made purely on the basis of the negative stereotypes and assumptions that transgender persons, men having sex with men and female sex workers are infected with HIV as they are 'promiscuous' and are having unsafe sex and that such negative stereotypes amount to discrimination under Article 15 of the constitution?

H. **WHETHER** a blanket prohibition against transgender persons, men having sex with men and female sex workers from donating blood and plasma, to their loved ones, family members and relatives is discriminatory and is grounded in stigma against transgender persons and not on any data or scientific rationale despite there being tests to

detect HIV and is thus a violation of their right to life and autonomy under Article 21 of the Constitution?

**GROUNDS**

6. That the Petitioner has filed the present Writ Petition seeking protection of their fundamental rights on the following grounds:

A. THAT excluding transgender persons, men having sex with men and female sex workers permanently from being blood donors violates their rights to equality and non-discrimination under Articles 14 of the Constitution.

B. THAT the impugned Guidelines by stating that the donor shall not be a person considered 'at risk' for HIV and permanently excluding transgender persons, men having sex with men and female sex workers as being from within this category and excluding them from donating blood amounts to discrimination on the basis of sex under Article 15 of the Constitution. It is now a settled position of law as held in *NALSA v. Union of India*, (2014) 5 SCC 438 and in *Navtej Johar v. Union of India* (2018) 10 SCC 1 that discrimination on the ground of sex under Article 15 would include discrimination on the basis of gender identity and sexual orientation and hence, excluding them only because they are transgender or engaged in same sex relationships, without any examination of actual risk of HIV, amounts to discrimination under Article 15 of the Constitution.

C. THAT this Hon'ble Court in *NALSA v. Union of India*, (2014) 5 SCC 438 has underlined that transgender persons shall have the full rights to be treated as equal citizens. The constitutional requirement to treat transgender persons with equal respect and non-discrimination and held that:" *Equality includes the full and equal enjoyment of all rights and freedom. Right to equality has been declared as the basic feature of the Constitution and treatment of equals as unequals or unequals as equals will be violative of the basic structure of the Constitution. Article 14 of the Constitution also ensures equal protection and hence a positive obligation on the State to ensure equal protection of laws by bringing in necessary social and economic changes, so that everyone including transgender persons may enjoy equal protection of laws and nobody is denied such protection. Article 14 does not restrict the word 'person' and its application only to male or female. Hijras/transgender persons who are neither male/female fall within the expression 'person' and, hence, entitled to legal protection of laws in all spheres of State activity, including employment, healthcare, education as well as equal civil and citizenship rights, as enjoyed by any other citizen of this country."* The treatment as equal citizens would include being allowed to be blood donors and not be discriminated on the basis of their gender identity.

D. THAT the impugned Guidelines in excluding transgender persons, men having sex with men and female sex workers, do not meet the test of intelligible differentia and

rational aim under Article 14 of the Constitution if the aim is to ensure that safe blood is available for donation. As held by this Hon'ble Court in *State of W.B. v. Anwar Ali Sarkar*, AIR 1952 SC 75: *"In order to pass the test of permissible classification two conditions must be fulfilled viz. (i) that the classification must be founded on an intelligible differentia which distinguishes those that are grouped together from others left out of the group, and (ii) that the differentia must have a rational relation to the objects sought to be achieved by the Act. The differentia which is the basis of the classification and the object of the Act are distinct and what is necessary is that there must be nexus between them."* If the intention behind the Guidelines is to facilitate safe and sufficient supply of blood with minimal risk of infections amongst donors and make the act of blood donation safe, it has no rational nexus with excluding these categories of persons as donors. Every unit of blood donated is tested for HIV and all infectious diseases including Hepatitis B, Hepatitis C, Malarial Parasite and HIV/AIDS and the risk of all persons can be minimised by taking information of their last high risk sexual contact and having a temporary deferral if necessary from the date of such contact. Therefore, completely excluding them from donating blood simply because they are transgender, homosexual or sex workers is a violation of their right to equality under Article 14 of the Constitution.

E. THAT the impugned Guidelines excluding transgender persons and men having sex with men from being blood

donors is made based on false and negative stereotypes and assumptions that transgender persons and homosexual men are promiscuous, have unsafe sex, have multiple sexual partners and have HIV/AIDS and not based on facts or actual risk. Such negative stereotypes are unlawful as it subordinates transgender persons and homosexual men as being inferior only on the ground of their gender identity and sexual orientation, and amounts to discrimination under Article 15 of the Constitution on the ground of sex as held by this Hon'ble Court in *Navtej Johar v. Union of India* (2018) 10 SCC 1 where it was held that: *"...discrimination will not survive constitutional scrutiny when it is grounded in and perpetuates stereotypes about a class constituted by the grounds prohibited in Article 15(1). If any ground of discrimination, whether direct or indirect is founded on a stereotypical understanding of the role of the sex, it would not be distinguishable from the discrimination which is prohibited by Article 15 on the grounds only of sex. If certain characteristics grounded in stereotypes, are to be associated with entire classes of people constituted as groups by any of the grounds prohibited in Article 15(1), that cannot establish a permissible reason to discriminate. Such a discrimination will be in violation of the constitutional guarantee against discrimination in Article 15(1)."*

F. THAT a blanket prohibition against transgender persons, men having sex with men and female sex workers from donating blood, to their loved ones, family members and relatives is discriminatory and is grounded in stigma

against transgender persons and men having sex with men, and not based on any data or scientific rationale. The recommendations on Blood Donor Guidelines in many countries of the world over have changed their donor recommendations and have not imposed any prohibition of transgender persons, have opted for shorter period such as 3 months deferrals in case of female sex workers and gay men from their last high risk sexual contact and hence the impugned clauses in the Guidelines are liable to be struck down.

G. THAT assumptions based on stereotypes which lead to discrimination and subordination cannot be permitted to continue. By excluding and prohibiting transgender persons, men having sex with men and female sex workers, from donating blood under the impugned Guidelines, they are denied equal dignity under Article 14 as they are deemed less worthy and subordinate in social participation and access to healthcare. This subordination is particularly pronounced given that the Respondents do not presume that non-transgender persons and non-LGBTQI persons are also as likely to have HIV and would be high – risk regardless of how many sexual partners they may have had or whether they have engaged in unprotected oral, anal, or vaginal sex. Therefore, prohibiting only transgender persons and men having sex with men and female sex workers from being donors on a mere presumption that they might be more likely to be infected and high-risk amounts to a violation of dignity and freedom by imposing limitations, disadvantages or

burdens through the stereotypical application of presumed group characteristics rather than on the basis of individual circumstance. As held by this Hon'ble Court in *Indian Young Lawyers' Association v. State of Kerala*, (2019) 11 SCC 1 *"Human dignity postulates an equality between persons. The equality of all human beings entails being free from the restrictive and dehumanizing effect of stereotypes and being equally entitled to the protection of law. Our Constitution has willed that dignity, liberty and equality serve as a guiding light for individuals, the state and this Court. .... Our Constitution marks a vision of social transformation. It marks a break from the past – one characterized by a deeply divided society resting on social prejudices, stereotypes, subordination and discrimination destructive of the dignity of the individual"*

H. THAT the impugned Guidelines excluding transgender persons, men having sex with men and female sex workers and prohibiting them from being able to be blood donors affects their membership in society and denies them participation in society by being able to donate blood when needed and being considered worthy human beings which deprives them their right to a life with dignity as guaranteed under Article 21 of the Constitution and hence, deserve to be set aside.

I. THAT it is further submitted that the definition of 'Significant risk', as per Section 2(v) of the HIV-AIDS (Prevention and Control) Act, 2017, means the presence of significant risk body substance (such as blood, semen,

vaginal secretions, breast milk, tissue etc) or a circumstance of constituting significant risk for transmission (sharing infected needles, sexual intercourse with an affected person, during child birth by an HIV +ve mother, transfusion of infected blood or other circumstances where any significant risk body substance, other than breast milk, of an HIV positive person, comes in contact with mucous membranes including eyes, mouth or nose, including open wounds, puncture wound injuries, person with dermatitis condition etc). The above classification of significant risk is subjective, depends on case-to-case basis and not based on gender or a community, which is in the case of the present NACO guidelines.

J. THAT restricting transgender persons and persons of different sexual orientations are already vulnerable, with little education, poverty, lack of employment and inaccessible welfare facilities, thus, depriving them of access to health care will further ostracize them. This Hon'ble Court in *NALSA v. Union of India* AIR 2014 SC 1863 had recognised the fundamental right of transgender persons as citizens of the country to possess an equal right to realise their full potential as human beings. Hence, the impugned guidelines barring transgender persons from blood donations would further ostracize them and contribute to their social subordination and violates their right to a dignified life under Article 21.

K. THAT internationally when many other countries have not placed any permanent deferments/ prohibitions on transgender persons from being included as blood donors and even restrictions for men having sex with men and female sex workers are limited restrictions based on their last contact, the impugned guidelines imposing a permanent deferment/ ban is in contravention of health and safety recommendations on blood donor guidelines accepted by the medical community globally and need to be set aside.

7. That the Petitioners have not filed any other petition before this Hon'ble Court or any other court seeking the same relief.

**PRAYER**

8. In view of the facts and circumstances stated hereinabove, it is most respectfully prayed that this Hon'ble Court may graciously be pleased to:-

A. Issue writ/ writs, order, direction, writ being in the nature of declaration, declaring and striking down clause 12 of general criteria under Blood Donor Selection Criteria of the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10.2017 to the extent it excludes transgender persons, men having sex with men and female sex workers from being blood donors, being unconstitutional and in violation of Articles 14, 15 and 21 of the Constitution;

B. Issue writ/ writs, order, direction, writ being in the nature of declaration, declaring and striking down clause 51 of general criteria under Blood Donor Selection Criteria of the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated 11.10.2017 to the extent it permanently defers transgender persons, men having sex with men and female sex workers from being blood donors on account of being at risk of HIV infection being unconstitutional and in violation of Articles 14, 15 and 21 of the Constitution; and

C. Grant such other reliefs as this Hon'ble Court may deem fit and proper in light of the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS, THE PETITIONER SHALL, AS IN DUTY BOUND EVER PRAY.

**DRAWN BY:**

**Adv. Thulasi K. Raj**

**DRAWN & FILED BY:**

**(ANINDITA PUJARI)**
ADVOCATE FOR THE PETITIONER

**SETTLED BY:**

**(JAYNA KOTHARI)**
SENIOR ADVOCATE

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION (CIVIL) NO. _____ OF 2021

(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)

IN THE MATTER OF:

THANGJAM SANTA SINGH

@ SANTA KHURAI

PETITIONER

VERSUS

UNION OF INDIA & ORS.

RESPONDENT

**AFFIDAVIT**

I, Thangjam Santa Singh @ Santa Khurai, D/o. Khurai Thoidingjam Leikai, aged about 45 years, R/o. at P.O, P.S - Porompat, Imphal East, Manipur – 795010, do hereby solemnly affirm and states as under:

1. That I am the Petitioner in the above captioned Petition and well conversant with the facts and circumstances of this case and hance competent to swear this affidavit.
2. That I state that I have no personal gain, private motive or oblique reason in filing the present Public Interest Litigation.
3. I say that I have read and understood the contents of the Synopsis & List of Dates at pages B to ..... and contents of Writ Petition as contained in Paras 1 to at pages ... to ..... and state that the averments of facts made therein are true to my knowledge and information derived from the record of the case and those of submission of law made in Question of law, grounds, prayer, certificate and interlocutory applications are true and correct to the best of my knowledge and belief.
4. That the Annexure P-1 to P-.... at pages ... to ... filed along with the Writ Petition are true copies of their respective originals.

9/2/2021

(S. SHAMPHABA SINGH)
Oath Commissioner (JUDICIAL)
Manipur Regd No. 437/2020

TH. SANTA SINGH

5. That the contents of the above affidavit are true and correct, no part of it is false and nothing material has been concealed therefrom.

(TH SANTA SINGH)
DEPONENT

**VERIFICATION:**

Verified at _____ on this day of February, 2021 that the contents of the above affidavit are true to the best of my knowledge and belief. No part of this affidavit is false and nothing material has been concealed there from.

(TH SANTA SINGH)
DEPONENT

Solemnly affirm before me on 9/2/2021 at 1.15 p.m. at the Court premises by the Deponent who is identified by .....

The Deponent seems to understand the contents fully well on their being read over and explained to him/her

9/2/2021
(S. SHAMPHABA SINGH)
Oath Commissioner (JUDICIAL)
Manipur Regd. No. 437/2020

ANNEXURE P-1



# Santa Khurai's efforts towards the Manipur queer community

A transwoman, Santa Khurai is a poet, writer and artist. She has been organising relief for the transgender community throughout this year.

By : Sentinel Digital Desk | 26 Dec 2020 9:45 PM

**Imphal:** Various organisations and activists of the queer community have organised relief for the community throughout the year. A Manipuri transgender woman (Nupi Maanbi), Santa Khurai started relief work for the community by distributing ration to 2,000 trans people, including trans men and women. She started her relief work in Imphal, Manipur.

Khurai is a writer, poet, and artist. She is also the secretary of the state-level apex body for queer All Manipur Nupi Maanbi Association (AMANA). Khurai's efforts started expanding

gradually. When she identified children of widows in her vicinity who could not attend online classes, she put up a fundraiser on Ketto to buy gadgets, wifi and stationery for those kids.

**Also Read** - Manipur Lottery Results Today - 03 February'21 -



Three mobile phones were given to three widows. Khurai also bought a Smart TV for the community library. This could help more and more children access to educational content. In some of her endeavours, she had the financial support of the National Council Churches in India (NCCI).

Khurai has been spending the last few months connecting with mental health professionals with the transgender community. She brought in Paonam Thoibi, a clinical psychologist to give counselling yo the trans community in the Transgender quarantine centre. Later on, the ones who had mental health issues reached out to Khurai for further support and counselling sessions. NCCI gives the fee of the counsellor.

**Also Read** - Manipur Lottery Results Today - 02 February'21 - Manipur State Singam Morning, Evening Lottery Result

Khurai has been closely working with many organisation to organise relief kits. A few of the organisation that she has been working with are Goonj in Delhi, SAATHII in Chennai and Mountain People in Maharashtra.

Khurai, however, is upset with the cisgender people, who have a 'fancy degree' in social work, and claim themselves to be helping the community But the reality is that, the funds never reach the person who deserves it. Khurai says that these people are exploiting the vulnerability of marginalised people.

**Also Read** - Smuggler Held with Critically Endangered Tortoises in Manipur

HEINRICH BÖLL STIFTUNG
INDIA

# Rescuing traditional queerness: An interview with Santa Khurai

## Interview

A Meitei indigenous Nupi Maanbi from Manipur exposed her hair after washing the hair with Chenghi (Rice water boiled with local herbs). Photo by Mitkhubi Haobijam (Nupi Maanbi) 

In the context of the field research carried out from November 2019 to February 2020 within the 'gender democracy' programme of the Heinrich Böll Stiftung India Office, one of the projects has been collecting interviews, voices and witnesses from members of the LGBTQIA+ community. Among the interviewees was Santa Khurai from Imphal in Manipur, one of the eight states within the NorthEastern Region (NER) of India. Santa Khurai represents the queer people and the transgender community of Manipur, having been their spokesperson for years. The most prominent theme in our discussion was a universal feeling by the people of Northeast India of being 'left out' – a sense of detachment caused by different factors. Northeast India's history is controversial since this region has always been a contested territory, linked with the Indian 'mainland' only through a 22 km stretch of border and surrounded by other South Asian countries, China and today's Myanmar. The state of Manipur itself was ruled by the Burmese kingdom until the early 19$^{th}$century and successively branched out to British India after the Anglo-Burmese rule. Geographical morphology and the annexed problems of limited connections creates an actual sense of disconnect, a liminal geographic space of fluid identities for the region and its people.

When I called Santa Khurai to discuss the interview, she resolutely asserted on the phone: "I am not going to compromise my indigeneity! I feel so detached from mainland India. Why don't people within the LGBTQIA+ community talk about queer people in their periphery?"

As we spoke with each other, Santa led the conversation to the topic of traditional queerness and the difficulties that indigenous queer communities in Manipur endured daily jeopardising their very existence. Through her in-depth research of ancient texts related to the region, she found legitimacy to their existence. Having learned the alphabet of Meitei Mayek, an ancient script of the Meitei indigenous community, she referred to these texts that, unlike modern writings, mentioned of the communities in this region. During our discussion, we explored the issue of networking faced by these communities.

With regard to queer identities, the focus of my research has been on understanding peoples' connection within the Indian queer community at large, especially the means of communication and of social media as tools for strategic reunion and aggregation. The underlying message guiding me throughout the research was Foucault's words, "the body is the site to analyse the shape of power"[1]. This thinking alludes to the idea that the physical body of a person is born with determines, be it by ethnicity or sex, their social roles and secures their existence in the world. The term coined "body politics" is a focal point for many researchers and civil society activists who engage with identities. Bodies have become a place of political control, regulating them in terms of sexuality,

health, violence, as well as sexual rights[2]. Yet, while acknowledging the inquired about aspects of social media and networking, Santa shed light on another controversial fact and our discussion took an unexpected turn: Some queer identities in Manipur are compromised by social organisations, non-state actors led by men. Those hierarchies of power are unquestionably linked to 'body politics'.

**Me:** I am researching how queer identities network among themselves here in India, starting from South India and moving North. You are the only person I know in the Northeast who belongs to the queer community, as of now. What is your experience?

