IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL WRIT JURISDICTION

WRIT PETITION (CIVIL) NO. 275 OF 2021

THANGJAM SANTA SINGH @ SANTA KHURAI

...PETITIONER

VERSUS

UNION OF INDIA & ORS.

...RESPONDENTS

PRELIMINARY AFFIDAVIT ON BEHALF OF RESPONDENT No. 1 / THE UNION OF INDIA

S.No.	Particulars	Page No.
1	PRELIMINARY AFFIDAVIT ON BEHALF OF RESPONDENT NO. 1	1-21
2	ANNEXURE A1	22-23
3	ANNEXURE A2	24-50
4	ANNEXURE A3	51-125
5	ANNEXURE A4	126-161
6	ANNEXURE A5	162-192
7	ANNEXURE A6	193-198
8	ANNEXURE A7	199-206
9	ANNEXURE A8	207-214
10	ANNEXURE A9	215-221
11	ANNEXURE A10	222-230
12	ANNEXURE A11	231-239
13	ANNEXURE A12	240-248
14	ANNEXURE A13	249-277
15	ANNEXURE A14	278-280
16	ANNEXURE A15	281-290
17	ANNEXURE A16	291-292
18	ANNEXURE A17	293-294

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I, B.K.Mishra, son of Shri B. Mishra, aged 54 years, working as Dy. Director in the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, the deponent herein, do hereby solemnly affirm and state on oath as under:

1. That I am working as Dy. Director in the Directorate General of Health Services in the Ministry of Health & Family Welfare,

NOTARY
A.N.SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

(MoHFW) Government of India. I am filing this affidavit in reply to the present Petition on behalf of the Union of India.

2. The Petitioners seek the following reliefs from this Hon'ble Court in the present Writ Petition:

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*

NOTARY A.N. SINGH Supreme Court of India Regd. No. 16959 Exp. Date:31.01.2025 GOVT. OF INDIA

unconstitutional and in violation of Articles 14, 15 and 21 of the Constitution;

3. At the outset it is important to note that a robust blood transfusion system (**'BTS'**) is an essential feature of any country's healthcare system without which quality medical care is impossible. Blood available in blood banks must not only be safe but also be clinically effective, and of appropriate and consistent quality. Ensuring the safety and availability of blood is a major public health responsibility.

4. However, provision of safe and quality blood for a country like India involves a highly complex operation involving various stakeholders, and the magnitude and complexity of issues raises several challenges. It is important that every effort be made to strengthen the integrity of India's BTS so as to instil confidence in people who have little option but to use the BTS in what may perhaps be the most difficult situation in their lives. In addition, since BTS entirely relies on blood donations, it is imperative that both the donor and the recipient at the opposite ends of BTS have complete faith that

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

the system functions in a manner that is safe, minimizing all possible risk of unsafe blood transfusion.

5. It is most respectfully submitted that the issues raised by the Petitioners fall within the domain of the executive, aided by medical, scientific and other technical experts, guided by evidence as well as their own professional experience. As such, the issues raised ought to be judged from the lens of a public health perspective and not merely from an individual rights perspective, being mindful of the practical realities of unequal access to quality healthcare in a vast and diverse nation.

BRIEF BACKGROUND

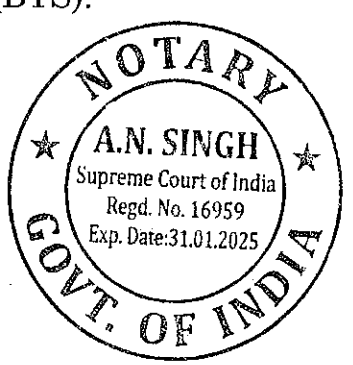
6. National Blood Policy focusses on sourcing blood from safe donor pool. Sourcing blood and components from high risk group is against the tenets of National Blood Policy. Blood Transfusion Services have to ensure that Blood/ Components are readily available by ensuring adequate collection, accessible enough to reach where it is most needed, affordable enough for the public at large, ensure safety against transfusion-transmitted infections ('**TTIs**') and of standard quality which provides requisite clinical benefit.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

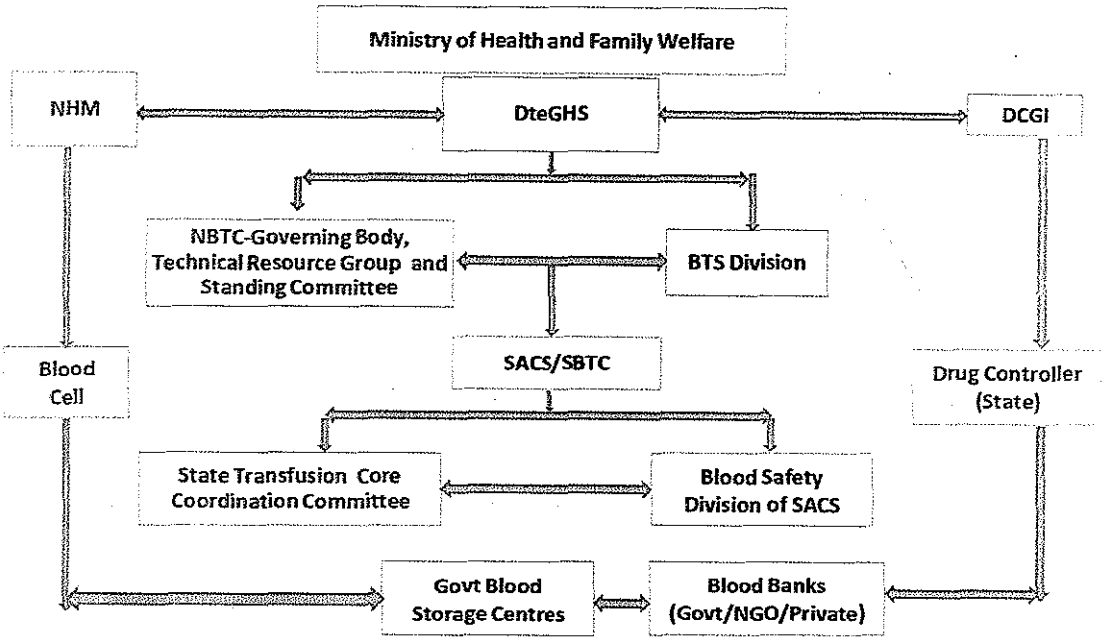
7. The National Blood Transfusion Council ('**NBTC**') within the Directorate General of Health Services under the MoHFW is the apex policy making body for blood transfusion services and blood safety in India. NBTC was constituted with the objectives to promote voluntary blood donation, ensure safe blood transfusion, provide infrastructure to blood centres, develop human resource and formulate and implement the Blood Policy.

True copy of Order dated 06.10.2022 re-constituting the Governing Body of the NBTC is annexed herewith and marked as **ANNEXURE A1 (Pg 22 to 23)**.

8. The NBTC is the policy formulating apex body in relation to all matters pertaining to operation of blood centres. It is the central body that coordinates the State Blood Transfusion Councils (SBTCs) and also ensures involvement of other Ministries and other health programmes for various activities relate to Blood Transfusion Services (BTS).



Organization of BTS in India



9. The NBTC is supported by a National Transfusion Services Core Coordination Committee under chairpersonship of Director General of Health Services and a Technical Resource Group.

10. Presently, the NBTC is housed within Directorate General of Health Services and functions through resources available with the Blood Transfusion Services Division. It is being empowered to fulfil its roles and responsibilities as the policy formulating apex body for all matters pertaining to the organization, operation, standards and training of a sustainable and safe blood transfusion service for the

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

country. Mechanisms for better coordination between NBTC and SBTC and providing technical, financial and managerial assistance to SBTC as needed to implement the national blood programme are being developed and implemented.

11. NACO/NBTC in collaboration with other institutions conducted a baseline assessment of 1126 NACO supported Blood Banks in July 2016 and the report "Assessment of NACO supported Blood Banks – A preliminary report 2016" was released on 28.07.2016. This was followed by a baseline assessment of all licensed Blood Banks in the country and the detailed report "Assessment of Blood Banks in India – 2016" was released on 01.12.2016. The Assessment of Blood Banks was carried out with the specific objectives of reviewing the existing situation in Blood Banks in terms of blood collection, voluntary blood donation, quality management systems, and other areas; and to categorize and grade the Blood Banks using a scoring system, for implementation of phased quality improvement systems. This assessment highlights the key issues, gaps, challenges, and gives possible opportunities to the state health officials and programme officers for taking necessary steps towards strengthening of the Blood Transfusion Services in the country.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

True copy of 'Assessment of NACO supported Blood Banks – A Preliminary Report 2016' is annexed herewith and marked as **ANNEXURE A2 (Pg 24 to 50)**.

True copy of 'Assessment of Blood Banks in India - 2016' is annexed herewith and marked as **ANNEXURE A3 (Pg 51 to 125)**.

GUIDELINES FOR BLOOD DONOR SELECTION AND BLOOD DONOR REFERRAL

12. After extensive consultations and deliberations among subject experts, the Governing Body of NBTC in its 26th meeting on 01.06.2017, approved the Guidelines for Blood Donor Selection and Blood Donor Referral dated 11.10.2017 ('**Guidelines**').

True copy of Minutes of 26th meeting of Governing Body of National Blood Transfusion Council dated 19.06.2017 is annexed herewith and marked as **ANNEXURE A4 (Pg 126 to 161)**.

True copy of Guidelines for Blood Donor Selection and Blood Donor Referral dated 11.10.2017 is annexed herewith and marked as **ANNEXURE A5 (Pg 162 to 192)**.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

13. The Petitioner has challenged Clauses 12 and 51 of the Guidelines as being violative of Articles 14, 15 and 21 of the Constitution of India to the extent they exclude transgender persons, men having sex with men and female sex workers from being blood donors. The said clauses are as under:

"Blood Donor Selection Criteria

General Criteria:

...

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.

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).

...

HIV Infection / AIDS

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

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

..."

[emphasis supplied]

14. By way of the impugned clauses, a special category of persons, who are considered to be at risk for HIV and Hepatitis B or C infections, are excluded from being blood donors.

15. The Petitioners contend that the impugned clauses are violative of Articles 14 and 15 of the Constitution since such exclusion constitutes discrimination on the ground of sex or gender identity. It is further argued that the exclusion does not meet the test of intelligible differentia and if the intention behind the Guidelines is to facilitate safe and sufficient supply of blood with minimal risk of infections amongst donors, it has no rational nexus with excluding these categories of persons as donors. Since the donated blood is tested for TTIs and information on the donor's sexual contact is collected, the Petitioners argue that the risk of TTIs can be minimised by collecting

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

the necessary information and having a temporary deferral if necessary, instead of an absolute exclusion.

REASONING BEHIND THE IMPUGNED CLAUSES

16. It is pertinent to note that the category of persons excluded under the Guidelines are those considered "at risk" for HIV, Hepatitis B or C infections. In this category of individuals, certain population groups have been specifically included. The Petitioners have impugned the inclusion of transgender persons, men having sex with men ('**MSM**') and female sex workers in this category.

17. The determination of population groups that should be excluded from being blood donors is done by subject experts based on scientific evidence. There is substantial evidence to show that transgender persons, men having sex with men and female sex workers are "at risk" for HIV, Hepatitis B or C infections. Reference in this regard may be made to the following select peer-reviewed studies published in reputed scientific journals:

a) *Prevalence of sexually transmitted infections among men having sex with men of urban Vadodara,* International Journal of

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959

Community Medicine and Public Health (2019) is annexed herewith and marked as **ANNEXURE A6 (Pg 193 to 198)**.

b) *Prevalence of HIV and sexually transmitted infections among clients of female sex workers in Karnataka, India: a cross-sectional study*, BMC Public Health (2011) is annexed herewith and marked as **ANNEXURE A7 (Pg 199 to 206)**.

c) *Geographic and behavioral differences associated with sexually transmitted infection prevalence among Indian men who have sex with men in Chennai and Mumbai*, International Journal of STD & AIDS (2021) is annexed herewith and marked as **ANNEXURE A8 (Pg 207 to 214)**.

d) *Sexually transmitted infections and HIV in self reporting men who have sex with men: A two-year study from India*, Journal of Infection and Public Health (2016) is annexed herewith and marked as **ANNEXURE A9 (Pg 215 to 221)**.

e) *Prevalence and Assessment of Clinical Management of Sexually Transmitted Infections among Female Sex Workers in Two Cities of India*, Infectious Diseases in Obstetrics and Gynecology (2011) is annexed herewith and marked as **ANNEXURE A10 (Pg 222 to 230)**.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

f) *HIV/AIDS-Related Risk Behaviors, HIV Prevalence, and Determinants for HIV Prevalence among Hijra/Transgender People in India: Findings from the 2014–2015 Integrated Biological and Behavioural Surveillance,* Indian Journal of Public Health (2020) is annexed herewith and marked as **ANNEXURE A11 (Pg 231to 239).**

g) *Worldwide burden of HIV in transgender women: a systematic review and meta-analysis,* Lancet Infectious Diseases (2012) is annexed herewith and marked as **ANNEXURE A12 (Pg 240 to 248).**

h) *Worldwide burden of HIV in transgender individuals: an updated systematic review and meta-analysis,* PLOS ONE (2021) ***(based on 98 studies from 34 countries, the meta-analysis concluded that transgender individuals are disproportionately burdened by HIV. HIV prevalence among transgender individuals varied by Geographic region between 13.5% to 29.9%.)*** is annexed herewith and marked as **ANNEXURE A13 (Pg 249 to 277).**

18. According to Annual Report of Department of Health and Family Welfare, Government of India for the year 2020-2021, the HIV

NOTARY A.N. SINGH Supreme Court of India Regd. No. 16959 Exp. Date:31.01.2025 GOVT. OF INDIA

prevalence among Hijras/Transgenders(H/TG), men who have sex with men (MSM) and female sex workers (FSW) is 6 to 13 times higher than adult HIV prevalence.

A true copy of relevant extracts of 2020-21 Annual Report of Department of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India is annexed herewith and marked as **ANNEXURE A14 (Pg 278 to 280)**.

19. Similar restrictions for blood donors in respect of population groups with a high prevalence of HIV and other TTIs exist all over the world. For instance, in most European countries, sexually active MSM are permanently deferred from donating blood.

A true copy of *Blood donor deferral policies across Europe and characteristics of men who have sex with men screened for human immunodeficiency virus in blood establishments: data from the European Men-who-have-sex-with-men Internet Survey (EMIS)*, Blood Transfus. (2018) is annexed herewith and marked as **ANNEXURE A15 (Pg 281 to 290)**.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

20. The scientific evidence placed above clearly shows that transgender persons, MSM and female sex workers are globally recognised as a population group with a higher prevalence of HIV and other TTIs. In particular, the evidence specific to India clearly establishes the basis for treating this category of individuals to be "at risk" for HIV, Hepatitis B or C infections as specified in the Guidelines. Thus, it is most respectfully submitted that the exclusion of transgenders, MSM, female sex workers as blood donors by including them in the category of those considered "at risk" for HIV, Hepatitis B or C infections is based on due consideration of scientific evidence.

21. Based on such scientific material, the NBTC, a body comprising medical and scientific experts, has prescribed the Guidelines which rightly exclude a category of individuals which are at risk for HIV, Hepatitis B or C infections and to include within that category, transgenders, MSM and female sex workers, who are scientifically proven to have a high prevalence of HIV and other TTIs.

One of the key strategies of BTS is component preparation from donated blood as to implement rational use of blood. The risk from

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

high risk donor is further multiplied by 3 times as three components are prepared from each unit of donated blood for use in three recipients.

22. It may also be noted that the Petitioners have not impugned the criteria for excluding individuals who are "at risk" for HIV, Hepatitis B or C infections but the inclusion of transgenders, MSM, female sex workers within that criteria. It is argued that their "at risk" categorization is rooted in stereotypes / stigma / prejudice and not scientific evidence. Thus, the material placed above is sufficient to meet the case of the Petitioners.

23. It may be kept in mind that the entire objective of a safe BTS is to ensure the health and safety of the recipient of the donated blood. Every effort has to be made to ensure that the recipient is shielded from an unfortunate result, especially since the consequences can be irreversible. Thus, even on the balance of individual rights of the blood donor versus the rights of the recipient, the right of the recipient to receive a safe blood transfusion far outweighs the right of an individual to donate blood. The integrity of the BTS is paramount from a public health perspective and constitutional courts should defer to the judgment of domain experts in this regard.

A.N. SINGH
Supreme Court of India
No 16959

A true copy of representation dated 28.11.2022 received from the Thalassemia Patients Advocacy Group objecting to the possible inclusion of transgenders, MSM and female sex workers as blood donors is annexed herewith and marked as **ANNEXURE A16 (Pg 291 to 292)**.

TESTING OF DONATED BLOOD AND INFECTION WINDOW PERIOD

24. The Petitioners argue that since the donated blood is tested for HIV and other relevant diseases, the risk of TTIs can be adequately minimised even if transgenders, MSM and female sex workers are allowed to donate blood. This submission is not sustainable for two reasons:

24.1 Infection window period:

24.1.1 The window period refers to the time between exposure to an infection agent and when a test can detect the infection in the human body. This period depends on the TTI and the type of test used. There is always a residual window period even with the best of tests, like Nucleic-acid testing ('**NAT**') test, which are conducted to screen blood donors.

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

24.1.2 Each TTI has one or more window periods, ranging from a few days to several months, depending on the infection, the screening marker used and the screening technology employed. During this window period, the infection is not yet detectable in a recently infected individual, and the individual may still be infectious.

24.2 Limitations of testing technologies: Most blood banks in India deploy non-NAT testing technologies. Even with NAT testing, which is only available in a small proportion of blood banks in India, a window period between 10-33 days still remains. (Reference https://www.cdc.gov/hiv/basics/hiv-testing/hiv-window-period.html).

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

A true copy of Nucleic acid testing-benefits and constraints, Asian Journal of Transfusion Science (2014) is annexed herewith and marked as **ANNEXURE A17 (Pg 293 to 294)**.

25. Due to the above limitations, it is submitted that even the most advanced testing technologies can never be completely full proof and it

is most critical to limit the pool of blood donors to individuals who present the least risk of TTIs as per available scientific evidence.

26. The Petitioners contend that instead of a complete exclusion, a deferral for a specific period may be considered for transgenders, MSM and female sex workers to donate blood, as is done in some developed countries. This submission may not be applicable in the Indian context. Developed nations have been successful in widely deploying NAT testing technology which reduces the window period for TTIs. There are a total of 3866 licensed blood banks in the country as per data on 30-11-2022. However, NAT testing is currently deployed in only a small fraction of the total blood banks in India since it is very expensive technology and requires trained manpower and specialized equipment requiring proper handling and regular maintenance. In India, the quality of the health system varies immensely across different geographies and one has to be mindful of this reality while framing Guidelines for the entire country.

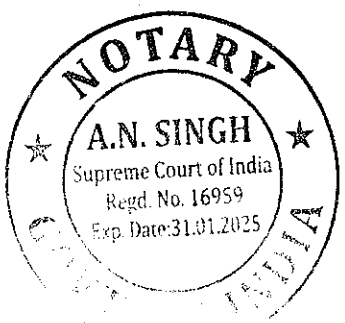
27. Population groups of trans-genders, MSM and female sex workers continue to be marginalized groups in the social fabric of India and find it difficult to seek timely treatment due to associated

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

stigma, even when they are infected. Due to this, the risk of transmission from these population groups further increases. There is also higher risk of transmission of new emerging diseases from these groups as was recently seen higher risk among MSM in the case of monkey pox.

28. In light of the above submissions, it is most respectfully submitted that the impugned Guidelines are not violative of Articles 14, 15 and 21 of the Constitution of India and categorizing transgenders, MSM and female sex workers in the category of individuals at risk of HIV, Hepatitis B or C is based on scientific evidence and due application of mind by domain experts.

29. It is humbly submitted that the prayers made by the Petitioners cannot be granted by this Hon'ble Court and the answering Respondent prays that the present Writ Petition be dismissed.



30. The present affidavit is filed bona fide and in the interest of justice.

DEPONENT

वी. के. मिश्रा / B. K. MISHRA
उप निदेशक / Deputy Director
स्वास्थ्य सेवा महानिदेशालय / Dte. G. H. S.
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
निर्माण भवन, नई दिल्ली / Nirman Bhawan, New Delhi

VERIFICATION

I, the deponent above named, do hereby verify that the contents of Para 1 to 30 of my above affidavit are prepared on the basis of instructions received by me and on the basis of legal advice received and no part of it is false and nothing material has been concealed therefrom to the best of my knowledge.

Verified at New Delhi on this 06.02.2023.

06 FEB 2023

I Identify the deponent who has Signed/Put T.I. in my presence

DEPONENT

NOTARY
A.N. SINGH
Supreme Court of India
Regd. No. 16959
Exp. Date:31.01.2025
GOVT. OF INDIA

वी. के. मिश्रा / B. K. MISHRA
उप निदेशक / Deputy Director
स्वास्थ्य सेवा महानिदेशालय / Dte. G. H. S.
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
निर्माण भवन, नई दिल्ली / Nirman Bhawan, New Delhi

Certified that the above Named Deponent identify by Shri/Smt. [illegible]
Solemenly affirmed before me at Delhi
S No.....
The contents of the affidavit which have been read & explained to me are true and correct

Notary

ATTESTED

06 FEB 2023

A.N. Singh, Adv.
Notary Public
Govt. of India, Delhi
Mob.: 9718139591, 7982539115

06 FEB 2023

ANNEXURE-A-1

22

No. IM 11012/09/2022-(NBTC/BTS)
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Sevices

Nirman Bhawan , New Delhi-110011
Dated the 6th Oct , 2022

ORDER

Subject: Re-constitution of the Governing Body of the National Blood Transfusion Council (NBTC) -reg.

With the approval of competent authority, it has been decided to re-constitute an interim governing body of National Blood Transfusion council (NBTC) in public interest and for smooth functioning of Blood Transfusion Services. The composition of the Committee of Governing body is as follows:

Ex-Officio Members:

DGHS	President
DDG/Addl.DDG, Dte.GHS	Director
AS&FA, MoHFW	Member
AS/JS(Policy/NHM)	Member
Representative of Secretary General, Indian Red Cross Society	Member
JS, NACO	Member
Representative of Chairperson, National Medical Commission	Member
Director, NIB or his representative	
Representative of Director General, Armed Forces Transfusion Centre	Member
DCGI, Dte.GHS	Member
One Member each from two SBTC on rotational basis of Meetings	Member (For one year)
ADG, Dte.GHS	Secretary

Non-Official Members:

1. President, Indian Association of Blood Banks
2. Secretary General, ISBTI.
3. Incharge Blood Bank, AIIMS, New Delhi
4. Incharge, Department of Blood Transfusion, Tata Memorial Hospital, Parel, Mumbai.
5. In-Charge Blood Transfusion Department, Safdarjung Hospital, New Delhi
6. In-Charge Blood Transfusion Department, ABVIMS and Dr. RML Hospital,New Delhi
7. In-charge Blood Transfusion Department, LHMC and associated hospitals, New Delhi

6/10/2022

8. Two Representatives from NGOs working for promotion of Blood donation, nominated by MoHFW for a period of three years as given under:
   (i) Representative of Akhil Bhartiya Terapanth Yuvak Parishad (ABTYP)

   (ii) Representative of Federation of Indian Blood Donors Organisation (FIBDO)

The existing rules for functioning of NBTC will be followed.