**Santa:** Talking about queer networking and queer union in India means to state that we are fighting for a common cause, regardless of religion and other social affiliations. You know how diverse India is. But in my experience, when it comes to the queer culture, looking at a national scenario, I think that communities from the Northeast are less represented because of the geographical location. We are isolated and have reduced access to transportation, first and foremost. Then we have a linguistic problem, as Northeastern languages are different and complex. Sometimes, I struggle to connect with people, as there are more than 30 languages only in Manipur[3]. The networking shrinks as we do not fit in the mainstream queer culture.

Considering our appearance, we have small eyes, flat noses, and other physical features that distinguish us. This leads to prejudice and discrimination. But within a region, language, food, appearance and clothing are commonalities that connect people, enabling them to come together and give them a sense of belongingness. Outside the region, we are less represented. At any event of national scale, I do not encounter many representatives from the Northeast. On such occasions, I often feel left out of the networking and hardly get a chance to address the reality of the region. Queerness is not the only topic being excluded from the conversation, as the feeling stems from the overall exclusion of Northeastern issues in public education, to the extent that generally the rest of the Indian people are not even familiar with us. This creates a sort of prejudice, a disconnect, and the potential for networking is lost. This divide also extends to Northeast queer people and the mainstream queer.

Santa Khurei in the library of a Puya [Meitei old scriptures] curator and translator of Meitei old script into modern Manipuri [Chanam Hemchandra, Naorenthong, Imphal West. Photo by Bonita Pebam [Assist. Researcher, Pheida – Gender at the Peripheryl licence infos

**Me:** Can you tell me something about the challenges of your everyday life as a queer person and as an activist?

**Santa:** As a queer person, my identity is challenging, because people question my body. People question queer bodies. People question queer identities, people question my life, my food, and how I sleep with my husband. Beyond me and my personal issues, young queer groups, which we call Nupi-Maanbi, who generally wear female make up and attires, get questioned and attacked.

**Me:** What does 'Nupi-Maanbi' mean?

**Santa:** 'Nupi' means 'girl, woman', and 'Maanbi' means 'alike, similar'. It is a Meitei[4] term.

**Me:** In your opinion and experience, with regard to the idea that bodies are a site for political struggle and control, what issues do you think should be raised with decision-makers in politics, with civil society (activists) and with grassroots society/community to address the needs and the challenges you face? In light of this, how would you define 'body politics'? How does 'body politics' affect your life?

**Santa:** First of all, I feel the need to address an overall issue: That people often conflate gender identity and sexual identity, and this is where confusion on bodies is coming from. Moreover, I think that the international community needs to look at the belief systems of cultures in their respective regions, rather than on a national scale. For example, when you say 'India', you cannot look at India through a 'pan-India' lens. India is manifold. If we collect narratives of queer indigenous people, those stories could become part of scientific literature that can be

disseminated to other countries, and further to do comparative studies. For example, sex reassignment surgery (SRS) came to Manipur as late as 2014 or 2015, but people would decide to identify as men or women, regardless of their sex at birth, without going through surgery or even hormone-therapy. In the early 1990s, when the HIV programmes started, they got the nomenclature 'MSM - Men having Sex with Men". At that time questions of privacy and visibility were not considered and NGOs did not ensure confidentiality, making public names of many of the participants to their programmes. Some of the people involved in the HIV programmes thus committed suicide. Before that, there was less visibility of people like me, like 'Nupi-Maanbi'.

In Manipur, there is a queer community called 'Shumang Lila', which is very visible. They claim cross-dress only for performing, and once off the stage are just cisgender[5] men. That is why they are treated with a sort of privilege. Then we have the 'Nupa Amaibi' transgender shaman peoples, who have a blessed voice. And then the 'Nupi-Maanbi', persons like me, who are far less accepted. The 'Shumang Lila' are much more accepted because they disguise as men out of the performance and even go for heterosexual marriages, but within the community they share stories about their non-conformity and queerness. 'Sumang' literally means 'courtyard' because earlier these artists performed their play in courtyards. Now, they have started performing on stages in front of an audience and in films. The actors, the singers, the musicians – all are men. There is also a Shuman Lila female group, who, in turn, dress up as men, but people prefer the play performed by the men, accepting this queer identity less. I questioned myself why the female Shumang Lila groups are less accepted. Women take the role of men and the way they speak and behave shows that they really have male attitudes. This is only my external observation. I never asked them about their sexuality. Likewise, I never was concerned whether the male performers dressing as female. I confirmed that they were non-conforming people. They do not say it openly so that they can be socially accepted.

I feel that when it comes to researching queer communities, academicians treat us as 'specimen' for their studies. They ask questions, which they are not supposed to ask to an individual – about their bodies. They ask about the privacy and intimacy of my romantic life instead of asking me about politics, social issues, or traditions. They often depict us as victims, but I am a person who enjoys my identity. I love the way I talk with my trans-sisters, lifting eyebrow, using code languages, moving hands to show delicacy; how transgender people express is beautiful to me. These expressions reflect our liveliness and freedom and I feel less ostracised from society. The questions that academicians have posed to me are totally out of context. There is a lot more to know about the language that we use, for example. Those are the aspects we need to explore more. Universities need to meet people from whom they can get great inspiration. International academic debates over multiple topics must be expanded to indigenous groups.

Before Christianity spread over the region, as far as I know – for sure in Manipur and Mizoram[6] – there was inclusion of gender plurality and multiplicity in the belief system. Northeast India is very disconnected from other South Asian countries, given that India belongs to South Asia. However, I think that universities in the Philippines or in Indonesia would be very interested in studying the Northeastern Indian queer culture. But I have no connection to Southeast Asia.

**Me:** Why did you mention the Philippines and Indonesia?

**Santa:** Because we are rooted with them. We are remarkably similar. For instance, New Year's Eve falls in the same month having close dates. There may also many other similarities that need in-depth research.

**Me:** Yes, right. The communication with the eyebrows you were mentioning, it is actually common in the Philippines now that you make me think about it.

**Santa:** Manipur was for a long time under the province of Burma. I suspect that there is a lot of literature to find in Yangon University. I want to deepen the research about Manipur's ancient history of queer communities. In Myanmar there is a figure called 'Nat Kadaw'. They are queer shamans who possess/ get possessed by 30 spirits. When they get possessed by those spirits, people offer the possessed shamans alcohol and chicken, and then when they feel that the spirits are around them, they smoke and spread the smoke around, to chase them out.

The 'Nupa-Amaibi' are gradually excluded from their ritual-occupation by certain cultural organisations. They are endangered. They are losing community. That is why I want to divulge knowledge about them. I want to at least keep their stories as art if I am not able to do anything to keep these traditions alive, or to make universities research on them. There are only a few clips of the documentary I made on them[7]. They call the god from underneath the water.

**Me:** What would you like to say to academicians and universities?

**Santa:** There are female and male Shamans in Manipur and researchers always do studies on female shamanism. In the meantime, in the recent years, an organisation has started to threaten them and have instructed them not to

wear female attire. So, because of that these people have started going back to the cloister. Male shamans hardly come out. Their dance is different from the dance performed by the female shamans. People like their dance very much. 'Lai Haroba' is a celebration for young people but because of this organisation, the shamans have certain restrictions in performing in 'Lai Haroba.' The importance of the ritual is gradually declining. This is a warning to our culture. If we were able to preserve this culture, the male shaman culture, at least this could be another clue for the international community on how different peoples, different queer people, occupy spaces and how the natural behaviour within shamanism is connected to the queer people.

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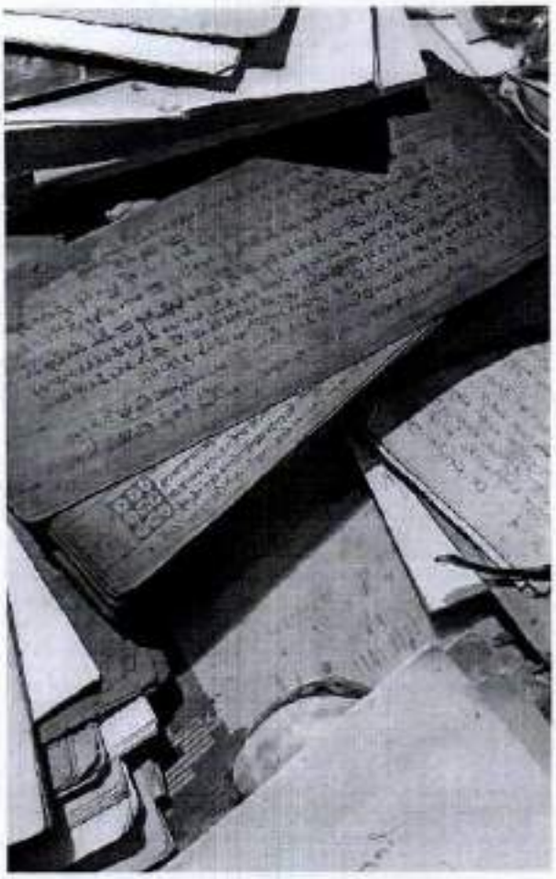

The leafs of the Puyas (Meitei ancient scriptures) which were written in ancient Manipur with ancient Meitei Mayek. These scriptures are found in Chanam Hemchandra library. Photo by Santa Khurai 

It is a bitter feeling to realise how much of the world has been lost or forgotten. There are voices that need to be heard and stories that need to be written down. As Santa said, "If we want to claim the very existence of gender identities in the traditions as a way to legitimise them, we need to start from the beginning."

My understanding of the meeting with Santa is that some queer identities in Manipur are put at stake by social organisations and non-state actors led by men. These hierarchies of power are unquestionably linked to 'body politics'. The concept of 'body politics' can be defined as: "All the cultural, social, economic and political policies and trends, legitimised by law or by strong public opinion, that render some bodies – or the decisions of some people upon their own bodies – 'abnormal', and labelling them as 'different' and, in doing so, limiting their freedom in terms of expression, health, education, work and, therefore, threatening their very right to happiness and deteriorating their life's quality."[8]

Unprivileged bodies experience injustice at different levels. There are bodies that rule, who can generally be allocated within a (white) male supremacy, and bodies who experience privilege or exclusion, depending on the rules produced by the former. Mainstream bodies legislate for mainstream bodies, limiting the freedom of the rest of the population. Indigenous queer identities in Manipur endure injustice, belonging to the non-mainstream bodies. Scarce presence of literature on the above mentioned themes render the divulgation of information about this social injustice even harder. I hope to fill part of this gap in the literature with these few lines, thanks to the precious testimony of Santa.

**Endnotes**

[i] Foucault, Michel, "Foucault on Modern Power: Empirical Insights and Normative Confusion." In Unruly Practices: Power, Discourse and Gender in Contemporary Social Theory, 1989, edited by N. Fraser, 73–94. Minneapolis: University of Minnesota Press.

[ii] Harcourt, Wendy, "Body Politics in Development: Critical Debates in Gender and Development", 2009, ed. Zed Books.

[iii] According to the SIL Ethnologue there are more than 400 spoken languages in India. Other references, as the one resulting from the Census of India held in 2001, indicate that India has 122 major languages and 1599 other languages. There is generally no unanimity in establishing the correct number of languages in India, as many classifications differ and distinguish between dialects, written languages and only spoken languages. Hindi is the official national Indian languages but is rarely spoken in the North East region.

[iv] Meitei is the language spoken in Manipur. It belongs to the Tibeto-Burman languages and is one of the officially recognised languages of India, having been included in the Eight Schedule to the Constitution of India in 1992.

[v] 'Cisgender' is a term that indicates people who conform and recognise their gender identity in the sex assigned at birth. For example, a cisgender woman is a person who has been born with female sexual organs, has been identified at birth from thirds (e.g. their parents, the medical team, etc.) as a woman and identifies herself as a woman within the society.

[vi] Mizoram is another state of the Northeast Indian region.

[vii] https://www.youtube.com/watch?v=ONA194bsLNo

[viii] My personal definition of 'body politics'.

**Alessandra Monticelli** is a student at the Humboldt University in Berlin, attending the course of Regional Studies in African and Asian sciences, with a focus on South Asia. Her areas of interest are gender democracy, LGBTQIA+ rights, and global elites and dominance. In her program is included a critical approach to the structures of power in knowledge production, the analysis of social inequality through a gendered lens, and critics to the capitalist globalization. Her research focuses on the rights of LGBTQIA+ identities and groups in India. From October 2019 to March 2020, she was a trainee at hbs India.

1. Foucault, Michel, "Foucault on Modern Power: Empirical Insights and Normative Confusion." In Unruly Practices: Power, Discourse and Gender in Contemporary Social Theory, 1989, edited by N. Fraser, 73-94. Minneapolis: University of Minnesota Press.
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6. Mizoram is another state of the Northeast Indian region.
7. https://www.youtube.com/watch?v=ONA194btLNo
8. My personal definition of 'body politics'.

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# Manipur's foremost transgender activist, Santa Khurai, looks back at the movement she helped shape

Santa Khurai's strength now is far removed from the fears that haunted her as a child growing up in a conservative family. Born in Imphal, Khurai says she always had "a sense of who I am and I never identified myself as a boy. Always as a girl."

Written by Asad Ali | Updated: November 30, 2017 10:11:14 am


You've come a long way: Santa Khurai, one of the leading activists of the trans community in Manipur. (Photo: Deepak Shijagurumayum)

In Imphal, sometime in the late '90s, Santa Khurai had her long nails broken with a brick in the dead of night, by a bunch of men. They pinned her on the ground in a dark alley off the nearby National Highway, and forced her to shout: "I am a boy but I act like a girl. I have a d*** and can have sex with girls." They beat her up with a bamboo baton till it broke. But Khurai didn't.

In her mid-30s now, Khurai is arguably Manipur's most famous transgender activist. Her work has created a wide visibility for the trans community in the region. She set up the first beauty salon run by a trans person in Manipur. Its success saw numerous salons mushroom throughout the state, all run by members of the transgender community.

It was a transformative idea. It gave them financial agency and a shot at a relatively better life. But it's something Khurai only grudgingly talks about now. "Because of the easy money, a lot of transpeople, even after all this time, want to work just there. Children are forced into it so they earn money at the cost of their studies," she says. Khurai shut her own salon, San Jen, in 2010. What had led her to start off the business? "Money," says Khurai bluntly.



"My parents didn't give me money because of my gender identity. Whenever I asked for money, my father refused, because I used to just buy girls' clothes. I had to be self-sufficient," says Khurai.

pooled her savings and borrowed money from friends to train at [illegible] in Delhi. "I used all of that to buy a pair of scissors, a water spray and a carpe opened the salon in a small room near where I stay in Imphal," says Khurai. She was also lucky. "Right after I opened my parlour, Hindi cinema was banned in Manipur. People started making videos and other films locally. Work started coming in. Small film companies hired me."

Her business flourished. Her desire to assert not just her own identity but also that of the community grew as well. 2010 was a significant year in her life — she was invited to be part of a Universal Periodic Review (UPR) working session, a UN human rights initiative, in Delhi. Once she returned to Manipur, she led the All Manipur NupiMaanbi Association (AMANA), a coalition working towards raising awareness of the rights of the transgender community.

Soon after Khurai joined, AMANA came up with the Trans Queen Contest North East. "We were trying to expand the AMANA network to the entire region. But the community wasn't coming forward. Fashion and beauty were the only things which seemed to bring out the community and so we decided that a trans-queen contest might be the best way ahead." It was, as both the community and government officials were involved in a larger discussion on legal rights.

However, that success was also earned the hard way. In the mid-90s, the Democratic Youth Federation of India organised the first state-level trans beauty contest in Manipur. It was a ticketed event and made a fair amount of money. After the show was over, the three top participants in the contest received empty envelopes, with "Sorry" written inside.

The "hijacking" of the trans community's efforts by non-trans groups from "from outside" is a regular phenomenon, says Khurai. "There are lots of non-LGBTQ groups which work in Manipur but why didn't they do anything before the NALSA verdict came? Why try to mobilise us only after that judgement? This clearly shows that they want to hijack the rights of the trans community and I am totally against it."

But the larger picture, acknowledges Khurai, isn't as bad as it used to be. "After the NALSA verdict of 2014, people definitely became more aware. I helped many in my state to get their gender identity changed through required documentation, which helped them get trans-identity passports," says Khurai. There are still policy and general cultural impediments, but Khurai says, "the community has to come forward. It's our duty to force the authorities to take forward the discussion. "

Khurai's strength now is far removed from the fears that haunted her as a child growing up in a conservative family. Born in Imphal, Khurai says she always had "a sense of who I am and I never identified myself as a boy. Always as a girl." She went

school. Tiffin breaks meant eating by myself in a corner," says Khurai. Her and three elder sisters were not supportive of her either, but — and Khurai says she's always surprised — her two younger brothers understood.

If friends were hard to come by and family unsupportive, love has been elusive. In college and after, there were a few men who liked her, says Khurai. "But I realised that it wasn't affection. It was just the sex," she says.

Khurai talks about a serious relationship she had with a Kashmiri man, an automobile engineer. "He came down to meet me and spent some nights here. Then he totally disappeared — from social media and otherwise," says Khurai, "I suffered a mental breakdown after that."

Last year,Khurai underwent a gender affirmation surgery in Australia. She crowdfunded the entire amount online, collecting over $5000. Shockingly, even for Khurai, there were no donations from India. But there are other complaints that Khurai would rather not talk about: "Corruption and casteism is deep-rooted in India and that has a negative impact on the trans community too. There's a lot of racism in the queer space, for example. I don't want to talk much about it. I keep going to mainland India as an activist and I might be attacked for personal reasons," she says.