The SAG officer of CHS cadre looking after work of BTS and NBTC may be designated as Director NBTC along with his current designation.

The decisions taken by the above mentioned NBTC, re-constituted as above will be implemented, however the same will be put up for ratification by the body of NBTC that will be constituted after the Miscellaneous Application in Writ Petition (Civil) No. 91 of 1992 for waiver of the Hon'ble Supreme Court, for transitioning of National Blood Transfusion Council (NBTC) from NACO to Dte.GHS is decided.

This issue with the approval of Hon'ble HFM

6/X/2022

(M. C. Shukla)
Joint Director, BTS

To

All members of the Committee as above

Copy to:

1. PS to Hon'ble HFM.
2. PS to Hon'ble MOS.
3. PPS to Secretary (Health).
4. PSO to DGHS.
5. PPS to Addl. Secretary (NACO)/AS and MD (NHM)/Addl Secretary (Food & Drug)/ Addl Secretary (Health).
6. Joint Secretary (Policy)/Joint Secretary (Regulation).
7. All President, State/UT Blood Transfusion Councils.
8. All Project Directors, State/UT AIDS Control Society.
9. All Mission Directors of States/UTs, National Health Mission.
10. Drug Controller General of India, CDSCO.
11. Secretary (NMC)/Secretary (IRCS).
12. Incharge/Deputy Govt. Advocate, Central Agency Section, Supreme Court Compound, New Delhi

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ANNEXURE-A-2 (24)

Assessment of NACO Supported blood banks
A Preliminary Report 2016

National AIDS Control Organization (NACO) and
National Blood Transfusion Council (NBTC),
Ministry of Health and Family Welfare, Government of India
in collaboration with
U.S Centers for Disease Control and Prevention (HHS/CDC)
Division of Global HIV and TB (DGHT), India,
Christian Medical College, Vellore
&
Christian Medical Association of India (CMAI), New Delhi

(25)

डॉ सी.वी. धर्मा राव
संयुक्त सचिव

Dr. C. V. Dharma Rao
Joint Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
राष्ट्रीय एड्स नियंत्रण संगठन
9वां तल, चन्द्रलोक बिल्डिंग, 36 जनपथ, नई दिल्ली -110001

Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation
9th Floor, Chandralok Building, 36 Janpath, New Delhi - 110 001

FOREWORD

Blood Transfusion Service is an indispensable part of a health care system. It is essential to ensure the provision of adequate, safe, appropriate and consistent quality of blood and blood components to all those who are in need of a transfusion. This requires a comprehensive approach in planning, designing and operationalizing of Blood Transfusion Services in India which is centrally coordinated and based on voluntary non-remunerated blood donation.

During the last two decades, the National Blood Transfusion Council (NBTC) and National AIDS Control Organization (NACO) have been making significant efforts to ensure access to safe and quality blood and blood products. There has been a substantial improvement in blood transfusion services; however, it is essential to ensure the quality of service delivery at the district, state and regional levels through an evidence-based approach.

This preliminary report would definitely be a useful guide and a reference material that would explain the current situation of blood transfusion services, the gaps, challenges and recommendations to improve the blood transfusion services in the country. This report will also serve as a baseline for assessing the effectiveness of future programmatic interventions.

I would like to congratulate the team at National Blood Transfusion Council and National AIDS Control Organization for taking this initiative. I would also like to thank the US Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT) India, Christian Medical College (CMC), Vellore and Christian Medical Association of India (CMAI) for their support.

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PREFACE

Since the inception of National AIDS Control programme in 1992, followed by the formation of National Blood Transfusion Council, the Blood Safety Programme in India has been making significant advancement in availability and access to safe and quality blood and blood components even to far-flung remote areas of the country. Some of the key strategies under NACP IV (2012-17) are, strengthening management structure of blood transfusion services and implementing quality management practices in blood transfusion services.

The Assessment of NACO supported Blood Banks was carried out with the specific objectives of reviewing the existing situation in Blood Banks in terms of collection of blood, voluntary blood donation, quality management systems, and other areas; and to categorize and grade the blood banks using a scoring system, for implementation of phased quality improvement systems. This report highlights the key issues, gaps, challenges, and possible opportunities to the State health officials and programme officers of State Blood Transfusion Council and State AIDS Control Societies.

I take this opportunity to extend my sincere appreciation to the team at NACO and NBTC for their valuable support. I also wish to express my thanks to the US Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT) India, Christian Medical College (CMC), Vellore and Christian Medical Association of India (CMAI) for providing technical assistance and support in completing the assessment and developing the report.

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27

Table of Contents

	Foreword	i
	Preface	iii
	Table of contents	v
	Abbreviation	vi
	Figures and Tables	vii
1.	Background	1
2.	Objectives	2
3.	Methodology	2
4.	Key Findings	5
	4.1 Basic details of blood banks	6
	4.2 Annual collection and voluntary blood donation	7
	4.3 Transfusion transmitted infections	10
	4.4 Component separation	14
	4.5 Quality Management Systems	15
	Assessment score by ownership	17
	Assessment score by annual blood collection	18
	Assessment score by voluntary blood donation	18
	Assessment score by EQAS participation	19
	Assessment score by accreditation status	19
5.	Conclusions	21
6.	Reference	22

Abbreviations

BB	- Blood Bank
BCSU	- Blood Component Separation Units
CHEMI	- Chemiluminescence
DAT	- Direct Antiglobulin Test
DCT	- Direct Coombs Test
ELISA	- Enzyme Linked Immuno Sorbent Assay
EQAS	- External Quality Assessment Scheme
FDA	- Food and Drug Administration
FFP	- Fresh frozen plasma
HIV	- Human Immunodeficiency Virus
HBV	- Hepatitis B virus
HCV	- Hepatitis C virus
HVPI	- Haemovigilance Program of India
IAT	- Indirect Antiglobulin Test
ICT	- Indirect Coombs Test
IH	- Immunohematology
IQC	- Internal Quality Control
IQR	- Interquartile range
NACO	- National AIDS Control Organisation
NAT	- Nucleic Acid Testing
NBTC	- National Blood Transfusion Council
NGO	- Non Governmental Organisation
NHP	- National Health Portal
PSU	- Public Sector Units
QC	- Quality Control
QMS	- Quality Management Systems
RPR	- Rapid Plasma Reagin
SBTC	- State Blood Transfusion Council
SD	- Standard deviation
SIMS	- Strategic Information Management System
SOPs	- Standard Operating Procedures
TTI	- Transfusion Transmitted Infection
TPHA	- Treponema Pallidum Hemagglutination Assay
VNRBD	- Voluntary, Non-Remunerated Blood Donation
VBD	- Voluntary Blood Donor/Donation
WHO	- World Health Organization

29

Tables and Figures

Tables

Table 1 - Details of technical areas included in the assessment 2
Table 2 - Scoring details and weight 3
Table 3 - State wise description of NACO supported blood banks 5
Table 4 - Basic details of blood banks 7
Table 5 - Annual blood collection and percentage of VBD 9
Table 6 - Transfusion Transmitted Infections by Category of blood banks 10
Table 7 - Number of blood banks scored <=35 16
Table 8 - Number of blood banks scored above 70 16
Table 9 - Mean assessment score by Category of blood banks 17
Table 10 - Assessment score (categories) by category of blood banks 17
Table 11 - Mean assessment score by ownership 18
Table 12 - Assessment score (categories) by ownership 18
Table 13 - Mean assessment score by annual collection 18
Table 14 - Mean assessment score by voluntary blood donation 18
Table 15 - Mean assessment score by EQAS enrolment 19
Table 16 - Mean assessment score by accreditation 19
Table 17 - Distribution of Blood banks by state and assessment score categories 20

Figures

Figure 1 - Availability of NACO supported BBs per 1 million population 6
Figure 2 - Licence status 7
Figure 3 - Annual collection and Voluntary donation 8
Figure 4 - Type of blood donation 8
Figure 5 - Percentage of voluntary blood donation by state 9
Figure 6 - Transfusion Transmitted Infections (%) 10
Figure 7 - HIV seropositivity - By state (%) 11
Figure 8 - HCV seropositivity - By state (%) 12
Figure 9 - HBV seropositivity - By state (%) 12
Figure 10 - Syphilis seropositivity- By state (%) 13
Figure 11 - Malaria Positivity– By state (%) 13
Figure 12 - Total blood collection and component separation 14
Figure 13 - Percentage of component separation – By state 14
Figure 14 - Categorisation of blood banks 15
Figure 15 - Mean assessment score - By state 15
Figure 16 - BBs with component- score 17
Figure 17 - BBs without component- score 17

Assessment of NACO supported Blood Banks

1. Background

Access to adequate, safe and quality blood and blood products is vital for any health care system which is primarily the responsibility of the government/national health authority of each country (Ramani, Mavalankar, & Govil, 2007). It is essential to establish a sustainable national blood system that should be supported by a national blood policy, strategic plan and appropriate legal instruments (WHO, 2011). In India, the National AIDS Control Organization (NACO) under the Ministry of Health and Family Welfare, and National Blood Transfusion Council (NBTC) which is the apex policy making body are the prime bodies responsible for the functioning of blood transfusion services and blood safety at the national level. At the state level, the respective state AIDS Control societies (SACS) and state Blood Transfusion Councils(SBTCs) are responsible for the smooth functioning of blood transfusion services.

The Supreme Court verdict in 1996 directed the government to improve the blood transfusion services (BTS) that resulted in establishing the National and State Blood transfusion Councils (NBTC/SBTC) for bringing about improvements in blood transfusion services. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993 through which the licensing of blood banks was brought under the dual authority of the state and central government (MoHFW, 2013). The state licensing authority issues the license, while the Drug Controller General (India) is the central license approving authority. In 2002, the WHO Guidelines on the clinical use of blood was adopted by NACO. In the same year, Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007a).

In 2007, the National AIDS Control Organization(NACO) developed standards for blood banks and blood transfusion services. This clearly spelled out the need for mandatory licensing and compliance to all regulatory norms; compliance to policies/ guidelines of NBTC; donor selection/ recruitment/ retention/ counseling based on voluntary non-remunerated regular repeat blood donors; appropriate blood collection procedures; mandatory testing of all donated Blood units for HIV, HBV, HCV, Syphilis, Malaria; transportation of blood and blood components ensuring cold chain maintenance; manpower requirements; maintenance of quality assurance system; regular maintenance and calibration of equipment; biosafety; waste disposal mechanisms; documentation, record keeping and regular reporting under blood the national programme (NACO, 2007b).