But Khurai hopes that society will understand some day. In a poem she wrote, dedicated to her father who had passed away in 2015, Khurai says, "He burned at the common crematorium; The place where many women too burned when they died; There he's gone, leaving no legacy of his own gender."



TAGS: Eye 2017

# ANNEXURE P-4

No. S-12016/5/2016 – NACO (NBTC)
Government of India
Ministry of Health & Family Welfare
National Aids Control Organization
(National Blood Transfusion Services)

9th Floor, Chandralok Building,
36, Janpath, New Delhi-110 001.
Dated : 11th October, 2017

To,

The Director/Member Secretaries of
All State Blood Transfusion Councils

**Subject: Guidelines for Blood Donor Selection & Blood Donor Referral.**

Sir/Madam,

It is informed that uniform guidelines for Blood Donor Selection and Blood Donor Referral have been approved by the Governing Body of NBTC in its 26th meeting which was held on 1st June, 2017. The guideline document is enclosed for your reference and necessary action.

This issues with the approval of AS & DG, NACO and President, NBTC.

Yours sincerely,

(Dr. Shobini Rajan)
Director, National Blood Transfusion Council

Copy to:

1. The Project Directors of all SACS
2. Website of NACO.

Encl: Guidelines of 29 pages on Blood Donor Selection & Blood Donor Referral.

# Guidelines

# for

# Blood Donor Selection

# and

# Blood Donor Referral

NATIONAL BLOOD TRANSFUSION COUNCIL
NATIONAL AIDS CONTROL ORGANIZATION
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI
OCTOBER 2017

**Introduction**

The primary responsibility of a Blood Transfusion Service is to provide a safe, sufficient and timely supply of blood and blood components to those in need. In fulfilling this responsibility the BTS should ensure that the act of blood donation is safe and causes no harm to the donor. It should build and maintain a pool of safe, voluntary non-remunerated blood donors and take all necessary steps to ensure that the products derived from donated blood are efficacious for the recipient, with a minimal risk of any infection that could be transmitted through transfusion.

The donor selection criteria detailed in these guidelines apply to donors of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood or through apheresis, including plasma for fractionation.

These guidelines are designed to promote best practise in Blood Transfusion Services to ensure the collection of donations from the lowest risk donors possible and also to ensure that every probable TTI reactive blood donor is referred for proper diagnosis and management of the infection and if confirmed, remains excluded from the donor pool.

**Donor Engagement**

**The key to safe blood transfusions is having safe and healthy donors.**

In order to ensure this, blood bank should follow these basic principles:

- Blood should be accepted only from voluntary, non-remunerated, low risk, safe and healthy donors. Replacement donors should be phased out.
- Efforts should be directed towards encouraging and retaining adequate numbers of healthy repeat donors.
- Donors should be appropriately recognised and thanked for their contribution.

Donor motivation is usually done by volunteers from the community using various communication materials and methods to draw prospective donors to come to the blood bank or to a blood donation camp. The minimum criteria for blood donation are verbally screened at this stage, i.e., age between 18-65 years, weight atleast 45 Kg and a Haemoglobin of atleast 12.5 grams. This activity is a bit different from the counselling, which is offered once the prospective donor reaches the blood bank or blood donation camp with the intention to donate. Once recruited, all first time donors should be encouraged to become regular repeat donors and retained with the Blood Transfusion Service through constant engagement through different communication media. The role of community organizations, civil society bodies and NGOs plays a critical role in these activities.

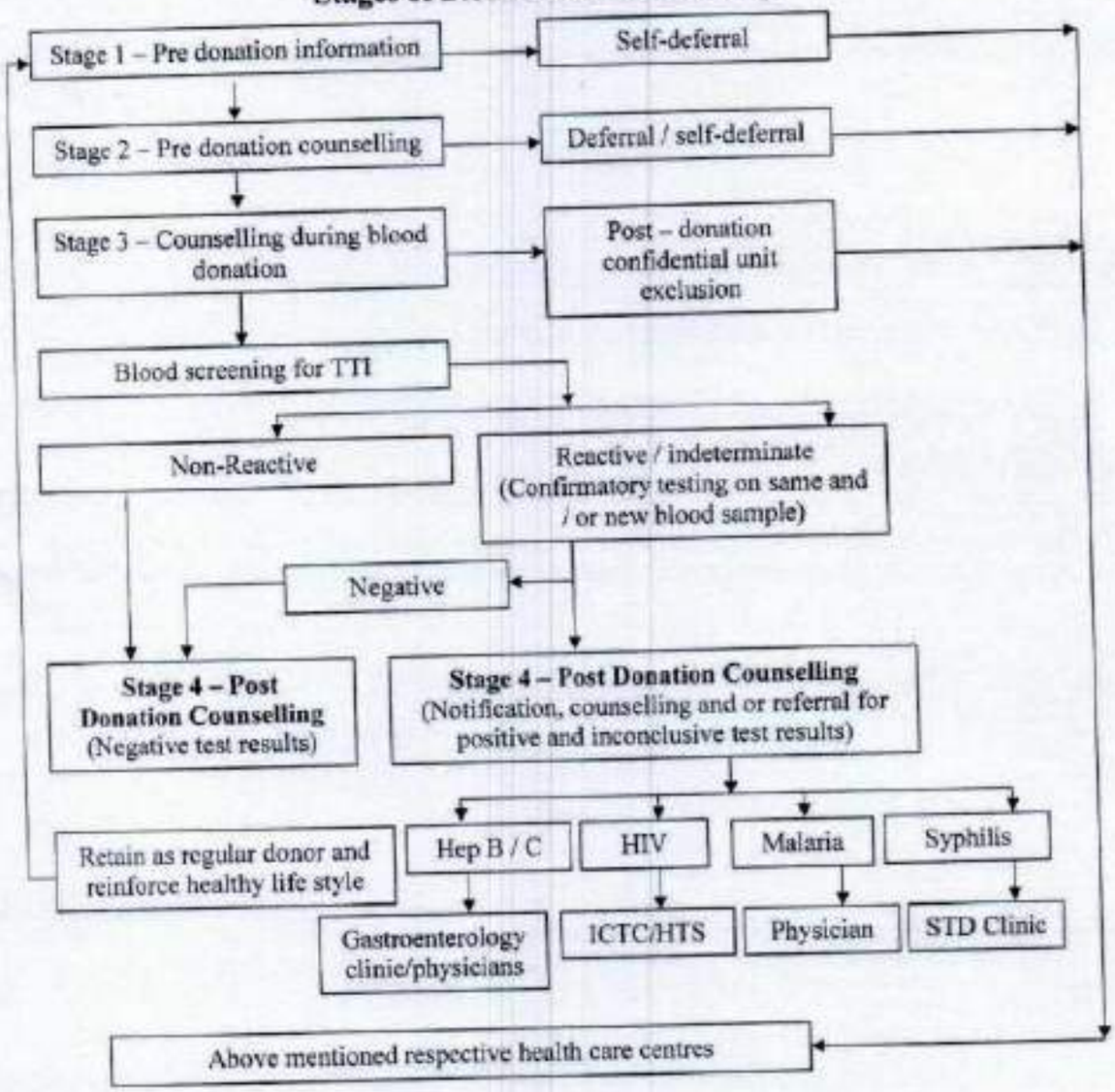
**Donor Selection and Counselling**

Once a prospective donor reaches the blood bank or blood donation camp, the following steps should be followed:

1. Pre-donation information
2. Pre-donation counselling
3. Donor Questionnaire and Health check up
4. Counselling during blood donation
5. Post-donation counselling

Counselling is to be provided by trained blood donor counsellors maintaining privacy and confidentiality. All blood banks may also train their donor organizers/paramedical staff/ medical officers to undertake counselling, in case a dedicated manpower is not available. Medical officer with minimum MBBS qualification should be responsible for reviewing the donor's health conditions and performing physical examination of the donor. Final call on donor selection is taken by the medical officer.

**Stages of Blood Donor Counselling**



***Pre-donation information*** should include information about:

- Nature and use of blood and its components and the importance of maintaining healthy lifestyles
- Eligibility for blood donation
- Rationale for the donor questionnaire and pre-donation health assessment
- Options for the donor to withdraw or self-defer at any time before, during or after donation
- Blood donation process and potential adverse donor reactions
- Common TTI, modes of transmission and window period
- Basic information on tests performed on donated blood
- Possible consequences for donors and donated blood in the case of abnormal TTI test results

Donors should be educated regarding the possible risks of blood donation and possible risks of transmission of transfusion transmissible infections and encouraged to share his medical history and details to enable appropriate deferral. This is an opportunity to talk to, dispel doubts and answer questions from donors. It can be done as a one-on-group and integrated with the activities undertaken for donor recruitment and retention and supported with simple IEC material and job aids like leaflets, posters etc.

***Pre-donation Counselling*** should focus on the donor and preferably be done one-on-one.

The objectives include:

- Understanding of Donor Questionnaire to enable correct responses
- Reiterate understanding of TTI testing and the disclosure of results
- Clarify any misunderstanding about donor selection, blood donation and blood screening
- Explain self-deferral
- Explain temporary and permanent deferral
- Familiarize donor to process of blood donation
- Obtain donor's Informed consent

***Donor Questionnaire and Health Check-up*** is administered to every prospective donor to enable a quick history taking, limited physical examination and blood test. Questionnaire should be prepared in English and Local languages which is simple and easy to understand to be answered by the donor. For donors who are illiterate, assistance should be given by counsellor/ donor registration staff.

Demographic details of the donor, date and time of donor selection and donation should be registered. Informed consent should be obtained in writing from the donors on the questionnaire.

Prior to blood donation, the consent of the donor should be obtained in writing with donor's signature or thumb impression after the procedure is explained and the donor is informed regarding testing of blood for all mandatory tests for safety of recipients. The donor should be provided an opportunity to ask questions and refuse consent. Efforts should also be made to obtain the correct contact details of the blood donors so that he can be contacted by the blood bank in future. Blood bank can ask to see a photo-identity but it should not be made mandatory to donate blood.

Every prospective blood donor should be subjected to a basic health check up by a Medical Officer through history taking, limited physical examination and Hb test to determine eligibility to enrol as a blood donor. In case a donor is to be temporarily or permanently deferred, he should be explained the reasons in understandable terms.

***Donor consent*** should be taken for the following understanding that:

1. Blood donation is a totally voluntary act and no inducement or remuneration has been offered.
2. Donation of blood/ components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure.
3. My donated blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma derived medicines, which may be used for larger patient population and not just this blood bank.
4. My blood will be tested for Hepatitis B, Hepatitis C, Malarial parasite, HIV/AIDS and Syphilis diseases in addition to any other screening tests required to ensure blood safety.
5. I would like to be informed about any abnormal test results done on my donated blood Yes/No

***Counselling during donation*** must be aimed at

- Ensuring that donors feel conformable during blood donation, including the venepuncture.
- Reducing donor anxiety and minimizing the risk of any adverse donor reactions such as fainting
- Giving post donation advice, including care of the venepuncture site
- Fostering donor trust and confidence for donor retention
- Thanking the donor for his valuable contribution

***Post-donation interaction*** includes

- Brief instructions on self-care
    - Plenty of fluids
    - No heavy work
    - No smoking or driving immediately post donation
    - Remove bandage after 6 hours
    - Contact details of blood bank in case of discomfort following donation
- Information about what to do in case of specific adverse donor reactions
- Message on healthy lifestyle and regular blood donation
- Donor feedback
- Issuance of donor card, donor certificate or a memento
- Reiteration for recalling of blood donor for abnormal test results

**Blood Donor Selection Criteria**

| General Criteria | | |
|---|---|---|
| **S.No.** | **Criteria** | **Recommendations** |
| 1. | Well being | The donor shall be in good health, mentally alert and physically fit and shall not be inmates of jail or any other confinement.<br>"Differently abled" or donor with communication and sight difficulties can donate blood provided that clear and confidential communication can be established and he/she fully understands the donation process and gives a valid consent. |
| 2. | Age | Minimum age 18 years<br>Maximum age 65 years<br>First time donor shall not be over 60 years of age, for repeat donor upper limit is 65 years.<br>For aphaeresis donors 18-60 years |
| 3. | Whole Blood Volume Collected and weight of donor | 350 ml- 45 kg<br>450ml – more than 55 kg<br>Apheresis– 50 kg |
| 4. | Donation Interval | For whole blood donation, once in three months (90 days) for males and four months (120 days) for females.<br>For apheresis, at least 48 hours interval after platelet/ plasma – apheresis shall be kept (not more than 2 times a week, limited to 24 in one year)<br>After whole blood donation a plateletpheresis donor shall not be accepted before 28 days.<br>Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation provided reinfusion of red cell was complete in the last plateletpheresis donation. If the reinfusion of red cells was not complete then the donor shall not be accepted within 90 days.<br>A donor shall not donate any type of donation within 12 months after a bone marrow harvest, within 6 months after a peripheral stem cell harvest. |
| 5. | Blood Pressure | 100-140mm Hg systolic 60-90 mm Hg diastolic with or without medications.<br>There shall be no findings suggestive of end organ damage or secondary complication (cardiac, renal, eye or vascular) or history of feeling giddiness, fainting made out during history and examination. Neither the drug nor its dosage should have been altered in the last 28 days. |

| | | |
|---|---|---|
| 6. | Pulse | 60- 100<br>Regular |
| 7. | Temperature | Afebrile;37°C/98.4°F |
| 8. | Respiration | The donor shall be free from acute respiratory disease. |
| 9. | Haemoglobin | >or =12.5g/dL<br>Thalassemia trait may be accepted, provided haemoglobin is acceptable. |
| 10. | Meal | The donor shall not be fasting before the blood donation or observing fast during the period of blood donation and last meal should have been taken at least 4 hours prior to donation.<br>Donor shall not have consumed alcohol and show signs of intoxication before the blood donation. The donor shall not be a person having regular heavy alcohol intake. |
| 11. | Occupation | The donor who works as air crew member, long distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work is required, shall not donate blood at least 24 hours prior to their next duty shift. The donor shall not be a night shift workers without adequate sleep. |
| 12. | Risk behaviour | The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination.<br>The donor shall not be a person considered "at risk" for HIV, Hepatitis B or C infections (Transgender, Men who have sex with men, Female sex workers, Injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood). |
| 13. | Travel and residence | The donor shall not be a person with history of residence or travel in a geographical area which is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there is no guidance in India. |
| 14. | Donor Skin | The donor shall be free from any skin diseases at the site of phlebotomy. The arms and forearms of the donor shall be free of skin punctures of scars indicative of professional blood donors or addiction of self-injected narcotics. |
| **Physiological Status for Women** | | |
| 15. | Pregnancy or recently delivered | Defer for 12 Months after delivery |
| 16. | Abortion | Defer for 6 months after abortion |
| 17. | Breast feeding | Defer for total period of lactation |
| 18. | Menstruation | Defer for the period of menstruation |

| | | |
|---|---|---|
| | **Non-specific illness** | |
| 19. | Minor non-specific symptoms including but not limited to general malaise, pain, headache | Defer until all symptoms subside and donor is afebrile |
| | **Respiratory (Lung)Diseases** | |
| 20. | Cold, flu, cough, sore throat or acute sinusitis | Defer until all symptoms subside and donor is afebrile |
| 21. | Chronic sinusitis | Accept unless on antibiotics |
| 22. | Asthmatic attack | Permanently Defer |
| 23. | Asthmatics on steroids | Permanently Defer |
| | **Surgical Procedures** | |
| 24. | Major surgery | Defer for 12 months after recovery. (Major surgery being defined as that requiring hospitalisation, anaesthesia (general/spinal) had Blood Transfusion and/or had significant Blood loss) |
| 25. | Minor surgery | Defer for 6 months after recovery |
| 26. | Received Blood Transfusion | Defer for 12 months |
| 27. | Open heart surgery Including By-pass surgery | Permanently defer |
| 28. | Cancer surgery | Permanently defer |
| 29. | Tooth extraction | Defer for 6 months after tooth extraction |
| 30. | Dental surgery under anaesthesia | Defer for 6 months after recovery |
| | **Cardio-Vascular Diseases (Heart Disease)** | |
| 31. | Has any active symptom (Chest Pain, Shortness of breath, swelling of feet) | Permanently defer |
| 32. | Myocardial infarction (Heart Attack) | Permanently defer |
| 33. | Cardiac medication (digitalis, nitro-glycerine) | Permanently defer |
| 34. | Hypertensive heart disease | Permanently defer |
| 35. | Coronary artery disease | Permanently defer |
| 36. | Angina pectoris | Permanently defer |
| 37. | Rheumatic heart disease with residual damage | Permanently defer |
| | **Central Nervous System/ Psychiatric Diseases** | |
| 38. | Migraine | Accept if not severe and occurs at a frequency of less than once a week |
| 39. | Convulsions and Epilepsy | Permanently defer |
| 40. | Schizophrenia | Permanently defer |
| 41. | Anxiety and mood disorders | Accept person having anxiety and mood (affective) disorders like depression or bipolar disorder, but is stable |