Since the inception of National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization (NACO) has been making significant strides towards ensuring access to safe and quality blood and blood products to all those who are in need of a transfusion. The goals and objectives of the programme are to ensure, provision of safe and quality blood even to far-flung remote areas of the country. NACO has been taking continuous steps to strengthen the blood banks across the country by providing equipment, consumables, manpower and capacity building. The efforts to modernizing blood-banks, establishing model blood banks, and setting up blood storage centers in rural areas have improved the quality of blood transfusion services in the country. The current phase of the National AIDS Control Programme (NACP IV 2012 -2017) emphasizes blood safety that aims to support 1,300 blood banks and aims to achieve 90,00,000 blood units from NACO supported Blood Banks and 95% voluntary blood donation in 2016-17. The key strategies under NACP IV are, strengthening management structure of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services; and new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

India has 1,126 National AIDS Control Organization (NACO), Ministry of Health and Family Welfare (MoHFW) supported blood banks out of the total 2,760 blood banks in the country (CDSCO, 2015). NACO has been providing technical and operational support to improve the efficiency and effectiveness of these blood banks thereby, increasing the availability and accessibility of safe and quality blood and blood products to those who are in need. Though there has been a substantial improvement in BTS in India over a period of time, there

(31)

are still gaps in ensuring access to quality blood and blood products to all those who are in need, that need to be addressed at the district, state and regional level through an evidence-based approach.

In order to have evidence-based programmes, and policies, accurate and updated information at the district, state and national level is an essential prerequisite. Lack of updated information is one of the key barriers affecting the planning and implementation of blood transfusion services across the country. Though current programmes emphasise quality management systems including EQAS and accreditation in blood banks, not much information is available related to this area. In specific, information on the existing practices of blood banks, their potential, and willingness to get involved in the programmes on quality management systems (QMS) are critical factors that will facilitate developing appropriate strategies and programmes related to QMS at the National level.

Therefore, facility-wise updated information on structural and programmatic components, the gaps and challenges are required which will not only facilitate better programmes and policies in BTS, but also serve as a baseline for specific programmes that are being and will be implemented at district, state, region, and national level. Considering the above factors, an assessment of all NACO supported Blood Banks was conducted in the country.

2. Objectives

The overall purpose of this assessment was to understand the current situation of NACO supported blood banks, in terms of facilities, services, gaps and challenges.

The specific objectives were,

- To develop an updated database with basic essential details of NACO supported blood banks in the country.
- To review the existing situation of blood banks in terms of collection of blood, voluntary blood donation, quality management systems, and other programme areas.
- To categorise and grade the blood banks using a scoring system, for implementation of phased quality improvement systems.
- To provide evidence for the formulation of evidence-based policies and programmes for blood transfusion services in India.

3. Methodology

This assessment was a cross-sectional survey that captured the current situation of NACO supported blood banks in the country. All NACO supported blood banks (1126) were included in the survey. The review focused on the following components:

Table -1 - Details of technical areas included in the assessment

S No	Component	Description
1	General	Basic details, Ownership, Category, License, etc
2	Collection and VBD	Annual Collection, VNRBD and donor management
3	Technical – IH, TTIs, components	Methodology, Performances
4	Quality Management System	Compliance to Quality System Essentials (QSE)
5	HR, Training, and Equipment	Availability and Participation

Tool: A self-assessment questionnaire that included all the above-mentioned components was developed in consultation with programme officials and experts from public health, epidemiology, bio-statistics, and transfusion medicine.

Data Handling and analysis Management: The database for this study was developed and maintained by Clinical Data Management Centre (CDMC), Department of Biostatistics, Christian Medical College, Vellore, India. In-built validation checks were incorporated in the system to confirm that all study related parameters are captured completely and accurately.

Data were analysed using SPSS Version 21 for Windows. The data were screened for outliers and extreme values using histograms, frequency distribution and Box plots. To summarize the whole data, frequency distributions and bar/pie charts were done for qualitative(categorical) variables such as ownership, type of blood banks etc., and descriptive statistics like mean, standard deviation, median, IQR, minimum, and maximum were done for quantitative variables such as, annual collection, voluntary blood donation, etc. Comparison of the mean of different variables was done using an independent t-test or ANOVA if the distribution was normal. Mann-Whitney or Kruskal-Wallis test was done if the data was not normally distributed.

Categorisation of blood banks and scoring: The blood banks have been categorized into two categories based on the availability of component separation facility and annual collection. The first category is blood banks with component separation facility that includes Model Blood banks and Blood component separation Units (BCSU). Model blood banks collect more than 10,000 units and BCSUs collect between 5,000 to 10,000 units of blood annually. The second category is blood banks without component separation facility that includes Major blood banks and District level blood banks (DLBB). Major blood banks collect between 3,000 to 5,000 units and district level blood banks collect up to 3,000 units annually.

Each component of the tool was given a weight based on the programmatic and quality priorities. The maximum achievable sum of all weighted scores under each component totalled 100 marks.

Table -2–Scoring details and weight

Details	With Components	Without Components
Licence	3	3
Annual Collection, VBD, Repeat donation and Counselling	11	16
Technical - IH, TTI and Component separation	43	38
Quality Management Systems	35	35
Reporting	8	8
TOTAL	**100**	**100**

The scoring pattern was different based on the category of blood banks that are, 1. Blood banks with component separation facility (n=427; Model blood bank and Blood component separation units) and, 2. Blood banks without component separation facility (n=674; District level blood banks and Major blood banks). Marks were allocated to each indicator under specific components based on the expected level of performance by these two categories of blood banks.

The blood banks were categorised based on the scores obtained by each blood bank that are less than and equal to 35 (Red); 36 to 70 (Yellow) and above 70(Green).

(33)

4. Key Findings

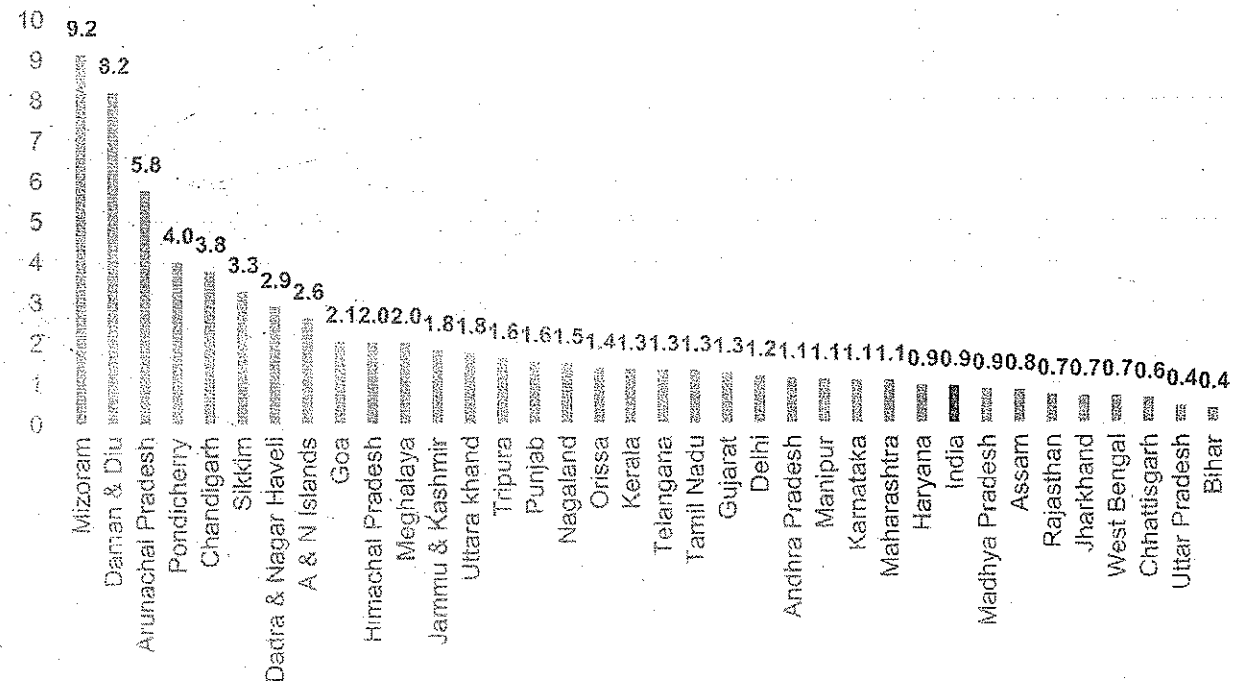
Out of 1126, NACO supported blood banks in the country, 1101 blood banks that reported were considered for analysis. Table- 3 indicates the state-wise details of NACO supported blood banks (n= 1126). Maharashtra (120) had the highest number of NACO supported blood banks followed by Tamil Nadu (95), Uttar Pradesh (89), Gujarat (77) and Karnataka (66).

Table -3–State wise description of NACO supported blood banks (n=1126)

State	No of BBs	%
Andaman and Nicobar	1	0.09
Andhra Pradesh	59	5.24
Arunachal Pradesh	8	0.71
Assam	26	2.31
Bihar	39	3.46
Chandigarh.	4	0.36
Chhattisgarh	16	1.42
Dadra & Nagar Haveli	1	0.09
Daman and Diu	2	0.18
Delhi	20	1.78
Goa	3	0.27
Gujarat	77	6.84
Haryana	24	2.13
Himachal Pradesh	14	1.24
Jammu & Kashmir	23	2.04
Jharkhand	23	2.04
Karnataka	66	5.86
Kerala	45	4.00
Madhya Pradesh	62	5.51
Maharashtra	120	10.66
Manipur	3	0.27
Meghalaya	6	0.53
Mizoram	10	0.89
Nagaland	3	0.27
Odisha	58	5.15
Puducherry	5	0.44
Punjab	43	3.82
Rajasthan	49	4.35
Sikkim	2	0.18
Tamil Nadu	95	8.44
Telangana	43	3.82
Tripura	6	0.53
Uttar Pradesh	89	7.90
Uttarakhand	18	1.60
West Bengal	63	5.60
India	**1126**	**100.00**

Considering the number of NACO supported blood banks in terms of population size, states such as, Bihar (0.4 blood bank), UP (0.4), Chhattisgarh (0.6), West Bengal (0.7), Jharkhand (0.7), Rajasthan(0.7), Assam(0.8) and Madhya Pradesh (0.9) recorded less number of blood banks per 1,000,000 (one million) population whereas the national average was 0.9 blood bank per 1 million population.

Fig 1- Availability of NACO supported BBs per 1,000,000 (1 million) population



4.1 Basic details of blood banks (n = 1101)

Category of Blood Banks: Thirty-nine percent (427) of NACO supported blood banks had component separation facility and the remaining 61% (674) blood banks did not have component separation facility.

At the state level, Delhi state had the highest percentage of blood component separation units (95%) out of the total available blood banks in the state, followed by Chandigarh (75%), Maharashtra (71.6%), Karnataka (61.5%), Gujarat (58.7%), and Kerala (57.8%). States like Odisha (9.6%), Madhya Pradesh (16.1%), Assam (19.2%), Bihar (17.9%), Tamil Nadu (23.2%), West Bengal (23.8%), Rajasthan (25.5%), Chhattisgarh (25%), and Uttarakhand (27.8%) had a low proportion of blood component separation facility. Andaman & Nicobar and Dadra Nagar Haveli had one each NACO supported blood banks that had component separation facility.

Ownership: The majority (867; 79%) of NACO supported blood banks were owned by the public sector and 21% (234) were owned by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. The non-governmental sector had a higher proportion (62.8 %) of component separation facilities compared to the public sector (32.3%).

Organizational Attachment: The majority of NACO supported blood banks (950; 86%) were attached to hospitals and only 14% (151) were stand-alone blood banks. Around 98.8% (857) of public sector blood banks were attached to hospitals whereas 39.7% (93) of charitable blood banks were attached to hospitals.

The majority of standalone blood banks (72.2%; 109) had blood component separation facilities, and only 33.5% (318) of blood banks that were attached to hospitals had blood component separation facilities.

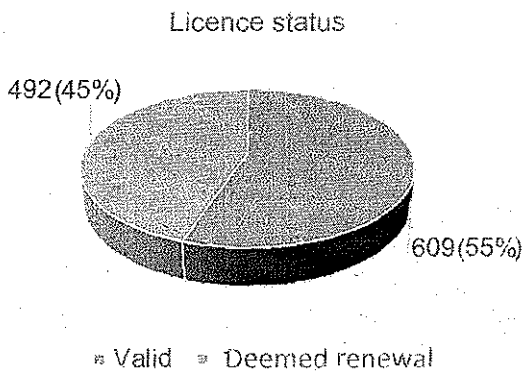
35

Table -4–Basic details of blood banks

Content	Specifics component	BBs with component	BBs without BBs	Total
Ownership				
	Public	280 (32.3%)	587 (67.7%)	867
	NGO/Trust/Charitable	147 (62.8%)	87 (37.2%)	234
Organizational Attachment				
	Attached to Hospitals	318 (33.5%)	632 (66.5%)	950
	Standalone	109 (72.2%)	42(27.8%)	151
Licence				
	Valid	306 (50.2%)	303(49.8%)	609
	Deemed renewal	121 (24.6%)	371 (75.4%)	492
Total		**427(39%)**	**674(61%)**	**1101**

*Licence details of blood banks:*The licence status was categorised as "valid"which means that the blood bank has current and active licence; and "deemed renewal"which means that the blood bank had applied for renewal which is pending. Around 55% (609) of blood banks had a valid and current licence and the remaining 45% (492) had applied for renewal. The majority of those blood banks (67.7%) that reported as "deemed renewal" had their last inspection by licencing authority during the last one year; 18.3% had their inspection between the last 1 to 2 years, 6.3% had between 2 to 3 years, 2.4% had between 3 to 4 years and 5.3% had their inspection before 4 years.

Fig -2–Licence status



4.2 Annual Blood collection and Voluntary blood donation

According to WHO, it is estimated that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010), which means India currently needs around 12.8 million units of blood.

During January 2015 to December 2015, the annual blood collection from 1101 blood banks(39.8%) out of 2760 blood banks in the country was 6,828,055, of which 80.5% (5,499,823) units were through voluntary blood donations and the remaining from replacement donations. Blood banks with component separation facility (n=427) collected around 70% of blood units (4,788,493) and the remaining (2,039,562) were collected by blood banks without component separation facility (n=674). Besides, blood banks with component separation facility collected 79.8% of the total collection through voluntary blood donation whereas, blood banks without component facility collected slightly higher percentage (82.3%) though voluntary blood donation.

Fig -3–Annual collection and Voluntary donation

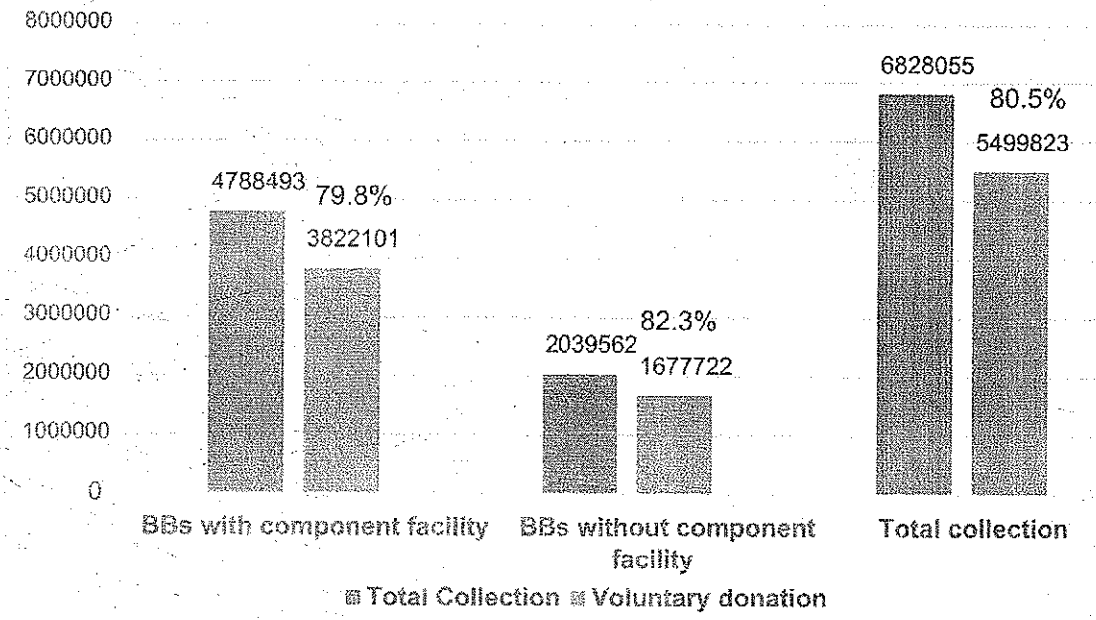
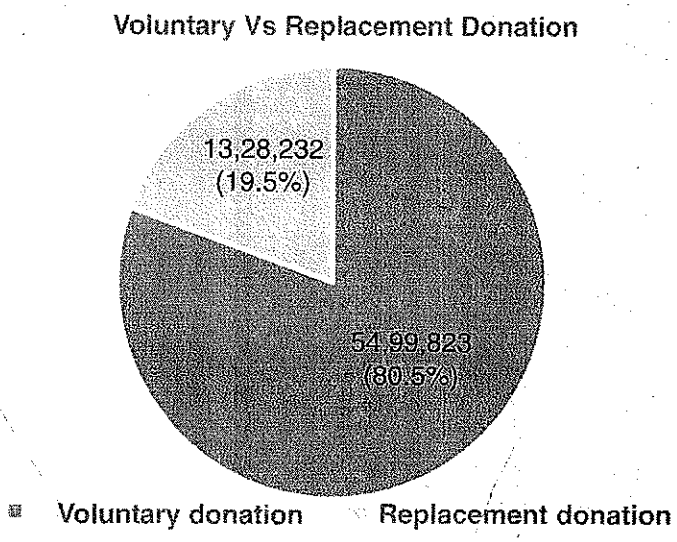
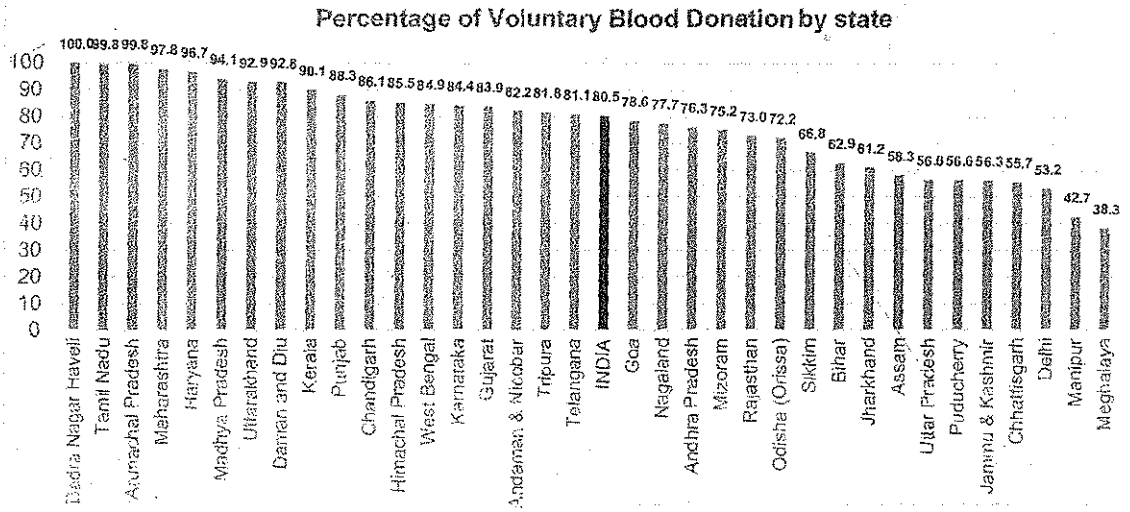


Fig 4- Type of blood donation



37

Fig 5–Percentage of voluntary blood donation by state



The state-wise details of voluntary, replacement and total donation are mentioned in Table-5.

Eighteen states have recorded more than 80% voluntary blood donation which is above the national average of 80.5%. States such as Dadra Nagar Haveli, Tamil Nadu, Arunachal Pradesh, Maharashtra, Haryana, Madhya Pradesh, Uttarakhand, Daman and Diu and Kerala reported more than 90% voluntary blood donation. States such as Meghalaya, Manipur, Delhi, Chhattisgarh, Jammu & Kashmir, Puducherry, Uttar Pradesh and Assam reported less than 60% of voluntary blood donation during January to December 2015.

Table -5–Annual blood collection and percentage of VBD

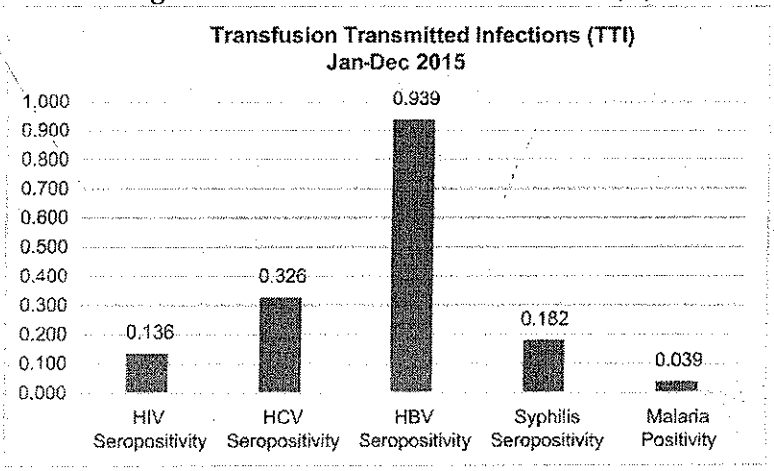
States	Total Voluntary donations	Total replacement donations	Total Collection (Jan - Dec 2015)	% VBD
Andaman & Nicobar	3,095	670	3,765	82.2
Andhra Pradesh	2,09,634	65,259	2,74,893	76.3
Arunachal Pradesh	4,944	12	4,956	99.8
Assam	84,043	60,066	1,44,109	58.3
Bihar	69,675	41,023	1,10,698	62.9
Chandigarh	76,778	12,421	89,199	86.1
Chhattisgarh	48,341	38,383	86,724	55.7
Dadra Nagar Haveli	7,497	-	7,497	100.0
Daman and Diu	1,576	122	1,698	92.8
Delhi	1,63,781	1,44,261	3,08,042	53.2
Goa	15,273	4,166	19,439	78.6
Gujarat	5,09,012	97,671	6,06,683	83.9
Haryana	1,67,745	5,747	1,73,492	96.7
Himachal Pradesh	30,001	5,099	35,100	85.5
Jammu & Kashmir	44,674	34,699	79,373	56.3

Jharkhand	77,882	49,383	1,27,265	61.2
Karnataka	3,30,583	61,318	3,91,901	84.4
Kerala	2,54,827	28,054	2,82,881	90.1
Madhya Pradesh	2,99,824	18,771	3,18,595	94.1
Maharashtra	7,87,548	17,778	8,05,326	97.8
Manipur	8,390	11,256	19,646	42.7
Meghalaya	5,178	8,358	13,536	38.3
Mizoram	18,543	6,115	24,658	75.2
Nagaland	7,038	2,017	9,055	77.7
Odisha (Orissa)	2,22,696	85,935	3,08,631	72.2
Puducherry	14,522	11,151	25,673	56.6
Punjab	1,85,996	24,661	2,10,657	88.3
Rajasthan	3,00,092	1,10,946	4,11,038	73.0
Sikkim	2,824	1,403	4,227	66.8
Tamil Nadu	3,88,636	689	3,89,325	99.8
Telangana	1,50,103	34,959	1,85,062	81.1
Tripura	23,238	5,171	28,409	81.8
Uttar Pradesh	2,96,938	2,27,250	5,24,188	56.6
Uttarakhand	91,603	6,957	98,560	92.9
West Bengal	5,97,293	1,06,461	7,03,754	84.9
INDIA	**54,99,823**	**13,28,232**	**68,28,055**	**80.5**

4.3 Transfusion Transmitted Infections (TTIs)

Transfusion transmitted infections (TTIs) are major problems associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Screening for TTIs such as, HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria, and Syphilis is mandatory in India. Due to the concerted and active efforts, the prevalence of TTIs has come down significantly over the years.