| | | |
|---|---|---|
| | | and feeling well on the day regardless of medication- |
| **Endocrine Disorders** | | |
| 42. | Diabetes | Accept person with Diabetes Mellitus well controlled by diet or oral hypoglycaemic medication, with no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease (in particular peripheral ulceration) -<br><br>Permanently defer person requiring insulin and/or complications of Diabetes with multi organ involvement-<br><br>Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks |
| 43. | Thyroid disorders | Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, Auto Immune Hypo Thyroidism)<br><br>Defer if under investigation for Thyroid Disease or thyroid status is not known<br><br>Permanently defer if:<br>1) Thyrotoxicosis due to Graves' Disease<br>2) Hyper/Hypo Thyroid<br>3) History of malignant thyroid tumours |
| 44. | Other endocrine disorders | Permanently defer |
| **Liver Diseases and Hepatitis infection** | | |
| 45. | Hepatitis | Known Hepatitis B, C- Permanently defer<br>Unknown Hepatitis-<br>Permanently defer<br>Known hepatitis A or E; Defer for 12 months |
| 46. | Spouse/ partner/ close contact of individual suffering with hepatitis, | Defer for 12 months |
| 47. | At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/ partner | Defer for 12 months |
| 48. | Spouse/ partner of individual receiving transfusion of blood/ components | Defer for 12 months |
| 49. | Jaundice | Accept donor with history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in neonatal period. |
| 50. | Chronic Liver disease/ Liver Failure | Permanently defer |
| **HIV Infection/AIDS** | | |
| 51. | At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers, | Permanently defer |

| | | |
|---|---|---|
| | Injecting drug users, persons with multiple sex partners) | |
| 52. | Known HIV positive person or spouse/ partner of PLHA (person living with HIV AIDS) | Permanently defer |
| 53. | Persons having symptoms suggestive of AIDS | Permanently defer person having lymphadenopathy, prolonged and repeated fever, prolonged & repeated diarrhoea irrespective of HIV risk or status |
| | **Sexually Transmitted Infections** | |
| 54. | Syphilis (Genital sore, or generalized skin rashes) | Permanently defer |
| 55. | Gonorrhoea | Permanently defer |
| | **Other Infectious diseases** | |
| 56. | History of Measles , Mumps, Chickenpox | Defer for 2 weeks following full recovery |
| 57. | Malaria | Defer for 3 months following full recovery. |
| 58. | Typhoid | Defer for 12 Months following full recovery |
| 59. | Dengue/ Chikungunya | In case of history of Dengue/Chikungunya: Defer for 6 Months following full recovery.<br>Following visit to Dengue/Chikungunya endemic area: 4 weeks following return from visit to dengue endemic area if no febrile illness is noted. |
| 60. | Zika Virus/ West Nile Virus | In case of Zika infection: Defer for 4 months following recovery.<br>In case of history of travel to West Nile Virus endemic area or Zika virus outbreak zone: Defer for 4 months. |
| 61. | Tuberculosis | Defer for 2 years following confirmation of cure |
| 62. | Leishmaniasis | Permanently defer |
| 63. | Leprosy | Permanently defer |
| | **Other infections** | |
| 64. | Conjunctivitis | Defer for the period of illness and continuation of local medication. |
| 65. | Osteomyelitis | Defer for 2 years following completion of treatment and cure. |
| | **Kidney Disease** | |
| 66. | Acute infection of kidney (pyelonephritis) | Defer for 6 months after complete recovery and last dose of medication |
| 67. | Acute infection of bladder (cystitis) / UTI | Defer for 2 weeks after complete recovery and last dose of medication |
| 68. | Chronic infection of kidney/ kidney disease/ renal failure | Permanently defer |
| | **Digestive System** | |
| 69. | Diarrhoea | Person having history of diarrhoea in preceding week particularly if associated with fever: Defer for2 weeks after complete recovery and last dose of medication |
| 70. | GI endoscopy | Defer for 12 months. |

| | | |
|---|---|---|
| 71. | Acid Peptic disease | Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), hiatus hernia:<br>Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding: |
| | **Other diseases/ disorders** | |
| 72. | Autoimmune disorders like Systemic lupus erythematosis, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis | Permanently defer |
| 73. | Polycythaemia Vera | Permanently defer |
| 74. | Bleeding disorders and unexplained bleeding tendency | Permanently defer |
| 75. | Malignancy | Permanently defer |
| 76. | Severe allergic disorders | Permanently defer |
| 77. | Haemoglobinopathies and red cell enzyme deficiencies with known history of haemolysis | Permanently defer |
| | **Vaccination and inoculation** | |
| 78. | **Non live vaccines and Toxoid:** Typhoid,Cholera,Papillomavirus, Influenza,Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague | Defer for 14 days |
| 79. | **Live attenuated vaccines**: Polio oral,Measles(rubella) Mumps, Yellow fever, Japanese encephalitis, influenza,Typhoid,Cholera,Hepatitis A | Defer for 28 days |
| 80. | Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum | Defer for 28 days |
| 81. | Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins | Defer for 1 year |
| | **Medications taken by prospective blood donor** | |
| 82. | Oral contraceptive | Accept |
| 83. | Analgesics | Accept |
| 84. | Vitamins | Accept |
| 85. | Mild sedative and tranquillizers | Accept |
| 86. | Allopurinol | Accept |

| | | |
|---|---|---|
| 87. | Cholesterol lowering medication | Accept |
| 88. | Salicylates (aspirin), other NSAIDs | Defer for 3 days if blood is to be used for Platelet preparation |
| 89. | Ketoconazole, Antihelminthic drugs including mebendazole, | Defer for 7 days after last dose if donor is well |
| 90. | Antibiotics | Defer for 2 Weeks after last dose if donor is well |
| 91. | Ticlopidine, clopidogrel | Defer for 2 Weeks after last dose |
| 92. | Piroxicam, dipyridamole | Defer for 2 Weeks after last dose |
| 93. | Etretinate, Acitretin or Isotretinoin. (Used for acne) | Defer for 1 month after the last dose |
| 94. | Finasteride used to treat benign prostatatic hyperplasia | Defer for 1 month after the last dose |
| 95. | Radioactive contrast material | 8 weeks deferral |
| 96. | Dutasteride used to treat benign prostatatic hyperplasia | Defer for 6 months after the last dose |
| 97. | Any medication of unknown nature | Defer till details are available |
| 98. | Oral anti-diabetic drugs | Accept if there is no alteration in dose within last 4 weeks. |
| 99. | Insulin | Permanently defer |
| 100. | Anti-arrhythmic, Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs(Digitalis) | Permanently defer |
| **Other conditions requiring Permanent deferral** | | |
| 101. | Recipients of organ, stem cell and tissue transplants<br>Donors who have had an unexplained delayed faint or delayed faint with injury or two consecutive faints following a blood donation. | Permanently defer |

**Recall and Referral Mechanism for Initial Sero-reactive Blood Donors**

***Information of test results***

- Donors who have consented to be contacted by the blood bank in case of an abnormal test result should be recalled to the blood bank so as to inform them about initial sero-reactive result of transfusion transmitted infection (TTI).
- Donors should be provided post-donation counselling prior to referring to appropriate medical services for confirmation of diagnosis, follow up and treatment whenever necessary.
- Adequate efforts must be made by the Blood Bank staff to contact the initial sero-reactive blood donors for recall-referral and the process should be documented on record.
- Result seeking blood donors, even if non sero-reactive, should also be informed of their TTI status with reiterated counselling to remain negative and continue to donate blood.
- State AIDS Control Societies shall make available updated list of ICTC along with contact details of counsellors to all licensed blood banks.

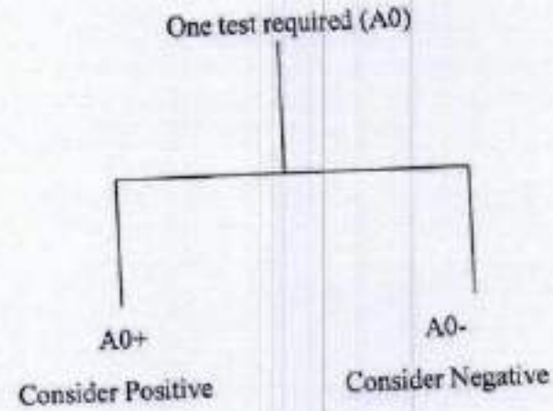
***Duties of a Blood Bank:***

- Consent of the Blood Donor shall be obtained for performing the screening tests and to be informed of the results thereof at the time of blood donation.
- It is not the primary duty of the Blood Bank or Blood Transfusion Service to confirm the diagnosis of any of the TTI screened for.
- Blood Bank shall repeat the test using the same technique using the pilot tube/ sample from blood bag prior to labelling the donor as initial sero-reactive and recalling for referral.
- All initial sero-reactive blood units shall continue to be discarded as per standard operating protocol of blood bank and compliance to Biomedical Waste Management Rules 2016.
- All initial sero-reactive donors shall be recalled, offered post donation counselling and referred to appropriate facility for further counselling, confirmation and management.
- Results shall not be informed over the telephone.
- A standard referral format for the same shall be used and Blood Bank shall maintain all records of recall and referral.
- Signatures of the blood donor shall be obtained on the consent form attached to the referral format so as to avoid litigation due to discordant results of screening at blood banks and confirmatory tests of reference centre.
- In case, the initial sero-reactive donor does not return to blood bank despite three consecutive weekly attempts, the list of HIV sero-reactive blood donors should be shared with the linked ICTC under shared confidentiality under guidance from State AIDS Control Society.

***Testing Strategy for HIV at Blood Banks***

Testing Strategy used in the Blood Banks for HIV is "Strategy I" and the test done in the blood bank is considered to be a test of triage (A0)

The blood unit is subjected to one test of high sensitivity for HIV reactivity. If non-reactive, the specimen shall be considered free of HIV (negative) and if reactive, the blood unit is considered as HIV positive and discarded. This strategy is focused on ensuring recipient safety and is also used in the setting of screening of organs, tissues, sperm and other donations.




Flow chart of Strategy I

1. Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of result of testing at the time of the donation by the blood bank along with complete contact details and telephone number.

2. All blood donors found to be initial HIV sero-reactive at blood bank shall be referred to Integrated Counselling and Testing Centres (ICTC) for counselling and confirmation.

3. Blood bank shall fill out the referral form as per standard format and send it along with referred donor.

4. Confidentiality shall be maintained at all levels.

***Algorithm for Blood Donors referred to ICTC***

- All initial sero-reactive donors referred to ICTC from Blood Bank shall be offered HIV pre-test counselling at the ICTC and consent taken to perform the HIV test.
- ICTC shall perform first test (A1). In case first test positive, ICTC shall perform remaining two tests and give a positive result after three sequential reactive tests.
- In case first test is negative, ICTC shall report the result as HIV inconclusive and recall the donor for re-testing after two weeks after thorough counselling for risk perception.
- All blood donors found to be positive for HIV shall be counselled to permanently defer them from the donor pool, in addition to referral for Pre-ART during post-test counselling.
- In addition, the message for all PLHA to permanently defer themselves/ spouses/ partners from donating blood shall be incorporated into the information for all PLHA during post-test counselling.

***Testing Strategy for other TTI at Blood Banks***

Similar to HIV, the blood unit is subjected to one test of high sensitivity for HBV, HCV, Malaria and syphilis reactivity. If non-reactive, the specimen is to be considered free of infection

(negative) and if reactive, the blood unit is considered as positive and discarded. This strategy is focused on ensuring recipient safety and is also used in the setting of screening of organs, tissues, sperm and other donations.

1. Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of result of testing at the time of the donation by the blood bank along with complete contact details and telephone number.
2. All blood donors found to be sero-reactive at blood bank for HBV, HCV, Syphilis and Malaria shall be referred to clinicians in the Out Patient Department of associated hospitals or others for assessment and re-testing.
3. Blood bank shall fill out the referral form as per standard format and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.

**Algorithm for Blood Donors referred to Clinicians**

- All initial sero-reactive donors referred to clinicians from Blood Bank. Donor shall be assessed by the clinician with history taking and clinical examination.
- Donor shall be referred to the laboratory for re-testing and confirmation of the test results.
- Donor shall be offered appropriate treatment by the assessing clinician or referred to a higher centre for the same.
- All blood donors found to be positive for HBV, HCV, Malaria and Syphilis should be counselled to defer themselves and their spouses/partners from the donor pool, in addition to appropriate management.

## Annexure 1

# Sample of Blood Donor Questionnaire

XYZ Blood Bank

*Thank you for coming forward to donate blood*

To ensure your safety as a blood donor and the safety of the patients who will receive your blood, please read the information leaflet provided and answer this questionnaire correctly. If you have any difficulty in filling this form please ask for help from the Blood Centre Staff. All details given by you will be kept confidential.

Donor's Name: _____

Date of Birth : _____

| | |
|---|---|
| | Sex: |
| | Age: |

Address (Resi): _____

_____

Address (Office): _____

_____

Contact Nos (Resi): _____ (Office) _____ (Mobile) _____

Email : _____

1. Have you donated Blood previously? Yes No

1.1 If yes how many times 1.2 Date of last donation:

1.3. Did you experience any ailment, difficulty or discomfort during previous donations?

1.4 What was the difficulty?

1.5 Have you ever been advised not to donate blood? Yes No

2.1 Are you feeling well today?

2.2 Have you eaten anything in the last 4 hours?

2.3 After donating blood do you have to engage in heavy work, driving heavy vehicle or work at heights today Yes No

3. Have you had / have any of the following? If yes, discuss with the doctor present:

- Allergy
- Cancer
- Fainting attacks
- Heart disease
- Lung disease
- Asthma
- Kidney disease
- Mental illness
- Amoebiasis
- Cold/Cough
- Liver disease
- Fever
- Endocrine disease
- Diabetes
- Syphilis
- Gonorrhoea
- Skin disease
- High/low BP
- Leprosy
- Epilepsy
- Blood/ Bleeding disorder
- Tuberculosis
- Polycythemia
- G – 6 PD deficiency

4. During past 12 months have you had any of the following?

| | | |
|---|---|---|
| 4.1 Received blood or blood components? | Yes | No |
| 4.2 Any accidents or operations? | Yes | No |
| 4.3 Received any vaccinations? | Yes | No |
| 4.4 Bitten by any animal, which can result in rabies? | Yes | No |
| 4.5 Had tattooing / ear piercing or acupuncture treatment? | Yes | No |
| 4.6 Have you been imprisoned for any reason? | Yes | No |

| | | |
|---|---|---|
| 5. Have you had jaundice in the last 1 year? | Yes | No |
| 5.1 Has your blood ever tested positive for hepatitis B or C? | Yes | No |
| 5.2 Have you had close contact with anyone (family / others) suffering from jaundice in the last 1 year? | Yes | No |
| 6. Have you had tuberculosis or typhoid during the last year? | Yes | No |
| 7. Have you had malaria or taken antimalarial drugs in the last 3 years? | Yes | No |

8. Have you had any of the following in the last 6 months?

| | | |
|---|---|---|
| Dental Procedure | Yes | No |
| Measles | Yes | No |
| Chicken Pox | Yes | No |
| Dengue | Yes | No |

| | | |
|---|---|---|
| 9. Have you taken any medicine in the last 7 days especially or antibiotic? | Yes | No |
| 10. Do you know that you should not give blood in following conditions? | Yes | No |

- If you were found to be HIV positive, Hepatitis B, C or Syphilis infections
- If you are having multiple sex partners or have engaged in male to male sexual activity
- If you have ever worked as a sex worker or had sex with a sex worker
- If you have ever injected any drug (esp. Narcotics) not prescribed by a qualified doctor
- If you suspect that you or your partner may have HIV or any other sexually transmitted disease

11. Do you or your sexual partner belong to any of the above or below categories? Yes No

11.1Do you have any reason to believe that you have been infected by the virus that causes AIDS? Yes No

11.2In the last 6 months have you had:

| | | |
|---|---|---|
| Night Sweats | Yes | No |
| Persistent Fever | Yes | No |
| Unexplained Weight Loss | Yes | No |
| Swollen Glands | Yes | No |
| Persistent Diarrhoea | | |

12. In case you are a woman:

a. Are you pregnant or have you had an abortion in the last 06 months? Yes No

b. Have you a child less than 1 year of age? Are you breast feeding? Yes No

**Consent**

*I understand that:*

(a) Blood donation is a totally voluntary act and no inducement or remuneration has been offered

(b) Donation of blood/components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure

(c) My donated blood, blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma derived medicinal products, all of which may be used for larger patient population and not just this blood bank

(d) My blood will be tested for Hepatitis B, Hepatitis C, Malaria Parasite, HIV/ AIDS and Syphilis diseases in addition to any other screening tests required ensuring blood safety.

(e) I would like to be informed about any abnormal test results done on my donated blood: Yes/No

Donor's Signature

Signature of Medical Officer

| MEDICAL ASSESSMENT | Name of Medical Officer: | Sign: |
|---|---|---|
| Donor's Name: _____<br>Weight: _____ Kgs | Hb Level: ≥ 12.5g/dl | < 12.5g/dl |
| History Check List | Feeling well/adequate sleep (> 5hrs) / Last meal within 4 hrs<br>Ever Hospitalized<br>Current illness or medications: | |
| Examination Check List | Unhealthy look/pallor/icterus/ alcohol smell<br>Infected wounds/ Venepuncture site lesions<br>Pulse: ..... beats/min BP: .....mmHg<br>Heart: ..... Lungs: ..... | |
| Counselling Points | Post donation instructions/ making a regular donor<br>Need for follow up for TTI purposes<br>How to contact for follow up purposes:<br>By a letter/ By phone/ By e-mail | |
| Outcome | Donor accepted/ Temporary deferral/ Permanent deferral | |
| Remarks / Reasons for Deferral: | | |

| REGISTRATION | Name of Medical Officer: | Date |
|---|---|---|
| Donor I.D No. | Blood Unit No. | Segment No. |
| Type of Bag: Single: | Double: Triple: | Quadruple: |

| BLOOD COLLECTION | Name of Phlebotomist: | Sign: |
|---|---|---|
| **Check**: Donor's Name<br>**Check Donation No**: On Donation record/ Blood Bags/ Specimen Tubes<br>**Start time:** ..... a.m/p.m Time Taken:..... mins<br>**Volume**: ..... ml | | |
| **Complications:** Faint: Fits: Double Prick: Haematoma:<br>Others (please specify):<br>**Management:** | | |

## Annexure 2

# REFERRAL SLIP FOR BLOOD DONORS

*(To be filled by Blood Bank Staff)*

Name and address of the Referring Blood Bank: -

Date of Referral .....Blood Bank ID No. .....

Name of Donor.....

Age ..... Gender ..... Phone Number .....Contact details.....

Name and designation of the referring person .....

| Reason for referral (to be ticked) | | Date of testing | Assay used (III gen/ Any other) |
|---|---|---|---|
| Counselling& testing for HIV | ☐ | | |
| Testing of HBsAg | ☐ | | |
| Testing of HCV | ☐ | | |
| Testing of VDRL/RPR | ☐ | | |
| Testing of Malaria | ☐ | | |

Address of referral centre (ICTC/Clinician).....

(Blood Bank seal with contact details)

---

*(To be filled by ICTC/Laboratory and retained in record)*

Name of Donor.....Date of performing test.....

PID No. /OPD Regn. No. .....

Investigation done .....

Results .....

(Seal of ICTC /Laboratory with contact details)

----------x----------x----------x----------x----------x----------

*(This part is to be filled by ICTC/Laboratory and returned to donor)*

Name of the Donor/Department .....

Donor ID No. ..... PID No/ OPD Regn. No. .....

Date of Sample draw.....

Instructions:

Please come for retesting after 2 weeks on

1. Result to be collected on_____
2. Repeat test at ICTCon _____

(Seal of ICTC /Laboratory with contact details)

## Annexure 3

## CONSENT FOR REFERRAL

I understand that

- during blood donation process I have been counseled regarding the importance of safe blood donation and have consented to testing of my blood and be informed of any abnormal test results.
- I understand that these screening tests conducted at blood bank are not diagnostic and may yield false-positive results.
- I understand that any willful misrepresentation of facts could endanger my health or that of patients receiving my blood and may lead to litigation.
- I understand that I have been contacted, counseled and referred by the blood bank for confirmation and management to appropriate facility.

Signature of Referring Blood Bank Staff

Signature of Donor

Place: ----------

Date : _____

## Annexure 4

## DUTIES AND RESPONSIBILITIES OF BLOOD BANK MEDICAL OFFICER

### 1) Administration, Oversight and Coordination

a) Overall supervision
b) Inventory management
c) Fulfilling regulatory requirements
d) Recording & reporting
e) Convening hospital transfusion committee meetings
f) Fulfilling program requirements
g) Undergo appropriate training programs
h) Provide consultation to supervisory and technical personnel on maintaining adequate inventory of all blood components.
i) In times of limited inventory, provide interface to attending physician and resident staffs on requests for those components in short supply
j) Evaluate function of blood bank periodically

### 2) Donor Management

a) Perform routine donor evaluation and monitoring, including physical examinations and phlebotomy site examination and review of periodic laboratory testing.
b) Provide consultation to Blood Bank technical and clerical personnel concerning donor selection and acceptability.
c) Evaluate and manage blood donor reactions.
d) Evaluate and follow-up donors with abnormal test results, including infectious disease testing.
e) Evaluation and approval of requests for specific components from specific donors
f) Selection of donors for specific patients
g) Evaluation of donor acceptability
h) Donor monitoring.

### 3) Camp Management

a) Medical officer should check the following :
b) Exact venue ,number of donors, time for the camp, refreshment for donors, furniture, space, mobile vans, appliances for collection and transportation of blood, and emergency box
c) Record and report the details about the blood camp to the Blood transfusion committee.

### 4) Testing (IH/ ID)

a) Provide consultation and support to technical and clerical staff concerning specimen and requisition acceptability.
b) Review and interpret:
   i) Blood typing discrepancies
   ii) Positive antibody screens
   iii) Antibody panels; prenatal titters
   iv) Positive direct/ indirect anti-globulin tests

c) Provide consultation to technical staff concerning additional evaluation of patients with complex serologic problems.
d) Review clinical significance of serologic findings and decide on additional testing required prior to transfusion.

5) **Component Management**

a) Provide consultation to apheresis nursing and technical staff concerning donor selection and acceptability.
b) Evaluate and manage apheresis donor reactions.
c) Provide medical direction of component collection via cell separator.
d) Evaluate and approve requests for selected and specialized blood components, including washed red cells and apheresis derived platelet

6) **QMS/QA**

a) Assists with developing, implementing, and maintaining the quality assurance with respect to
   i) Organisation
   ii) Personnel
   iii) Technical
   iv) Document control
   v) Infrastructure management
   vi) Equipment
   vii) QA
   viii) Audits
b) Perform the initial review of the Quality Control records with the quality manager
c) Ensure staff and departmental compliance with all regulatory, safety, and institution policies and procedures.
d) Ensure that all work is done according to the required standards
e) Ensure the SOP is followed at all critical steps of process flow like donor screening , phlebotomy site cleaning, phlebotomy, temperature maintenance during blood transport, calibrated centrifuge and trained technical staff in component lab
f) Ensure the application of Good Manufacturing Practices (GMP)/Good lab practices(GLP)/Good Clinical Practices(GCP).

7) **Training**

a) Cross training of different levels of staff
b) Competency management
c) Plans and Helps in Conduction of the refresher and regular training program of the staff in the blood bank
d) Helps in evaluating the knowledge of the new staff and arrange for the training programs.

8) **Clinical Services**

a) Provide consultation to clinical staff concerning selection and acceptability of donors for autologous transfusion.
b) Consult with the attending physician and resident staffs as necessary.

c) Determine risks of transfusion in: patients with complex serologic problems and patients who require transfusion before routine serologic testing can be completed. Provide consultation to attending physician and resident staffs as indicated
d) Review initial workup of all transfusion reactions reported to the Blood Bank.
e) Determine additional evaluation required and prepare a written interpretation for review and discussion with the in-charge blood bank and provide consultation to attending physician and resident staffs as indicated.
f) Provide initial evaluation of patients who are candidates for therapeutic apheresis. This includes: review of patient problem; prepare initial draft of consultation report and review with the Consultant Transfusion Medicine to select appropriate patients for therapeutic apheresis; determine the apheresis protocol to be used; determine methods to be used for evaluating patient response to therapeutic apheresis.
g) Obtain informed consent for therapeutic apheresis from patients.
h) Schedule therapeutic apheresis procedures with apheresis personnel.
i) Complete therapeutic apheresis worksheets and write the detailed orders for the apheresis procedure.
j) Write daily apheresis orders.
k) Evaluate patient pre-procedure and document procedure/"SOP" note.
l) Evaluate and manage patient reactions during therapeutic apheresis.
m) Monitor and evaluate patient response to therapeutic apheresis.
n) Participate in Haemovigilance

**9) Biosafety & Infection Control**

a) Ensure universal precautions to be followed consistently by all the staff of blood bank
b) Ensure Infection control practices including BMW management

## DUTIES AND RESPONSIBILITIES OF BLOOD BANK NURSE

**1) Donor Management**

a) Assist with donor room preparations, prepare and distribute supplies and equipment, maintain drugs & consumables and equipment management.
b) Assist MO in preparing the patient for phlebotomy procedure.
c) Assist MO in donor selection.
d) Provide information related to donor screening & post donation instructions to donors
e) Perform phlebotomy& manage post donation care
f) Collect samples in pilot tubes, supervise transportation of pilot tubes & collected blood bags to the respective labs
g) Maintain documentation related to donor records
h) Assist in apheresis procedure, donor eligibility and donor care.
i) Perform duties assigned by the BB MO in charge
j) Assist in Donor motivation activities

**2) Camp Management**

a) Ensure that all the documents and records are made ready before the camp.
b) Ensure that all the equipment's and furniture's are made available.
c) Arranges all the apparatus and equipment's required for the mobile blood collection unit.
d) Assist in storage and transportation of collected blood.

e) Records the concerns about the blood donation camp

3) **Administrative/ Programme management/ Regulatory Aspects**

a) Coordinate activities in blood collection unit, including work flow and work assignments
b) Coordinate preparation of monthly, quarterly & annual reports to be sent to SACS/SBTC/Drug Control Departments.

**4) QMS/QA**

a) Perform quality control of donor related equipment, and maintain records as per D& C act

**5) Training**

a) Assist in training new staff.
b) Instruct new nursing staff in specific tasks and job techniques as required
c) Training of other clinical department nurses on bedside transfusion practices

**6) Clinical Services**

a) Obtain informed consent for therapeutic apheresis from patients.
b) Help MO in scheduling therapeutic apheresis procedures with apheresis personnel.
c) Help MO in Completing therapeutic apheresis worksheets
d) Maintain the records of daily apheresis orders, pre-procedure records and document procedure/"SOP" note.
e) Maintain the records related to management of patient reactions during therapeutic apheresis.
f) Maintain records and reports with patient response to therapeutic apheresis
g) Assist in Haemovigilance

**7) Biosafety & Infection Control**

a) Ensure Universal precautions are followed strictly
b) Ensure Infection control practices including BMW management

**RESPONSIBLITIES FOR BLOOD BANK TECHNICIANS**

**1) Donor Management**

a) Assist in Donor motivation activities
b) Assist in donor room activities including assisting in apheresis procedures
c) Identifies and communicates abnormal test reports by alerting supervisory personnel& safe disposal of TTI reactive units as per BMW regulation.

**2) Testing**

a) Understands blood bank methods, demonstrates knowledge of testing processes which includes donor screening, blood grouping, cross matching, IH testing, TTI screening.

b) Organize work by matching blood requests with test tube labelling; sorting samples; checking labelling; logging samples; cross matching and reserving units ready for issue, keeping work surfaces clean and orderly.

**3) Component management**

a) Performs blood component separation, labelling, quality control of blood components produced.

**4) Administrative/ Programme management/ Regulatory Aspects**

a) Perform duties as assigned by the BB MO
b) All activities & records to be maintained as per relevant SOP & D&C act.
c) Document all the necessary information in the required blood bank records in the respective work area
d) Assist staff nurse & MO in preparation of reports.
e) Maintains donor/patient confidence by keeping laboratory information confidential.

**5) QMS/QA**

a) Assist in preparation of SOPs
b) Maintains quality results by running standards and controls, verifying equipment function through routine equipment maintenance and advanced trouble shooting; calibrating equipment utilizing approved testing procedures; monitoring quality control measures and protocols.
c) Perform & maintain records of QC procedures related to reagent, kits & equipment's.

**6) Training**

a) Responsible for in house staff training.

**7) Clinical Services**

a) Ensures the issue of blood components / units for patient care.

**8) Biosafety & Infection Control**

a) Ensure Universal precautions are followed strictly
b) Ensure Infection control practices including BMW management

## TERMS OF REFERENCE FOR THE COUNSELLOR AT BLOOD BANKS

**1. Donor Education**

a) To explain the blood donor of the entire blood donation process (sic).
b) To ensure that the donor understands all questions and responds accurately to the donor questionnaire.
c) To inform the donor that his/her blood will be tested for blood group serology and markers of TTI and the test results will be given to the donor.

d) To ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate and the donor is willing to be informed of their test results.

**2. Donor Education regarding Blood Donation Process**

a) To ensure that donors feel comfortable during blood donation process, including the venepuncture.
b) To reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting.
c) To give post-donation advice, including care of the venepuncture site.
d) To secure donors' cooperation in the confidential unit exclusion or post-donation information process.
e) To clarify doubts or concerns raised by donors.
f) To alleviate donors' anxiety.

**3. Donor Education regarding TTI Reactivity**

a) To keep the donor informed about the health implications of the positive TTI test results for the donor and the donated blood (discard) and the suitability of the donor for future blood donations.
b) To guide and help the blood donor with positive screening results in further investigation, management, treatment and care, if necessary.
c) To encourage donors to provide all relevant information, including the possible source of infection.
d) To explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.
e) To provide information on precautions for preventing the transmission of infection to others.

**4. Donor Deferral and Preventive Health Education**

a) To explain and clarify of the nature of the deferral (permanent or temporary) Example: Donor with low haemoglobin: refer to a health-care institution for haematological investigation and further management, and provide information on nutrition.
b) To encourage temporarily deferred donor to return for future blood donations after the defined deferral period.
c) To keep the donor informed about the donor deferral period: i.e. until screening test is non-reactive on follow-up.
d) To encourage individuals to self-defer if they are suffering from an infection, disease or health condition that may make them unsuitable to donate blood.

**5. Referral and Linkages**

a) To provide information and refer donors for further investigation, management, treatment and care, if necessary.
b) To organise and scheduling Blood Donation Camps (sic.).
c) To mobilize communities for blood donation.

d) To organize and lead mobile blood donations in colleges, workplaces, etc.
e) To give blood donation lectures at workplaces, schools and voluntary organisations.
f) To prepare donor cards and certificates to voluntary blood donors.
g) To maintain effective communication and working relationship with team members, other health workers and clients.
h) To develop list of prospective donor groups by using organizational, professional, and industrial listings and directories.
i) To contact prospective donor groups to explain requirements and benefits of participation in blood donor program.
j) To visit prospective or participating blood donor group to discuss blood program.
k) To distribute promotional material and use audio-visual aids to motivate groups to participate in blood-donor program.
l) To arrange specific date of blood collection for blood-donor group and confirm appointment in writing.

**6. Donor Identification and Motivation**

a) To identify donors with rare-type blood from blood-bank records, and telephone donors to solicit and arrange blood donation.
b) To increase donors' trust in the BTS and encourage them to adhere to donor selection criteria while responding to the donor questionnaire.
c) To foster donor trust and confidence for donor retention.
d) To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening and encourage regular blood donation.

**7. Reporting and Record Keeping**

a) To keep records of organizations participating in program.
b) To record information for mobile blood-collection unit, such as space available, staffing required, and number of donors anticipated.
c) To consult blood bank records to answer questions, monitor activity, or resolve problems of blood donor groups.
d) To prepare reports of blood-donor program and donor recruitment activities.

**8. Self-Motivation and Monitoring**

a) Develop and maintain continuing personal and professional development to meet the changing demands in the area of blood donor services.
b) Monitor own performance against objectives and standards.
c) Keep up-to-date on job-related issues as appropriate and keep log of own performance and in-service training log for purposes of appraisal.

## Annexure 5

## Counselling Checklist

**Pre-Donation Information**

Ÿ Use simple language
Ÿ Avoid using medical terms
Ÿ Avoid using slang language
Ÿ Discuss one key idea completely before moving on to the next
Ÿ Use the counselling skills of summarizing YOUR OWN explanation to ensure the donor has understood.

**Pre-Donation Counselling**

Ÿ Ensure the donor understands the donor questionnaire and responds accurately to all questions
Ÿ Ensure the donor understands that his/her blood will be tested for blood group serology and markers of TTI and the test results will be given to the donor
Ÿ Ensure the donor is in a position to give informed consent to donate and recognizes that his/her signature affirms that responses provided to the questionnaire are accurate
Ÿ Ensure the donor is willing to be informed of his/her test results

**Donor Selection and Health Check**

(not a counsellor role)

**Counselling during Blood Donation**

Ÿ Ensure that donors feel comfortable during blood donation, including the venepuncture
Ÿ Reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting
Ÿ Give post-donation advice, including care of the venepuncture site
Ÿ Secure donor's cooperation in the confidential unit exclusion or post-donation information process
Ÿ Foster donor trust and confidence for donor retention

**Post-Donation Counselling**

Ÿ Explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.
Ÿ Encourage donors to provide all relevant information, including the possible source of infection.
Ÿ Clarify doubts or concerns raised by donors.
Ÿ Alleviate donors' anxiety
Ÿ Provide information on precautions for preventing the transmission of infection to others.
Ÿ Provide information and refer donors for further investigation, management, treatment and care, if necessary

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# No blood from you, you're LGBTQ'

Dr Farah Ingale, Senior Internal Medicine Specialist, Hiranandani Hospital in Vashi, said, "They are categorised as High Risk Group mainly because they have multiple sexual partners and there is an high incidence of HIV.





WRITTEN BY

Anagha Sawant

SOURCE

DNA

Updated: Jul 18, 2017, 07:05 AM IST



What can be termed as clear case of discrimination, National Aids Control Organisation (NACO) considers Lesbian Gay, Bisexual and Transgender community as 'High Risk Group' and hence says the community is not allowed to donate blood.

This has been revealed following a Right To Information (RTI) query filed by RTI activist Chetan Kothari on April 26. The RTI was received by the NACO's Blood Safety Division on June 22 and Jolly Lazarus, Central Public Information Officer has replied to the RTI on June 30. The CPIO was not available to comment on the issue.

Dr Farah Ingale, Senior Internal Medicine Specialist, Hiranandani Hospital in Vashi, said, "They are categorised as High Risk Group mainly because they have multiple sexual partners and there is an high incidence of HIV.

There are tests before blood transfusion, but they are not 100 per cent accurate every time. So, it is better to avoid rather than taking risks. In India, not many are aware about their medical history."

LGBTQ activist Harish Iyer came down heavily on the government authority.