Fig-6 Transfusion Transmitted Infections (%)



39

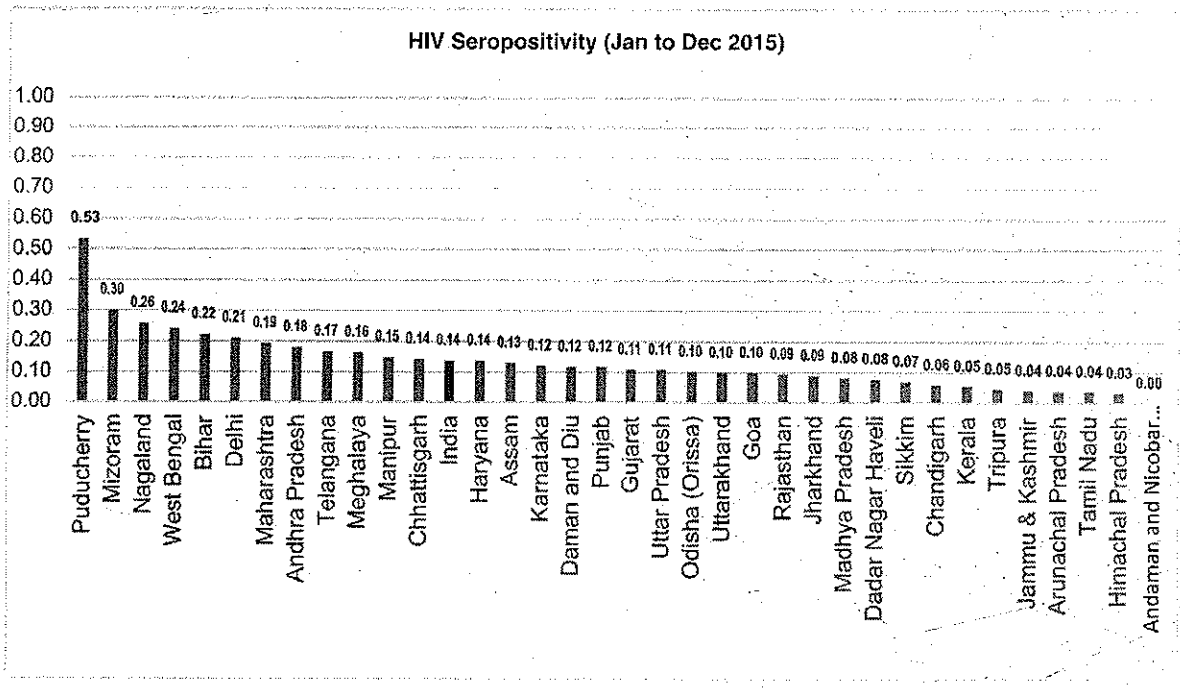
The seropositivity of transfusion transmitted infections (TTI) among blood donors in the year 2015 is depicted in Fig-6. HIV positivity was found to be 0.136%, Hepatitis C was 0.326%, Hepatitis B-0.939%, Syphilis 0.182% and Malaria 0.039%. However, there is a huge variation between states.

Transfusion Transmitted Infections by Category of blood banks: The blood banks with component facility indicated a higher positivity of HIV (0.141); HVC (0.363) and HBV (0.969). However, Syphilis (0.309) and Malaria (0.053) were found to be higher in blood banks without component facility compared to blood banks with the component facility.

Table-6 Transfusion Transmitted Infections by Category of blood banks

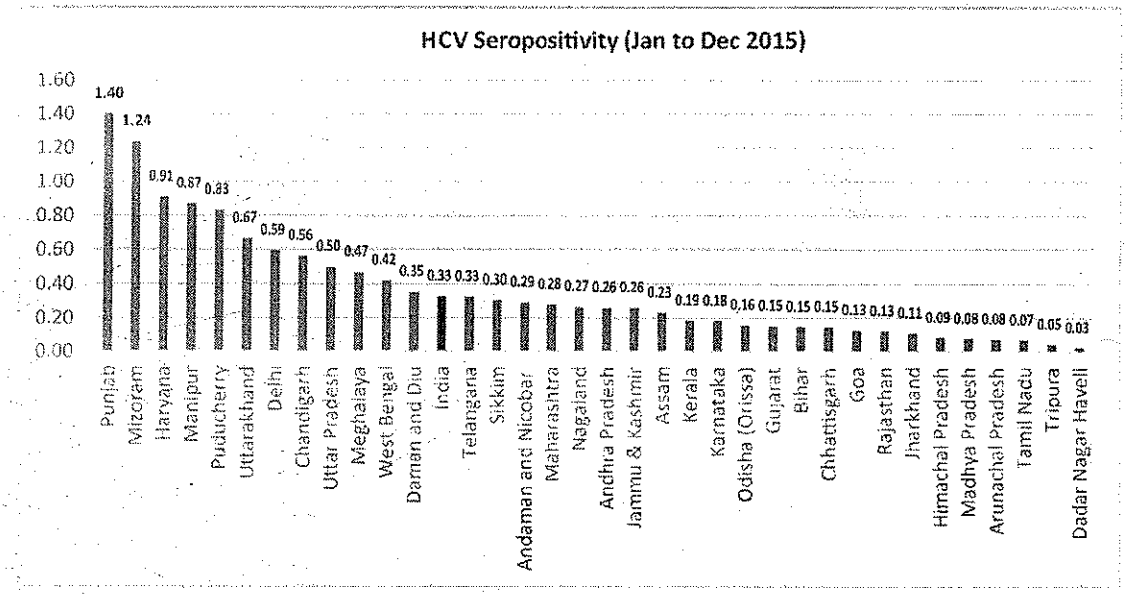
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.141	0.363	0.969	0.127	0.033
BBs without component facility	0.126	0.241	0.867	0.309	0.053
Overall	**0.136**	**0.326**	**0.939**	**0.182**	**0.039**

Fig-7 HIV seropositivity – By state (%)



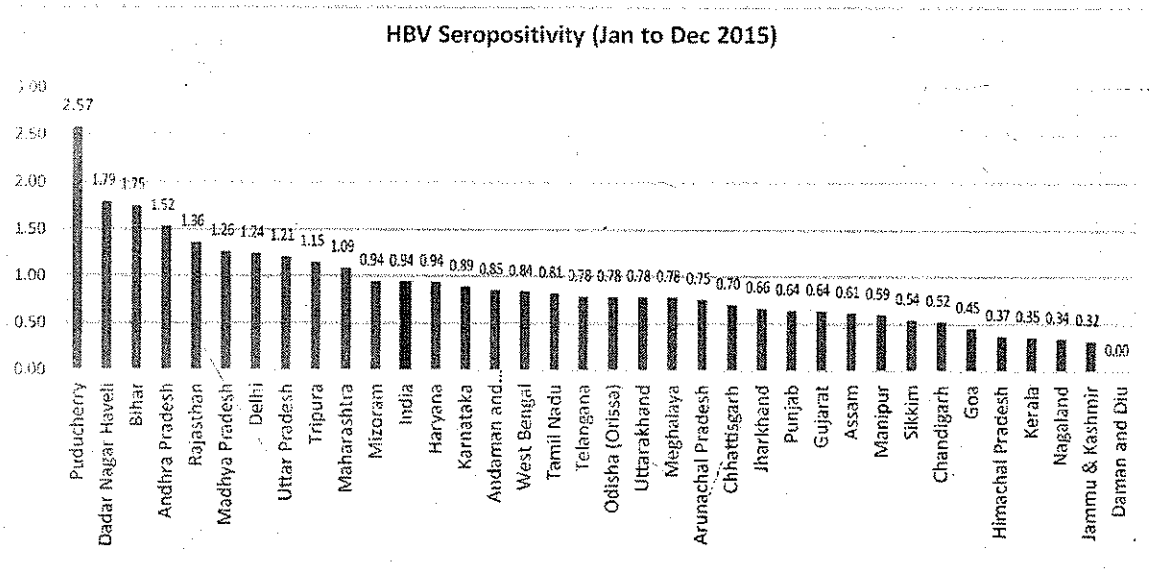
The majority of states indicated lower positivity than the national HIV positivity level which was 0.136%. However, Puducherry (0.53%), Mizoram (0.30%), Nagaland (0.26%), West Bengal (0.24%), Bihar (0.22%), Delhi (0.21%), Maharastra (0.19%), Andhra Pradesh (0.18%), Telangana (0.17%), Meghalaya (0.16%), Manipur (0.15%) and Chattisgarh (0.14%) recorded a higher positivity than national positivity level.

Fig-8 HCV seropositivity – By state (%)



In terms of Hepatitis C, States like, Punjab(1.40%), Mizoram(1.24%), Haryana(0.91%), Manipur(0.87%), Puducherry(0.83%), Uttarakhand(0.67%), Delhi(0.59%), Chandigarh(0.56%), UP(0.50%),Meghalaya(0.47%), West Bengal(0.42%), and Daman and Diu(0.35%) recorded higher positivity level than the national average of 0.326%.