LGBTQ activist Harish Iyer came down heavily on the government authority labeling the entire LGBTQ community as High Risk Group. "Everybody is 'High Risk'. The blood given to any laboratory needs to be tested. If a straight person donated blood, is it offered to a beneficiary without testing? What's the point in declaring an entire community as High Risk? This is nothing but discrimination. Don't the non-LGBT people engage in high risk behaviour?

Don't they visit commercial sex workers? Do they not engage in drugs? The medical fraternity needs to stand up against this."

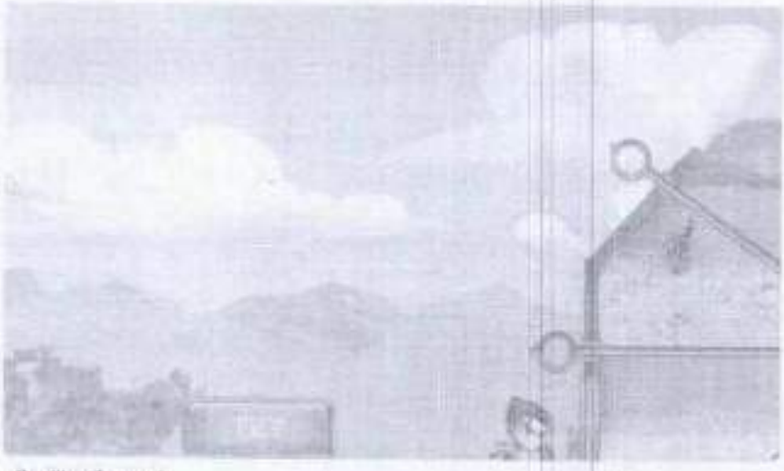
Kothari, on his part, said the purpose of filing the RTI was to get a clear picture as many European countries don't allow the LGBTQ community to donate blood. "Many government blood banks aren't aware about the guidelines. Some also believe it's better to lose a donor rather than getting into any legal trouble," he said.

**What a shame**

If a straight person donated blood, is it offered to a beneficiary without testing? Don't the non-LGBT people engage in high risk behaviour?

HIV | lesbian | Gay | National AIDS Control Organisation (NACO) | Blood donation | Transgender Community | Bisexual | LGBTQ community





https://www.scoopwhoop.com/indias-lgbtq-cant-donate-blood/

ANNEXURE P-6

LGBTQIA
Jul 21, 2017 at 15:11

# India's LGBTQ Can't Donate Blood For The Most Bizarre Reason, According To An RTI Reply

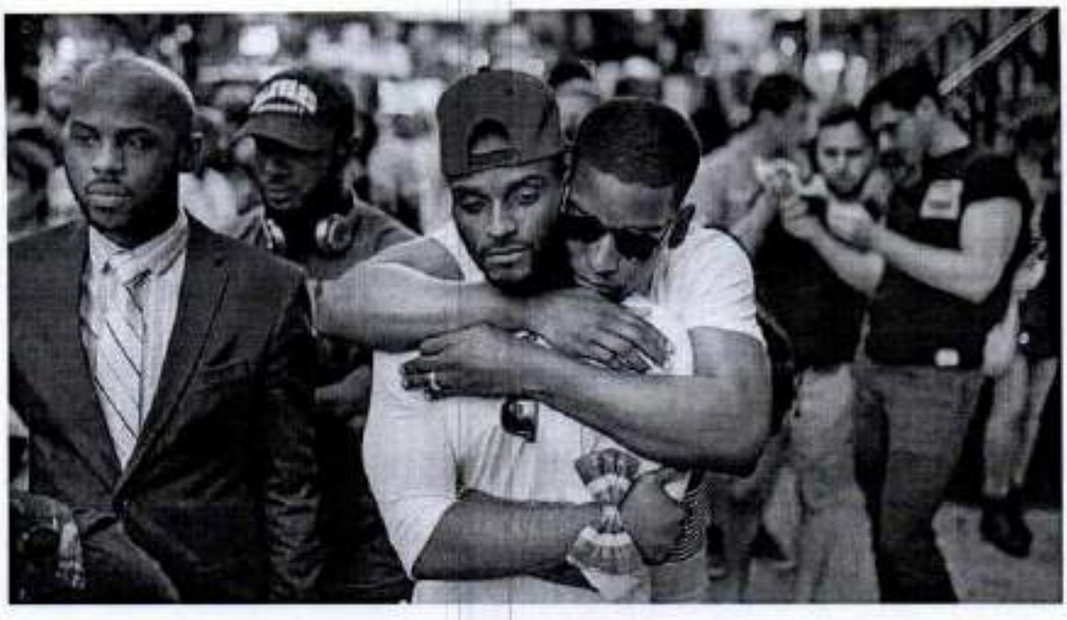
Shabdita Pareek


In case you had any doubts, it has been confirmed yet again that we are the champions of discrimination. We discriminate on the basis of region, religion, caste, sex, food habits and so much more.

As if all that wasn't regressive enough, it has come to light that we've been discriminating against the LGBTQ community by not allowing them to donate blood.

**An RTI has revealed that the National AIDS Control Organisation (NACO) considers the lesbian, gay, bisexual and transgender community as a "high-risk group" (for HIV), thus banning them from donating blood.**

https://www.scoopwhoop.com/indias-lgbtq-cant-donate-blood/



This absolutely nonsensical practice came to light after RTI activist Chetan Kothari filed an RTI query regarding the same.

After the National Aids Control Organisation (NACO) received his application, the Central Public Information Officer replied.

As reported by the DNA, Dr Farah Ingale, Senior Internal Medicine Specialist at Hiranandani Hospital in Vashi, said:
They are categorised as High-Risk Group mainly because they have multiple sexual partners and there is a high incidence of HIV. There are tests before blood transfusion, but they are not 100 per cent accurate every time. So, it is better to avoid rather than taking risks. In India, not many are aware about their medical history.

https://www.scoopwhoop.com/indias-lgbtq-cant-donate-blood/

The LGBTQ community is already deprived of their basic moral and legal rights in our country. On top of that, banning them from donating blood is plain insulting. But it's not just India that deems the LGBTQ community unfit for donating blood. Many European countries also follow the same practice. And this RTI was filed by Kothari to get a clarity on the same.

Rightly furious at this, LGBTQ activist Harish Iyer told DNA:

Everybody is 'High Risk'. The blood given to any laboratory needs to be tested. If a straight person donated blood, is it offered to a beneficiary without testing? What's the point in declaring an entire community as High Risk? Don't the non-LGBT people engage in high risk behaviour? Don't they visit commercial sex workers? Do they not engage in drugs?
**How do officials determine the sexuality of a person who volunteers to donate blood?**
**Don't straight people have multiple sexual partners as well?**

*Feature image source: youspeakindia*

# Blood not needed if you're gay: The stigma attached to Mumbai blood banks

Both the donor questionnaire and health check-up are administered to every prospective donor

**Topics**
Section 377 | Hiv | Aids

BS Web Team | New Delhi
Last Updated at September 26, 2018 12:46 IST


*People react after the Supreme Court verdict which decriminalises consensual gay sex, in New Delhi, Thursday, Sept 6, 2018.*

**ALSO READ**

Blood test significant diagnostic method for disease detection

Gay pride and prejudice

Supreme Court rules it's not a crime to be a homosexual in India anymore

Blood moon: Get ready to watch century's longest lunar eclipse tonight

Immunotherapy: Pros and cons of treating cancer

Despite a landmark verdict on Section 377 by the Supreme Court, which decriminalised gay sex in the country, the Maharashtra arm of National Blood Transfusion Council (NBTC) recently issued a newly-updated blood donor screening questionnaire to Mumbai-based blood banks. The new questionnaire, designed on the lines of developed nations, will now mandate the blood collectors to ask the male donors about their sexual behaviour and whether they have multiple partners or engaged in the male-to-male sexual activity. For decades, the ban on homosexuals to donate blood exists in India and those who are at high risk of suffering from prolonged diseases such as cancer, allergies, respiratory ailments and organ failure are also not allowed to donate blood.

For the first time after the apex court judgment, a government-body has chalked out a clear ban on homosexual men and women donating blood. According to blood banks, earlier questionnaires asked donors whether they have any reason to believe that they might have been infected by HIV, hepatitis, malaria or other illness.

**ALSO READ: Blood banks gasp for oxygen, India sees shortage of 1.9 mn units in 2016-17**

NBTC's 2017 revised guidelines, on the selection of blood donors reiterate that transgenders, bisexual men and female sex workers

never donate blood as they have a higher risk of contracting HIV and Hepatitis B and C.

Both the donor questionnaire and health check-up are administered to every prospective donor to enable a quick history taking, physical examination and blood test.

Dr Shobhini Rajan, in charge of blood safety at National Blood Transfusion Council, told *The Times of India*, "The new questionnaire aims to reinforce pre-donation screening as blood units are subjected to tests only after collection. The donors cannot be at high risk of contracting infections and donate blood."

Ashok Row Kavi of Humsafar Trust emphasizes the need to address the confidentiality in a better way. He says, "How are homosexuals supposed to give away such intimate details? Though such questions are necessary for screening, but the donors are to be made comfortable to share their information. Most importantly, blood banks must seek gay community counsellors' help before questioning the male donors, reported the *TOI*.

Many developed nations require blood donors to answer questions about their sexual orientation and partners. Dr Shobhini Rajan, in charge of blood safety at National Blood Transfusion Council, told *The Times of India* that India's National Blood Policy clearly defines the precondition that blood donors should not be at a high risk of contracting infections. The new questionnaire aims to reinforce pre-donation screening as blood units are subjected to tests only after collection."

***With Inputs from The Times of India***



*First Published: Wed, September 26 2018. 12:46 IST*

READ MORE ON SECTION 377 HIV AIDS GAY RIGHTS HEPATITIS BLOOD DONATION

PREVIOUS STORY

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NEXT STORY

Budget 2021: FM Sitharaman proposes doubling of healthcare spending

Exercise-h added to study

ANNEXURE P-8

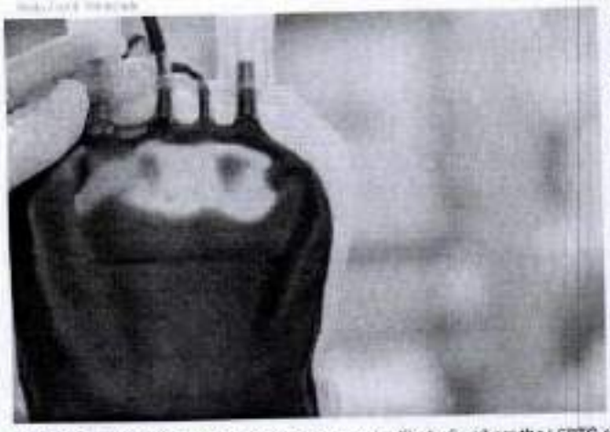


# Pride and Prejudice: SC gives equality, but blood banks don't want 'gay donors'

In Focus

Updated: Sep 18, 2018 | 10:51 IST | Times Now Digital

The Maharashtra chapter of the National Blood Transfusion Council has issued a new questionnaire format for blood donors which seems to be drafted to weed out homosexual, transgender or female sex workers.



**Mumbai:** Following a historic verdict by the Supreme Court which decriminalised gay sex in the country, the Maharashtra chapter of the National Blood Transfusion Council (NBTC) has approached blood banks in Mumbai with a rather unusual request. In its most recent correspondence, the Maharashtra chapter sent an updated format of the blood donor screening questionnaire to operational blood banks in the city.

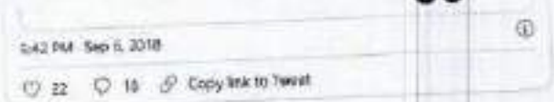
From now onwards, those in Mumbai looking to donate blood will have to answer questions about their sex life and number of sexual partners as a result of the new questionnaire format. In a country like India where the LGBTQ community has been ostracised for decades, this is the first time a government-body has spelled out a clear ban on homosexual men and women donating blood.

Established in 1996, the National Blood Transfusion Council cited a guideline revision made in October of 2017 that restricts gay and bisexual men, female sex workers and transgender from donating blood. In fact, the scope of the ban has been extended to those suffering from chronic illnesses such as allergies, organ failure, respiratory ailments, and cancer.

**Blood Donors India**
@BloodDonorsIn

I'm taking a step away from our blood donation cause to pause a minute to say: Congrats, India ! Congrats, the #LGBTQ community ! "History owes you an apology"...

> **Twitter India** @Twitterindia
> Over 300,000 Tweets discussing #section377 and #LGBTQ in the past 12 hours and the conversation is still on the rise! Congrats to the #LGBTQ community in #LoveWins
>
> via @trendsmap trendsmap.com/v/pGo2/w




Those employed by blood banks say that earlier questionnaires asked donors whether they have any reason to believe that they might have been infected by HIV, hepatitis, malaria or other such diseases. However, the new format makes it mandatory for those looking to donate blood to respond to questions inquiring him about 'multiple sex partners or engagement in male to male sexual activity'.

Most developed countries require blood donors to answer such questions about their sexual orientation and partners, a blood transfusion officer was quoted as saying. In charge of blood safety at National Aids Control Organisation, Dr Shobhini Rajan told The Times of India that India's National Blood Policy clearly defines the precondition that blood donors should not be at a high risk of contracting infections. The Supreme Court verdict has no role to play in this case, she said.

**Must Read:** India Floods: Impact of man-made activities and opening of dam gates



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ANNEXURE P-9

Department of Health & Social Care

**Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)**

# Donor Selection Criteria Report (2017) Version 2

Published July 2017

## Contents

# 1. Executive Summary

1.1 The criteria that are used by the UK blood services to select blood donors on the basis of behaviours that may increase the risk of acquiring and transmitting blood borne infections (BBI) last underwent major review by SaBTO in 2011. That review led to a change in selection criteria for potential blood donors who are men who have sex with men (MSM). The selection criteria were changed from a permanent deferral to a twelve month deferral from last sexual contact in England, Scotland and Wales Blood Services in 2011, and by The Northern Irish Blood Transfusion Service in 2016. Another working group later reviewed the evidence base for selection of living and deceased donors of cells and banked tissues in the UK in relation to MSM behaviour. The SaBTO recommendation on Tissues & Cells on MSM Donor Selection review was published in July 2013.

1.2 Since the change in selection criteria for MSM the routine ongoing surveillance has shown that the risks of transmission of BBI have not increased. A large anonymised, unlinked survey of over 65,000 blood donors has been carried out since the last review to better measure donors understanding and compliance with donor selection criteria. There is high but not perfect concordance with the existing selection criteria. In addition, since that last review more comprehensive data is now available about the risk of acquiring BBI from a wide range of social behaviours. These data have been used to model the likely future concordance with selection criteria and the estimated risk of TTI (Transfusion Transmitted Infections).

1.3 Over the past two decades there have been a number of national and international judicial inquiries into the transmission of Human Immunodeficiency Virus (HIV) and hepatitis C virus (HCV) by blood and plasma products in the UK. A common theme of these judgements is the legal liability of Blood Services for harm caused by TTI. These legal proceedings attracted significant media and political attention and led to reputational damage and loss of trust in Blood Services and Government.

1.4 In November 2015 a review of donor selection criteria for MSM was announced by the then Public Health minister, Jane Ellison. In January 2016 SaBTO decided that this would be best done as part of a comprehensive review of donor selection criteria including other behaviours where there may be an increased risk of acquiring blood borne infections and thus potential to transmit to recipients of blood, tissues or cells. A working group was set up specifically to review the evidence base for donor selection, deferral and exclusion in the UK in relation to sexual behaviours that may increase the risk of acquiring specific blood-borne infections; HIV, hepatitis B virus (HBV), HCV and Syphilis. In addition, the group was asked to review the risk that these infections could be acquired following

procedures that involve piercing of the skin as well as flexible endoscopy, a procedure specifically covered by blood safety legislation.

1.5 The working group included SaBTO members, invited professional experts and representatives of stakeholder organisations. These included representatives of groups affected by the current selection criteria and patients who have diseases that are treated with multiple blood component transfusion. The first working group meeting was immediately followed by a public meeting which had been advertised to organisations and individuals who had made their interest in this issue known over the preceding months.

1.6 All Substances of Human Origin (SoHO) have a risk of transmitting infection to recipients of those substances. After considering the available evidence the working group decided to adopt the same level of tolerance of risk as was done in the 2011 review, i.e. the risk that a potentially infectious donation is not detected on routine screening due to a window period infection is less than one in a million donations. Consideration of other risks to recipients resulted in the Working Party recommending a more stringent criterion for potential donations from people who have injected drugs in the past.

1.7 The full report explores many relevant issues as listed in individual chapters, including; ethics, motivation, epidemiological data on BBI, international practice, the performance of tests for diagnosing BBI, and statistical modelling of the risk of TTI.

## The Working Party recommended for blood donation:

No deferral after:

1.8 Endoscopy, body piercing, acupuncture or tattooing carried out in UK

1.9 This would require a legislative change in respect of the deferral periods following endoscopy, body piercing and tattooing, or acupuncture by UK based qualified practitioners.

Three-month deferral after:

1.10 Endoscopy, body piercing, acupuncture, tattooing performed out of UK or non-commercial premises in the UK or for acupuncture, someone who is not considered a 'qualified practitioner'. As above, any change will require a change to the law.

1.11 Sex between men.

1.12 Sex with a person who has received money or drugs for sex.

1.13 Someone who has received money or drugs for sex (Sex will need to be defined in the Donor Selection Guidelines, recommend as physical anal, oral or vaginal sex).

Three-month deferral after:

1.14 Sex with a partner resident and sexually active in a high risk area.

1.15 Sex with a partner who was previously resident and sexually active in a high risk area for HIV/ AIDS and who has not been screened by the blood service.

1.16 Sex with a high-risk partner (ie with HIV, HBV, HCV, syphilis, HTLV, person who has received money or drugs for sex, person who has injected or been injected with non- medically prescribed drugs).

One Year deferral after:

1.17 Injection of not medically prescribed drugs.

1.18 Will require a legislative change.

## The Working Party recommended for gamete donation:

1.19 For sperm donor tested at donation and then five months with sperm released if negative. This will require a change in legislation;

or

1.20 Sperm donor s tested at donation by serology, quarantine for 3 months, repeat serology and test by NAT, sperm released if negative;

or

1.21 In exceptional circumstances with risk assessment and recipient consent, sperm donor tested at donation by serology and NAT, sperm released if negative.

1.22 For egg donation, donor tested by serology 2 months prior to donation, retested at start of medication by serology and NAT, donation released if negative.

## The Working Party recommended for haematopoietic Stem cells (HSC) and tissue donation:

No deferral after:

1.23 Body piercing, acupuncture or tattooing carried out in UK

1.24 For donors with long term partners born in areas where HIV endemic and partner is tested negative

Three-month deferral after:

1.25 Body piercing, acupuncture, tattooing performed outside of UK.

1.26 Sex with a partner resident and sexually active in a high risk area.

1.27 Sex with a partner who was previously resident and sexually active in a high risk area and who has not been screened.

1.28 Sex with a high-risk partner (ie with HIV, HBV, HCV, syphilis, HTLV, commercial sex worker, injecting drug user).

1.29 Sex between men.

1.30 Sex with a commercial sex worker.

1.31 Commercial sex work (receiving money or drugs for physical sex). Injection of not medically prescribed drugs

1.32 This deferral period may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation.

One Year deferral after:

1.33 Habitual use of intravenous drugs for addiction.

1.34 This can be reduced to 3 months supported by individual risk assessment together with single NAT testing and bacterial screening if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a life-saving transplantation.

Tissue and cell establishments:

1.35 In contrast to blood donation which is managed by the four UK blood services, there are many providers of tissues and cells. The establishments have to comply with EU Directive for donor selection and testing as a minimum requirement which does not require Nucleic Acid Testing (NAT) as a mandatory test. Non blood service establishments are advised to consider the SaBTO recommendations for suitability of application within their organisation taking into consideration of the testing algorithms used to screen donor samples for transmissible infections. It is recommended that a deferral period following a behaviour which may put a donor at higher risk of a Blood Borne Infection should be at least a minimum of two infectious window periods unless after risk assessment the recipient's clinical circumstances indicate that there is likely to be more harm from avoiding the cellular product/tissue than from transmitting an infection.

ANNEXURE P-10

# Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

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## Guidance for Industry

**This guidance is for immediate implementation.**

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances or https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Biologics Evaluation and Research**
**April 2020**
**Updated August 2020**

# Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

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## Guidance for Industry

Note: Changes have been made to update the guidance of the same title dated April 2020, including:

- Revised Section III to update the recommended deferral for individuals who had sex with a person who has exchanged sex for money or drugs and individuals who had sex with a person who has engaged in non-prescription injection drug use.
- Other minor editorial changes.

# Preface

## Public Comment

Given the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2015-D-1211 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA webpage titled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Additional copies of this guidance are also available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

## Questions

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

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# Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

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Note: Changes have been made to update the guidance of the same title dated April 2020, including:

- Revised Section III to update the recommended deferral for individuals who had sex with a person who has exchanged sex for money or drugs and individuals who had sex with a person who has engaged in non-prescription injection drug use.
- Other minor editorial changes.

Contains Nonbinding Recommendations

# Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

## Guidance for Industry

*This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.*

## I. INTRODUCTION

This revised guidance document provides you, blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. We (FDA) are also recommending that you make corresponding revisions to your donor educational materials, donor history questionnaires and accompanying materials, along with revisions to your donor requalification and product management procedures. This guidance also incorporates certain other recommendations related to donor educational materials. This updates the guidance of the same title dated April 2020. The April 2020 guidance superseded the December 2015 guidance of the same title (Notice of Availability, 80 FR 79913 (December 17, 2015)). The recommendations contained in this guidance apply to the collection of blood and blood components, including Source Plasma.

The recommendations in this revised guidance reflect the Agency's current thinking on donor deferral recommendations for individuals with increased risk for transmitting HIV infection. Based on the Agency's careful evaluation of the available data, including data regarding the detection characteristics of nucleic acid testing, FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing public health emergency. In particular, there is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating

Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

As a result of this public health emergency, there is a significant shortage in the supply of blood in the United States (U.S.), which early implementation of the recommendations in this guidance may help to address (even though the recommendations in this guidance are broadly applicable beyond the COVID-19 public health emergency). For this reason, this revised guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices. Because this revised guidance is being issued without prior public comment in light of the COVID-19 public health emergency, it is intended to remain in effect for the duration of this public health emergency, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). However, as noted, FDA expects that the recommendations set forth in this revised guidance will continue to apply outside the context of the current public health emergency. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with an updated guidance that incorporates any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

## II. BACKGROUND

The emergence of Acquired Immune Deficiency Syndrome (AIDS) in the early 1980s and the recognition that it could be transmitted by blood and blood products had profound effects on the U.S. blood system (Refs. 1, 2, 3). Although initially identified in men who have sex with men (MSM) and associated with male-to-male sexual contact, AIDS was soon noted to be transmitted by transfusion of blood products, and by infusion of clotting factor concentrates in individuals with hemophilia (Refs. 4, 5). Subsequently, AIDS was also found to be associated with heterosexual transmission through commercial sex work and with intravenous drug use (Refs. 6, 7). The understanding of risk factors for AIDS in 1983 informed the first blood donor deferral policy, which at that time was the only way to reduce the chance of transmission of AIDS

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).
[2] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

through blood product transfusion. In 1984, AIDS was reported to be associated with the virus now known as HIV, opening the door to development of donor screening tests.

Beginning in 1983, FDA issued recommendations for providing donors with educational material on risk factors for AIDS and for deferring donors with such risk factors in an effort to prevent transmission of the agent responsible for AIDS (later understood to be caused by HIV) by blood and blood products (Refs. 1, 8, 9, 10). Providing donor educational material and asking at-risk donors not to donate was demonstrated to have a significant impact on preventing HIV transmission prior to the availability of testing (Ref. 11). However, thousands of recipients of blood and blood components for transfusion and recipients of plasma-derived clotting factors became infected with HIV before the causative virus was identified and the first screening tests for HIV were approved in 1985 (Refs. 1, 3, 9).

From September 1985 to December 2015, FDA recommended that blood establishments indefinitely defer male donors who have had sex with another male, even one time, since 1977, due to the strong clustering of AIDS illness and the subsequent discovery of high rates of HIV infection in that population (Ref. 12). The use of donor educational material, specific deferral questions, and advances in HIV donor testing (e.g., HIV antibody assays, p24 antigen assays, and nucleic acid tests (NAT)) then reduced the risk of HIV transmission from blood transfusion from about 1 in 2500 units prior to HIV testing to a current estimated residual risk of about 1 in 1.47 million transfusions (Refs. 13, 14). The development of pathogen inactivation procedures for products manufactured from pooled plasma in the 1980s improved the safety of these products by inactivating lipid-enveloped viruses. No transmissions of HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV) have been documented through U.S.-licensed plasma-derived products in the past two decades (Ref. 15).

During the period from 1997 to 2010, FDA and HHS held several public meetings, including workshops and Blood Product Advisory Committee (BPAC) meetings to further review evidence and to discuss its blood donor deferral policies to help prevent the transmission of HIV (Refs. 16, 17, 18, 19, 20). In September 2010, an Interagency Blood, Organ & Tissue Safety Working Group on MSM (BOTS Working Group), consisting of representatives from the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), HHS Office of Civil Rights, Office of the Assistant Secretary for Health (OASH), and FDA, was charged by the Assistant Secretary for Health with exploring the feasibility of a data and science-driven policy change. Subsequently, the BOTS Working Group designed and implemented one operational assessment and three research studies to gain more information to help inform a potential policy change. In addition, it considered the possibility of conducting a pilot study to assess the effect of a policy change. However, following review of comments received in response to a *Federal Register* notice titled, "Request for Information (RFI) on Design of a Pilot Operational Study To Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex With Other Men (MSM)" (77 FR 14801, March 13, 2012) (Ref. 21), requesting comment on potential pilot study designs, as well as further considerations regarding the significant statistical, financial and logistical challenges in implementing such a study, the BOTS Working Group decided that such a pilot study examining the potential effects of a policy change would not be feasible. Instead, the BOTS Working Group determined that resources at HHS could be used in more efficient ways to carefully

review the studies that had been initiated and to consider other study designs or interventions. The following information became available by mid-2014 and was subsequently reviewed by the BOTS Working Group, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), which met on November 13, 2014, and the BPAC, which met on December 2, 2014:

1. An operational assessment that examined quarantine release errors. Such errors occur when a blood establishment accidentally releases a unit of blood that should not have been released due to issues with donor qualification or testing. It became clear at an FDA workshop held in September 2011 that HIV risk from quarantine release errors has been minimized effectively by increased use of computerized inventory management, with a remaining small risk of human errors. Following the workshop, a White Paper was produced by AABB on this topic which described several measures that could be taken to characterize and prevent such errors (Ref. 22). Quarantine release errors now appear to contribute minimally to the risk of HIV transmission through the blood supply (Ref. 23).

2. The Donor History Questionnaire (DHQ) Study, which involved cognitive interviews with potential donors. After receiving donor educational materials, the potential donors completed the donor history questionnaire, and were then interviewed regarding their responses (Ref. 24). The key result of this study, which was highly consistent for both individuals who only have sex with partners of the opposite sex and MSM, was that individuals respond to questions posed by the questionnaire as if they were answering the more general and subjective question in the self-assessed context of "is my blood safe," rather than providing an answer to the literal questions as asked.

3. The REDS-II Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study 2011-2013, which was a pilot blood donor surveillance study that evaluated four viral markers (HBV, HCV, human T cell lymphotrophic virus (HTLV), and HIV) in just over 50% of the nation's blood supply (Ref. 25). It also determined behavioral risk factors that were associated with donations of blood that tested positive for one of these viruses compared with control donations. Key findings from this study included that for each of these viral infections, the primary behavioral risk factors were consistent with the known epidemiology for each infection in the U.S. Sex with an HIV-positive partner and a history of male-to-male sexual contact remained the two leading independent risk factors for HIV infection in blood donors as originally observed in CDC-funded studies from the early 1990's. Sex with an HIV-positive partner was associated with a 132-fold increase in risk (multivariable adjusted odds ratio) for being HIV-positive, and a history of male-to-male sexual contact was associated with a 62-fold increase in risk. By comparison, the increase in risk for a history of multiple sexual partners of the opposite sex in the last year was 2.3-fold.

4. The Blood Donation Rules Opinion Study (BloodDROPS), which examined the opinions of MSM regarding the blood donor deferral policy through web-based surveys of the MSM community and non-compliant MSM who donated blood

(Ref. 26). A key finding was that MSM, who comprise approximately 7% (Ref. 27) of the U.S. male population, represented an estimated 2.6% of male blood donors. Although the data were determined by different methodologies, they suggested an increase in the proportion of blood donors reporting MSM behavior from 0.6% in 1993 and 1.2% in 1998. In the male blood donor survey, 83 of 3,183 respondents reported donating after male-to-male sexual contact. However, the prevalence of HIV infection in male blood donors who reported that they were MSM was determined to be 0.25%, which is much lower than the estimated 11-12% HIV prevalence in those reporting regular MSM behavior (Ref. 28). This indicates that considerable self-selection likely took place in individuals who presented to donate.

5. Epidemiologic data from countries that had changed their deferral policy for MSM indicated no safety concerns (Refs. 29, 30). The most robust data measuring the impact of these policy changes came from Australia (Ref. 30). Australia has a voluntary blood donor system and a similar percentage of men reporting male-to-male sexual contact at some time during their lives as in the U.S. (5% compared with 7%) (Ref. 27). During the five years before and five years after a change from a lifetime deferral to a one-year deferral in Australia, there was no change in risk to the blood supply, defined by the number of HIV positive donations per year and the proportion of HIV-positive donors with male-to-male sex as a risk factor. In addition, the compliance rate with the one-year MSM deferral among male donors in Australia following the policy change was >99.7% (Ref. 31).

Other information was considered in 2014 regarding alternatives to time-based deferral strategies, such as individual risk assessment. Data of concern at the time were that the rate of partner infidelity in ostensibly monogamous heterosexual couples and same-sex male couples was estimated to be about 25%, and that condom use was associated with a 1 to 2% failure rate per episode of anal intercourse (Refs. 32, 33, 34, 35). In addition, prevalence of HIV infection was significantly higher in MSM with multiple male partners compared with individuals who have only multiple opposite sex partners (Ref. 36).

Following careful review of all the options, it was ultimately determined that the available information was not sufficiently compelling to adopt the approach of individual risk assessment without further scientific evaluation of the validity of asking questions regarding monogamy or the use of safe sexual practices. Instead, the BOTS Working Group and ACBTSA and BPAC advisory committee opinions agreed that the available scientific evidence supported a move to a 12-month deferral period. At the same time, they recommended further study of alternatives to time-based deferrals. FDA subsequently also concluded that the available evidence strongly supported a change from the indefinite deferral to a 12-month blood donor deferral policy for MSM. This change was implemented in December 2015.

Even before the change in the blood donor deferral policy for MSM was made, the Transfusion Transmissible Infections Monitoring System (TTIMS) was implemented in the United States in order to facilitate monitoring of the safety of the U.S. blood supply for a variety of different

pathogens following changes in donor deferral criteria that might be made (Ref. 37). FDA has used TTIMS to further investigate and develop information to facilitate the refinement of blood safety screening measures over the past several years.

Data from the two years following effective implementation of the 12-month donor deferral criteria for MSM comparing the rates of HIV in those donating blood indicate that there has been no increase in risk to the blood supply from the change that was made. Additionally, other countries, including the United Kingdom and Canada have moved to a 3-month deferral period for MSM, and to date, there have been no reports from these countries suggesting safety concerns following the implementation of this change. In fact, preliminary information communicated to FDA by foreign regulators indicates that compliance of MSM with the donor deferral criteria may be increased. The totality of the surveillance information and the experience with a 3-month deferral in other countries, combined with the uniform use of nucleic acid testing for HIV, HBV, and HCV, which can detect each of these viruses well within a 3-month period following initial infection, leads the Agency to conclude that at this time a change to a recommended 3-month deferral is scientifically supported. FDA expects that this change will not be associated with any adverse effect on the safety of the blood supply, and it will continue to monitor the safety of the blood supply using the TTIMS.

In addition to the deferrals noted above for MSM, FDA has evaluated the available scientific evidence that could support modification of several other blood donor deferrals related to risk for HIV. Based on the experience in the United Kingdom and Canada, along with the detection characteristics of the nucleic acid testing noted above that has been implemented for HIV, HBV, and HCV, the Agency has determined that the recommended deferrals for commercial sex work (CSW) and injection drug use (IDU) can be changed from indefinite deferrals to 3-month deferrals. In addition, for similar reasons, the 12-month deferral for a recent tattoo or piercing can be reduced to 3 months. FDA also believes that by aligning many of the deferrals to asking about a 3-month period, donor recall of events will be enhanced, and this could potentially enhance the safety of the blood supply.

To comply with global regulatory requirements on deferral policies, it is acknowledged that manufacturers of blood and blood components, including Source Plasma, collected in the U.S. and intended for further manufacturing use in other countries, may not be able to implement all of FDA's recommended shortening of deferral policies noted in this guidance, and instead may elect to maintain longer deferral policies.

Finally, FDA remains committed to further investigating individual risk assessment as an alternative to time-based deferrals. A study of this approach is currently be initiated and should provide valuable information regarding the feasibility of implementing this approach in the future.

## III. RECOMMENDATIONS

The following sections summarize the revised recommendations related to blood donor deferral and requalification related to reducing the risk of HIV transmission by blood and blood products.

### A. Donor Educational Material and Donor History Questionnaire

1. Blood establishments must provide educational material to donors before each donation explaining the risk of HIV transmission by blood and blood products and risk factors associated with HIV infection so that donors can self-defer (see 21 CFR 630.10 (b)). We recommend the donor educational materials explain that individuals with risk factors for HIV need to be aware of the signs and symptoms associated with acute HIV infection, namely fever, enlarged lymph nodes, sore throat and rash.[3] The educational material must be presented to donors in a manner they will understand, which may include oral, written, or multimedia formats, and must instruct the donor not to donate when a risk factor for HIV infection is present (see 21 CFR 630.10(b)). The donor educational material should indicate that individuals who have engaged in any activity or who have any risk factor that would result in a deferral (see section III.B. of this guidance) should not donate blood or blood components.

2. We recommend that blood collection establishments update their donor educational material, DHQ, including full-length and abbreviated DHQs, and accompanying materials (e.g., flow charts) and processes to incorporate the recommendations provided in this guidance.