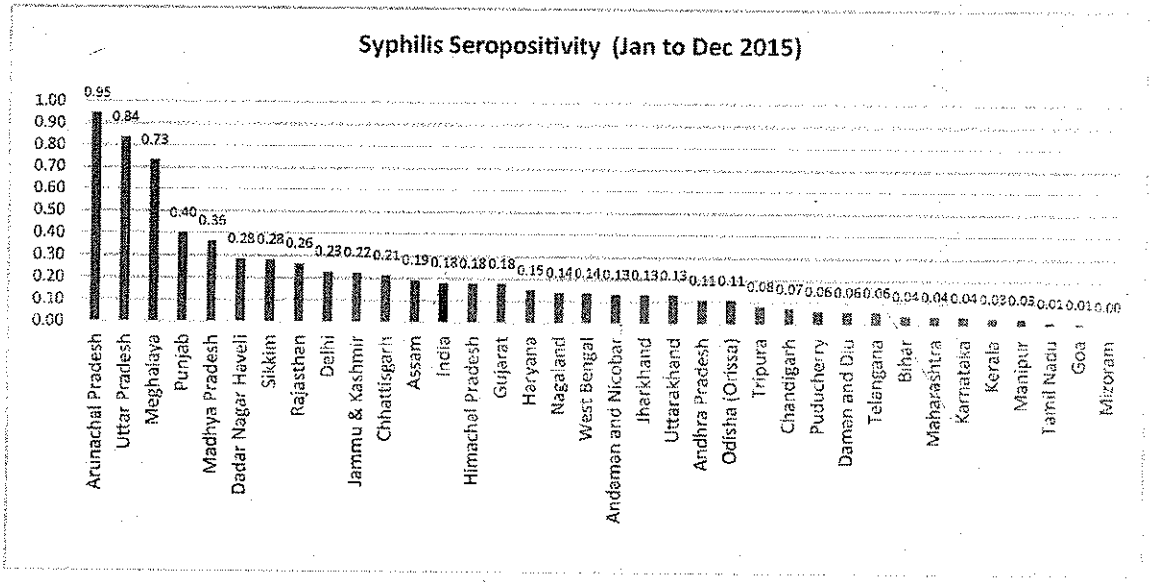
Fig-9 HBV seropositivity – By state (%)



Hepatitis B was found to be higher than the national average of 0.94% in states like Puducherry(2.57%), Dadra Nagar Haveli(1.79%), Bihar(1.75%), Andhra Pradesh(1.52%), Rajasthan(1.36%),Madhya Pradesh (1.26%), Delhi(1.24%), U.P(1.21%), Tripura(1.15%) and Maharashtra(1.09%).

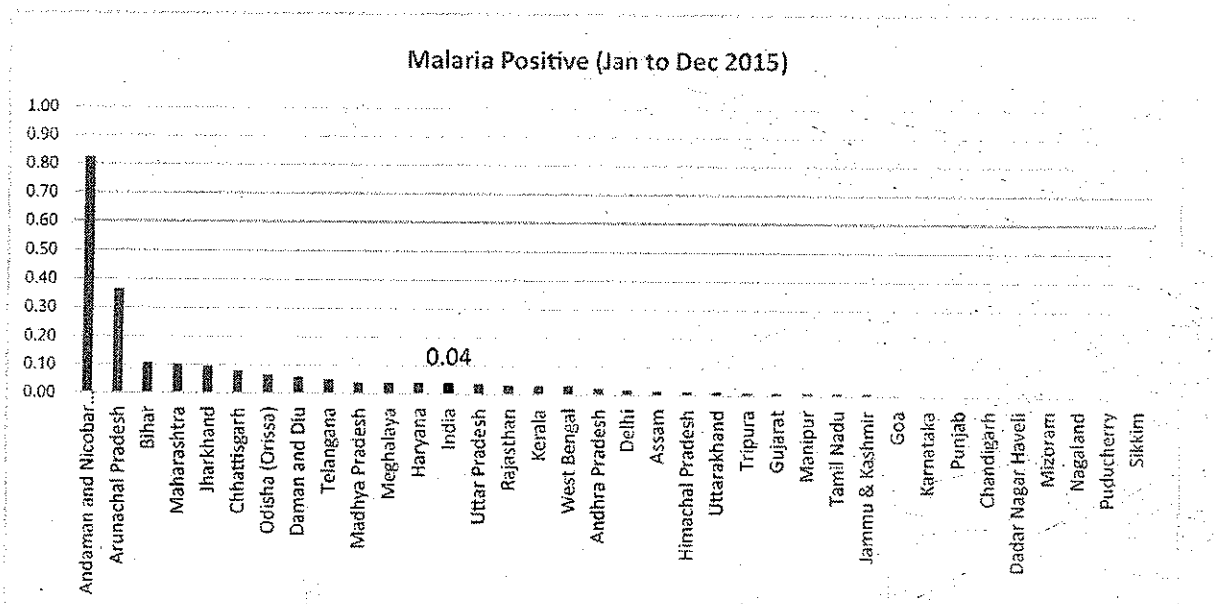
(41)

Fig-10 Syphilis seropositivity- By State (%)



Syphilis sero-positivity was found to be higher than the national average of 0.18% in states like Arunachal Pradesh(0.95%),Uttar Pradesh (0.84%), Meghalaya(0.73%), Punjab(0.40%), Madhya Pradesh(0.36%), Dadra Nagar Haveli(0.28%), Sikkim(0.28%), Rajasthan(0.26%), Delhi(0.23%), Jammu &Kashmir(0.22%), Chhattisgarh(0.21%) and Assam(0.19%).

Fig-11 Malaria Positivity– By state (%)



The majority of the states indicated a lower positivity of Malaria than the national positivity of 0.04%, whereas states like Andaman and Nicobar Islands, Arunachal Pradesh, Bihar,Maharashtra, Jharkhand, Chattisgarh,Odisha, Daman and Diu, Telangana, Madhya Pradesh, Meghalaya, Haryana recorded a higher positivity.

4.4 Component Separation

At the country level, 64.34% of blood units collected by blood banks with component facilities were used for component preparation.

Fig-12 Total blood collection and component separation

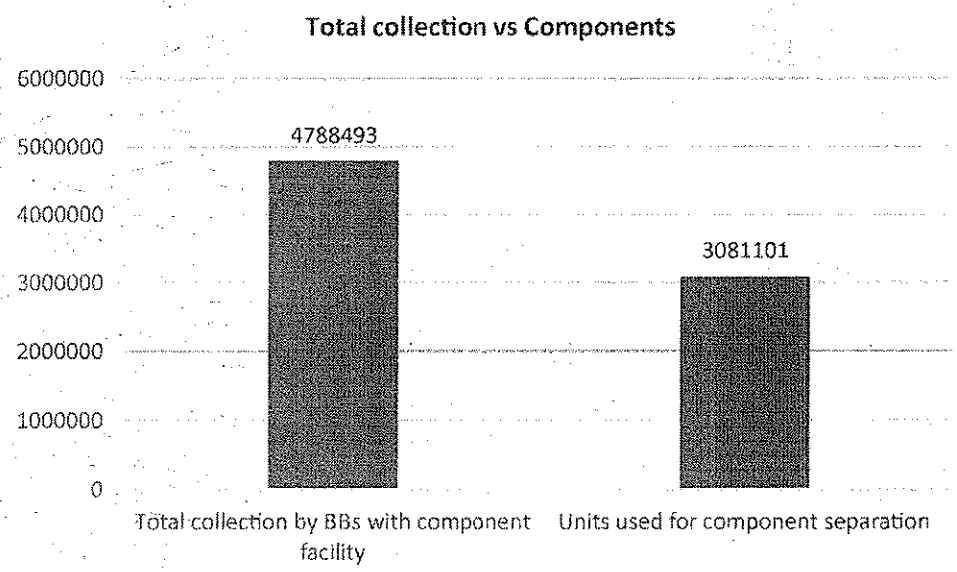
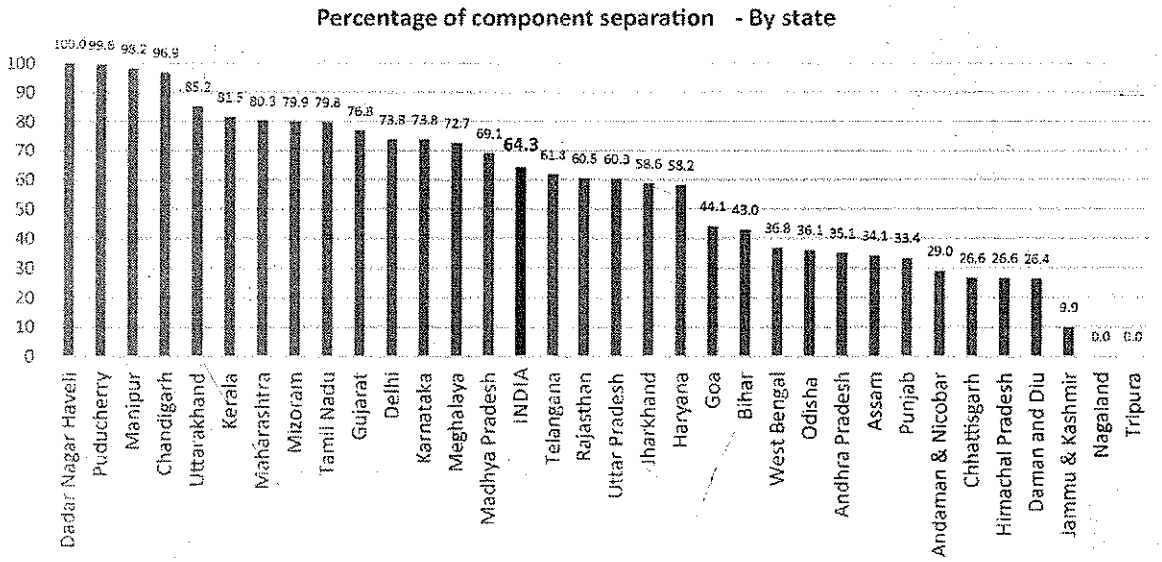


Fig-13 Percentage of component separation – By state



The percentage of component preparation was higher than the national average of 64.3% in Dadra Nagar Haveli, Puducherry, Manipur, Chandigarh, Uttarakhand, Kerala, Maharashtra, Mizoram, Tamil Nadu, Gujarat, Delhi, Karnataka, Meghalaya and Madhya Pradesh. States such as Sikkim and Arunachal Pradesh did not have any NACO supported blood banks with component separation facility.

4.5 Quality Management Systems

As mentioned in the methodology section, the blood banks were assessed and categorised based on the scores obtained. Adequate importance and weight were given to technical aspects and adherence to quality management systems. At the national level, the majority of blood banks (78%) scored between 36 to 70; 19% scored above 70 and 3% scored less than or equal to 35. The mean score was 60.27 (SD: 12.05).