3. We recommend that the updated DHQ include the following elements to assess donors for risk:

   a. A history ever of a positive[4] test for HIV,
   b. A history in the past 3 months of exchanging sex[5] for money or drugs,
   c. A history in the past 3 months of non-prescription injection drug use[6],
   d. A history in the past 3 months of sex with any of the following individuals: a person with a history ever of a positive test for HIV, a person with a history in the past 3 months of exchanging sex for

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[3] See CDC website at https://www.cdc.gov/hiv/basics/whatishiv.html.
[4] In this context, "positive" includes reactive test results on an HIV diagnostic assay and repeatedly reactive or reactive results on antibody or NAT blood donor screening assays, respectively.
[5] Throughout this guidance the term "sex" refers to having anal, oral, or vaginal sex, regardless of whether or not a condom or other protection is used.
[6] Non-prescription injection drug use includes not only the injection of non-prescription drugs, but also includes the improper injection of legally-prescribed drugs, such as injecting a prescription drug intended for oral administration or injecting a prescription drug that was prescribed for another individual.

money or drugs, or a person with a history in the past 3 months of non-prescription injection drug use,

e. A history in the past 3 months of receiving a transfusion of Whole Blood or blood components such as packed red blood cells, platelets, or plasma,
f. A history in the past 3 months of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes,
g. A history in the past 3 months of a tattoo, ear or body piercing,
h. A history in the past 3 months of syphilis or gonorrhea, or treatment for syphilis or gonorrhea,
i. For male donors: a history in the past 3 months of sex with another man,
j. For female donors: a history in the past 3 months of sex with a man who has had sex with another man in the past 3 months.

Note: In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported.

## B. Donor Deferral

We recommend that you defer as follows:

1. Defer indefinitely an individual who has ever had a positive test for HIV[7].

2. Defer for 3 months from the most recent event, an individual who has exchanged sex for money or drugs.

3. Defer for 3 months from the most recent event, an individual who has engaged in non-prescription injection drug use.

4. Defer for 3 months from the most recent sexual contact, an individual who has had sex with a person who has ever had a positive test for HIV.

5. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has exchanged sex for money or drugs in the past 3 months. If the individual has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.

[7] A donor deferred because of a repeatedly reactive or reactive result on an antibody or a NAT blood donor screening assay, respectively, may be considered for re-entry by a requalification method or process found acceptable for such purposes by FDA (21 CFR 610.41(b)). Under 21 CFR 630.35(b), deferred donors with a previously false-positive result on an HIV diagnostic test may be considered for re-entry by a requalification method or process found acceptable for such purposes by FDA (21 CFR 630.35(b)). We recommend that you contact FDA for recommendations on a case by case basis for an acceptable requalification method or process.

6. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has engaged in non-prescription injection drug use in the past 3 months. If the individual has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.

7. Defer for 3 months from the most recent allogeneic transfusion, any individual who has a history of receiving an allogeneic transfusion of Whole Blood or blood components.

8. Defer for 3 months from the most recent exposure, any individual who has a history of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes.

9. Defer for 3 months from the most recent tattoo, ear or body piercing, an individual who has a history of tattoo, ear or body piercing. However, individuals who have undergone tattooing within 3 months of donation are eligible to donate without deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink. Individuals who have undergone ear or body piercing within 3 months of donation are eligible to donate without deferral if the piercing was done using single-use equipment.

10. Defer for 3 months after completion of treatment, an individual with a history of syphilis or gonorrhea, or an individual with a history of diagnosis or treatment for syphilis or gonorrhea in the past 3 months.

11. Defer for 3 months from the most recent sexual contact, a man who has had sex with another man during the past 3 months.

12. Defer for 3 months from the most recent sexual contact, a female who has had sex during the past 3 months with a man who has had sex with another man in the past 3 months.

We recommend that you defer indefinitely an individual with hemophilia or related clotting factor deficiencies requiring treatment with clotting factor concentrates for reasons of donor safety, rather than based upon the risk of HIV infection.

Note: Under 21 CFR 630.5 and 630.10(a), FDA requires the responsible physician of a blood collection establishment to determine the eligibility of a donor, and to defer any donor if the donation could adversely affect the health of the donor or the safety of the blood or blood component.

C. **Donor Requalification**

1. A donor deferred for any of the factors in section III.B. 2-12 of this guidance may be eligible to donate after the 3-month deferral period, provided the donor meets all other donor eligibility criteria.

2. A donor previously deferred indefinitely for: exchanging sex for money or drugs, for engaging in non-prescription injection drug use, or, for a male donor, having sex with another man, may be eligible to donate, provided the donor meets all donor eligibility criteria.

D. **Product Retrieval and Quarantine; Notification of Consignees of Blood and Blood Components**

If you collected blood or blood components from a donor who tests reactive for HIV on that donation, or when you are made aware of other reliable test results or information indicating evidence of HIV infection, you must follow the HIV "lookback" requirements in 21 CFR 610.46.

In addition, we recommend that you take the following actions if you determine that blood or blood components have been collected from a donor who should have been deferred according to the recommendations in section III.B. 2-12 of this guidance, for reasons other than a positive HIV test result.

1. If you collected blood or blood components from a donor who should have been deferred according to the recommendations in section III.B. of this guidance, we recommend that you quarantine and destroy any undistributed in-date blood or blood components collected from that donor.

2. If you distributed blood or blood components collected from a donor who should have been deferred according to the recommendations in section III.B. of this guidance, we recommend that you notify consignees of the in-date blood and blood components collected from the donor during the period that he or she should have been deferred. We recommend that the consignee retrieve and quarantine the in-date blood and blood components collected from that donor during the period he or she should have been deferred. We do not recommend retrieval and quarantine of plasma pooled for further manufacturing into products that are manufactured under processes that include validated viral clearance steps, which have been shown to be robust in the clearance of lipid-enveloped viruses.

## E. Product Disposition and Labeling

1. We recommend that you destroy or re-label blood or blood components that were collected from a donor who should have been deferred based on risk factors for HIV infection in accordance with the recommendations in section III.B. of this guidance. If you re-label the blood or blood components as described in this section, they may be released for research.

    a. You must use the following statement to prominently re-label the blood or blood components originally collected for transfusion in accordance with 21 CFR 606.121(f):

    "NOT FOR TRANSFUSION: Collected From a Donor Determined To Be At Risk For Infection With HIV"

    And,

    "Caution: For Laboratory Research Only"

2. You must destroy or re-label blood or blood components, including Source Plasma, collected from a donor who currently tests reactive for HIV or collected from a donor deferred for reactive HIV testing (21 CFR 610.40(h)). If you re-label the blood or blood components, including Source Plasma, in accordance with 21 CFR 610.40(h) and 606.121, the blood or blood components may be released for research or for manufacture into noninjectable products or in vitro diagnostic reagents when no other suitable sources are available. You must label the reactive unit with the "BIOHAZARD" legend (21 CFR 610.40(h)(2)(ii)(B)), and:

    a. You must use the following statement to prominently re-label the blood or blood components originally collected for transfusion (21 CFR 606.121(f)):

    "NOT FOR TRANSFUSION: Collected From a Donor Determined To Be Reactive for HIV"

    In addition, you should use one of the following cautionary label statements, as applicable:

    "Caution: For Laboratory Research Only"

    or

    "Caution: For Further Manufacturing into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources"

or

"Caution: For Further Manufacturing Use as a Component of a Medical Device For Which There Are No Alternative Sources"

b. You must use the following statement to prominently re-label the un-pooled blood or blood components, including Source Plasma, originally collected or intended for further manufacture (21 CFR 610.40(h)(2)(ii)(C)):

"Collected from a Donor Determined to be Reactive for Infection with HIV"

In addition, you should use one of the following cautionary label statements, as applicable:

"Caution: For Laboratory Research Only"

or

"Caution: For Further Manufacturing into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources"

or

"Caution: For Further Manufacturing Use as a Component of a Medical Device For Which There Are No Alternative Sources"

## F. Testing Requirements and Considerations

Section 610.40(a) (21 CFR 610.40(a)) requires establishments that collect blood or blood components to test each donation intended for transfusion or for use in manufacturing a product, for evidence of infection due to HIV type 1 (HIV-1) and HIV type 2 (HIV-2). In addition, 21 CFR 610.40(b) requires you to use one or more approved screening tests as necessary to reduce adequately and appropriately the risk of transmission of HIV-1 and HIV-2. FDA has considered the use of licensed donor screening tests for antibodies to both HIV-1 and HIV-2 as necessary to reduce adequately and appropriately the risk of transmission of HIV. In addition, FDA recommends the use of licensed HIV-1 nucleic acid donor screening tests to meet the requirements under 21 CFR 610.40(b).

You must defer a donor who tests reactive by a donor screening test for HIV-1 or HIV-2 (21 CFR 610.41) and you must perform further testing using a supplemental test on donations that test reactive on a screening test, when available. If no supplemental test is available, you must perform one or more licensed, approved or cleared tests as adequate and appropriate to provide additional information regarding the donor's infection status. (21 CFR 610.40(e)). You must make reasonable attempts to notify a donor who has been

deferred based on the results of tests for communicable diseases (21 CFR 630.6). Where appropriate, donors who are deferred because of reactive test results should be provided information about the need for medical follow-up and counseling.

## IV. IMPLEMENTATION

You may implement the recommendations once you have revised your DHQ, including the full-length and abbreviated DHQ, and accompanying materials to reflect the new donor deferral recommendations.

Licensed blood establishments must report changes to their approved application to FDA in accordance with 21 CFR 601.12.

1. Licensed blood establishments that revise their DHQs and accompanying materials must report the change to FDA in a Changes Being Effected (CBE) Supplement under 21 CFR 601.12(c)(5) (see 21 CFR 601.12(a)(3)). The blood and blood components collected using the change may be distributed immediately upon receipt of the supplement by FDA. Include the following information in your CBE Supplement:

    a. Form FDA 356h "Application to Market a New or Abbreviated New Drug, or Biologic for Human Use."
    b. Cover letter describing the request and contents of the supplement.
    c. The DHQ and accompanying document(s). Please highlight the modifications.

2. Licensed blood establishments that implement a revised version of the DHQ and accompanying materials prepared by the AABB Donor History Task Force or the Plasma Proteins Therapeutic Association (PPTA) found acceptable by FDA must report the changes to FDA in an annual report under 21 CFR 601.12(d), noting the date the process was implemented.

3. Unlicensed establishments are not required to report this change to FDA.

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新型コロナウイルス MAY 10, 2020 / 12:14 PM / UPDATED 9 MONTHS AGO

# Brazil's Supreme Court throws out rules that limit gay men donating blood

3 MIN READ

By Fabio Teixeira

RIO DE JANEIRO (Thomson Reuters Foundation) - Brazil's Supreme Court has overturned rules that limit gay and bisexual men from donating blood in a decision considered a human rights victory for LGBT+ people in the country.

The move came as more nations review restrictions on blood donations imposed during the 1980s HIV/AIDS crisis, with some countries imposing blanket bans, some waiting periods after gay sex, and others - like Italy - having no limitations at all.

After almost four years in court, seven of 11 Supreme Court justices voted on Friday in favor of overthrowing guidelines that barred men who had sex with other men from giving blood for 12 months, ending any waiting time.

The Supreme Court said the ban was unconstitutional as it imposed restrictions on gay and bisexual men, backing Supreme Court Minister Edson Fachin who argued this offended the basic human dignity of gay and bisexual men.

"Instead of the state enabling these people to promote good by donating blood, it unduly restricts solidarity based on prejudice and discrimination," wrote Fachin in his vote.

The decision comes after several nations have relaxed rules on blood donations in recent weeks as supplies face mounting pressure due to the coronavirus pandemic.

The United States, Denmark and Northern Ireland have all changed the rules so men can give blood three months after their latest gay sexual encounter rather than wait for one year, a policy LGBT+ campaigners have long decried as discriminatory.

Many countries introduced blood donation controls in the wake of the HIV/AIDS epidemic in the 1980s when infected blood, donated by drug users and prisoners, contaminated supplies.

But the issue has increasingly become a totem of continued stigma against LGBT+ people, with campaigners saying individual assessments of sexual history and risk for all potential blood donors would be safer and fairer.

In Brazil the case reached the Supreme Court in 2016, but it took until 2020 for a majority to be reached.

Minister Alexandre de Moraes, one of the four who voted against overthrowing the ban imposed by the Ministry of Health, argued that the waiting period was not discriminatory but based on technical studies.

For LGBT+ activists, the ruling was celebrated as a victory in a country where same-sex marriage is legal but LGBT+ people often face discriminatory government policies.

"A historical victory for the LGBT population! And the measure benefits everyone who needs donations, as blood stocks are almost always insufficient," wrote federal politician Samia Bomfim on Twitter after the decision.

**IN THE SUPREME COURT OF INDIA**

**(CIVIL ORIGINAL JURISDICTION)**

**I.A. No. OF 2021**

**IN**

**WRIT PETITION (CIVIL) NO. _____ OF 2021**

(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)

**IN THE MATTER OF:**

THANGJAM SANTA SINGH
@ SANTA KHURAI ...PETITIONER

VERSUS

UNION OF INDIA & ORS. ...RESPONDENTS

TO,
THE HON'BLE CHIEF JUSTICE OF INDIA
AND HIS COMPANION JUDGES OF
THE HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE
PETITIONER ABOVENAMED

**AN APPLICATION FOR INTERIM RELIEF**

**MOST RESPECTFULLY SHOWETH:**

1. The Petitioner, who is a member of the transgender community, is filing the present Writ Petition in public interest, on behalf of all transgender persons, challenging the Guidelines on Blood Donor Selection and Blood

Donor Referral, 2017 issued on 11.10.2017 by the NBTC (National Blood Transfusion Council), NACO (National Aids Control Organization), Ministry of Health and Family Welfare, Government of India which permanently defers/prohibits transgender persons, female sex workers and men having sex with men, from donating blood and being blood donors. Such a prohibition is a violation of the right to equality, dignity and life under Articles 14, 15 and 21 of the Constitution.

2. The Petitioner prays that the averments made in the Writ Petition may be read as part and parcel of this Application. The Petitioners crave leave of this Hon'ble Court to refer to and to rely upon the averments made in the Writ Petition which are not being reiterated herein for the sake brevity.

3. That this Hon'ble Court may kindly consider that the impugned Guideline which permanently defers transgender persons, men having sex with men and female sex workers, does not meet the test of intelligible differentia and rational aim under Article 14 of the Constitution of India more so if the aim is to ensure that safe blood is available for donation.

4. This Hon'ble Court may kindly consider that if the intention behind the Guidelines is to facilitate safe and sufficient supply of blood with minimal risk of infections amongst donors and make the act of blood donation safe, the impugned clauses of the guidelines have no rational

nexus with excluding these categories of persons as donors. Every unit of blood donated is tested for HIV and all infectious diseases including Hepatitis B, Hepatitis C, Malarial Parasite and HIV/AIDS and the risk of all persons can be minimised by taking information of their last high risk sexual contact and having a temporary deferral if necessary, from the date of such contact. Therefore, completely excluding them from donating blood simply because they are transgender, homosexual or sex workers is a violation of their right to equality under Article 14 of the Constitution.

5. That this Hon'ble Court may kindly consider that a blanket prohibition against transgender persons, men having sex with men and female sex workers from donating blood, to their loved ones, family members and relatives is discriminatory and is grounded in stigma against transgender persons and men having sex with men, and not based on any data or scientific rationale. The recommendations on Blood Donor Guidelines in many countries the world over have changed their donor recommendations and have not imposed any prohibition of transgender persons, have opted for shorter period such as 3 months deferrals in case of female sex workers and gay men from their last high risk sexual contact and hence the impugned clauses in the Guidelines are liable to be struck down.

6. That this Hon'ble Court may kindly consider that restricting transgender persons and persons of different sexual orientations who are already vulnerable, with little

education, poverty, lack of employment and inaccessible welfare facilities thus depriving them of access to health care will further ostracize them. This Hon'ble Court in *NALSA v. Union of India* AIR 2014 SC 1863 had recognised the fundamental right of transgender persons as citizens of the country to possess an equal right to realise their full potential as human beings. Hence, the impugned guidelines barring transgender persons from blood donations would further ostracize them and contribute to their social subordination and violate their right to a dignified life under Article 21.

7. That in view of the above it is most respectfully submitted that the impugned clauses of the guideline are violative of article 14, 15 and 21 of the Constitution of India besides being contrary to the law laid down by this Hon'able Court in NALSA judgement. Hence, it is submitted that the Petitioner has a good case on merits. That irreparable loss and injury shall be caused if the impugned guideline to the extent it permanently defers/prohibits transgender persons, men having sex with men and female sex workers from being blood donors is not stayed. Further, no prejudice would be caused to any of the Respondents if the present application is allowed.

8. This application is bonafide and in the interest of justice.

**PRAYER**

It is therefore, most respectfully prayed that this Hon'ble Court may be pleased to:

a. Grant ad interim exparte stay of the effect and operation of clause 12 of general criteria under Blood Donor Selection Criteria in the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated on 11.10.2017 to the extent it excludes transgender persons, men having sex with men and female sex workers from being blood donors;

b. Grant ad interim Ex-Parte stay of the effect and operation of clause 51 of General Criteria under Blood Donor Selection Criteria in the Guidelines for Blood Donor Selection and Blood Donor Referral, 2017 dated on 11.10.2017 to the extent it permanently defers transgender persons, men having sex with men and female sex workers from being blood donors; and

c. Pass any other order/directions that this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

**AND FOR THIS ACT OF KINDNESS, THE PETITIONER SHALL, AS IN DUTY BOUND EVER PRAY.**

**DRAWN BY:**

**Adv. Thulasi K. Raj**

**DRAWN & FILED BY:**

A. Pujari

**(ANINDITA PUJARI)**

**ADVOCATE FOR THE PETITIONER**

**SETTLED BY:**

**(JAYNA KOTHARI)**

**SENIOR ADVOCATE**