Fig-14 Categorisation of blood banks by assessment score

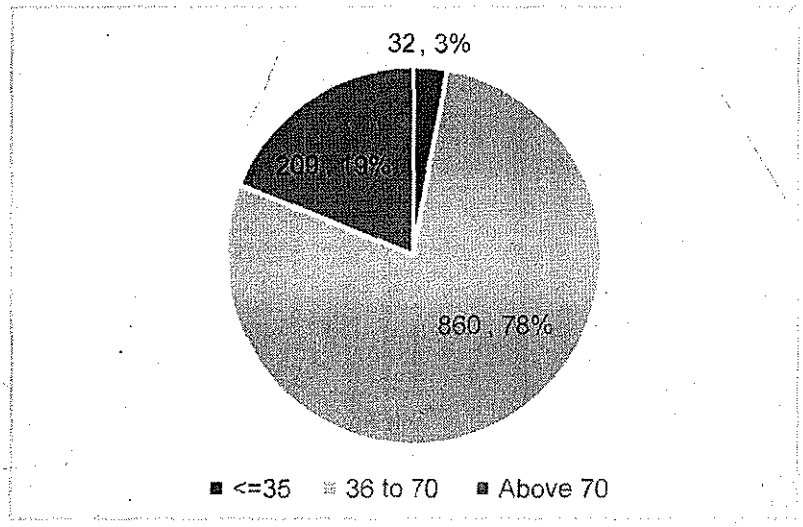
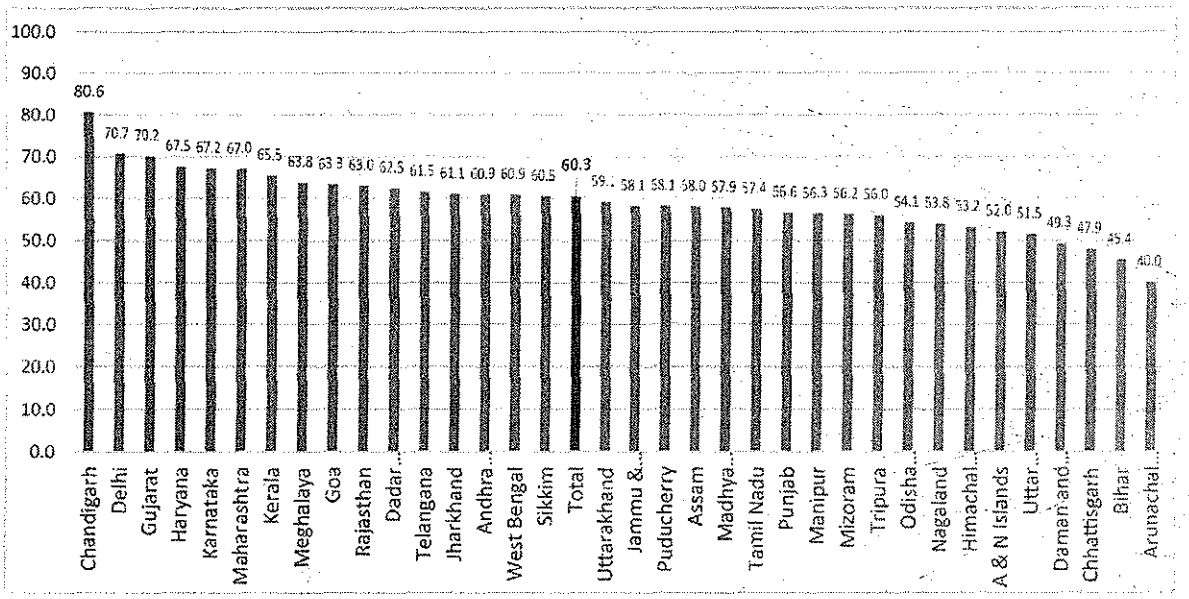


Fig-15 - Mean assessment score- By state



Sixteen states in the country scored more than the national average of 60.27, of which, states such as Chandigarh (80.6), Delhi (70.7) and Gujarat (70.2) scored more than 70. Nineteen states in the country scored less than the national average, of which, Arunachal Pradesh (40), Bihar (45.4), Chhattisgarh (47.9) and Daman and Diu (49.3) scored less than 50.

The number of blood banks (by state) that scored less than or equal to 35 is mentioned in Table-7. Most of the blood banks were in Uttar Pradesh (11), followed by Bihar (7) and Odisha (3).

Table-7 – Number of blood banks scored <=35

State	No of BBs
Uttar Pradesh	11
Bihar	7
Odisha (Orissa)	3
Arunachal Pradesh	2
Punjab	2
Tamil Nadu	2
Andhra Pradesh	1
Chhattisgarh	1
Jammu & Kashmir	1
Madhya Pradesh	1
Rajasthan	1
Total	**32**

The number of blood banks (by state) that scored more than 70 is mentioned in Table-8. The majority of blood banks that scored above 70 was from Maharashtra (42), followed by Gujarat (39), Karnataka(21), Delhi(13), Rajasthan (12) and Kerala (10).

Table-8 – Number of blood banks scored above 70

State	No of BBs
Maharashtra	42
Gujarat	39
Karnataka	21
Delhi	13
Rajasthan	12
Kerala	10
Haryana	8
West Bengal	8
Madhya Pradesh	7
Tamil Nadu	7
Jharkhand	6
Uttar Pradesh	6
Andhra Pradesh	5
Odisha (Orissa)	5
Punjab	5
Telangana	5
Chandigarh	4
Uttarakhand	3
Assam	2
Jammu & Kashmir	1
TOTAL	**209**

Assessment score by Category of blood banks: The mean score of blood banks with component facilities was found to be higher (64.72; SD: 11.57) than the mean score of blood banks without component facilities (57.45; SD: 11.50).

Table-9 Mean assessment score by category of blood banks

Category of blood banks	Mean	SD
BBs with component facility (427)	64.72	11.57
BBs without component facility (674)	57.45	11.50
Overall	**60.27**	**12.05**

Further analysis indicated that there were more blood banks (28 blood banks) who scored less than or equal to 35 among blood banks without component separation facility, compared to only 4 blood banks with component separation facility.

Fig-16 BBs with component- score

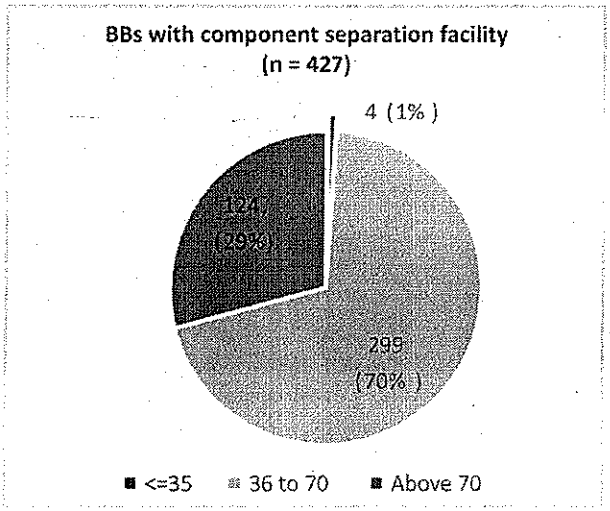


Fig-17 BBs without component- score

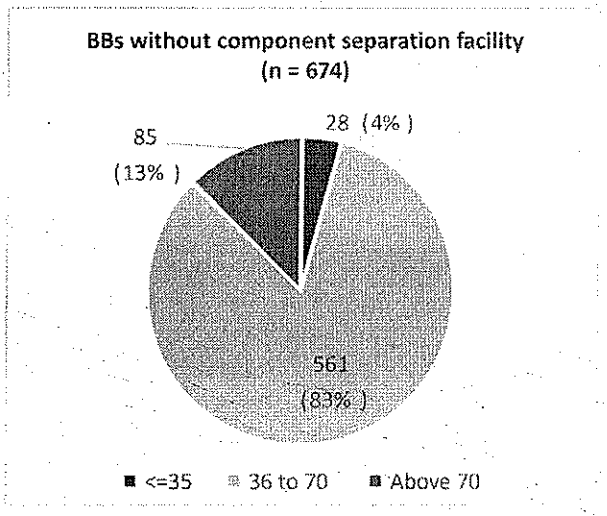


Table-10 Assessment score (categories) by Category of blood banks

Category of blood banks	<=35	36 to 70	Above 70	Total
BBs with component facility	4	299	124	427
	.9%	70.0%	29.0%	100.0%
BBs without component facility	28	561	85	674
	4.2%	83.2%	12.6%	100.0%
Overall	**32**	**860**	**209**	**1101**
	2.9%	**78.1%**	**19.0%**	**100.0%**

Assessment score by ownership: The mean assessment score of NGO/Trust/Charitable owned blood banks (67.27; SD: 11.21) was found to be higher than the public sector blood banks(58.38; SD: 11.57). It was also found that there were more public sector blood banks (29 blood banks) in the less than or equal to 35 category compared to only 3 blood banks from NGO/Trust/Charitable owned blood banks.

Table-11 Mean assessment score by Ownership

Ownership	Mean	SD
Public (867)	58.38	11.57
NGO/Trust/Charitable (234)	67.27	11.21
Overall	**60.27**	**12.05**

Table-12 Assessment score (Categories) by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	29	715	123	867
	3.3%	82.5%	14.2%	100.0%
NGO/Trust/Charitable	3	145	86	234
	1.3%	62.0%	36.8%	100.0%
Overall	32	860	209	1101
	2.9%	78.1%	19.0%	100.0%

Assessment score by Annual blood collection: The mean assessment score of blood banks that collected more than 5000 blood units (65.79; SD: 11.46) was found to be higher than blood banks that collected between 3001 to 5000(58.88; SD: 9.48) and less than 3000 blood units (55.91; SD: 11.43).

Table-13 Mean assessment score by annual collection

Annual collection	Mean	SD
Up to 3000 (483)	55.91	11.43
3001 to 5000 (183)	58.88	9.48
Above 5000 (435)	65.79	11.46
Overall	**60.27**	**12.05**

Assessment score by voluntary blood donation: Table -14 provides the mean assessment score by percentage of voluntary blood donation. The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score.

Table-14 Mean assessment score by voluntary blood donation

% VBD	Mean	SD
<25% (58)	51.07	13.01
25-49% (92)	57.77	11.87
50 - 74% (149)	57.89	11.78
75-90% (182)	58.59	11.57
Above 90 (620)	62.65	11.47
Overall	**60.27**	**12.05**

Assessment score by participation in External Quality Assessment scheme (EQAS) for Immunohematology and Transfusion transmitted infections (TTI): The mean score was found to be higher among the blood banks that were part of EQAS for immunohematology (78.45; SD: 9.55) compared to those who were not enrolled in EQAS (58.86; SD: 11.05). The similar situation was found among those blood banks that were part of EQAS for Transfusion-transmitted Infections as well.

Table-15 Mean assessment score by EQAS participation

EQAS for IH	Mean	SD
Enrolled (79)	78.45	9.55
Not enrolled (1022)	58.86	11.05
EQAS for TTI		
Enrolled(88)	78.02	8.57
Not enrolled(1013)	58.73	11.04

Assessment score by Accreditation status: The mean score was found to be higher among blood banks that were accredited by National Accreditation Board of Hospitals and Health care providers (NABH) compared to those that were not accredited.

Table-16 Mean assessment score by Accreditation

NABH	Mean	SD
No accreditation(926)	59.64	11.43
Accreditation(25)	89.12	5.85
Overall	**60.27**	**12.05**

However, only 25 blood banks among the 1101 blood banks have been accredited by NABH. Maharashtra (9) and Gujarat(9) had the highest number of accredited blood banks.

The list of blood banks under different categories of score is given in Table- 17

Table-17 Distribution of Blood banks by state and assessment score categories.

State	Score			
	<=35	36 to 70	Above 70	Total BBs
Andaman & Nicobar	0	1	0	1
Andhra Pradesh	1	50	5	56
Arunachal Pradesh	2	6	0	8
Assam	0	24	2	26
Bihar	7	32	0	39
Chandigarh	0	0	4	4
Chhattisgarh	1	15	0	16
Dadra Nagar Haveli	0	1	0	1
Daman and Diu	0	2	0	2
Delhi	0	7	13	20
Goa	0	3	0	3
Gujarat	0	36	39	75
Haryana	0	16	8	24
Himachal Pradesh	0	14	0	14
Jammu & Kashmir	1	21	1	23
Jharkhand	0	15	6	21
Karnataka	0	44	21	65
Kerala	0	35	10	45
Madhya Pradesh	1	54	7	62
Maharashtra	0	74	42	116
Manipur	0	3	0	3
Meghalaya	0	6	0	6
Mizoram	0	10	0	10
Nagaland	0	3	0	3
Odisha (Orissa)	3	44	5	52
Puducherry	0	4	0	4
Punjab	2	36	5	43
Rajasthan	1	34	12	47
Sikkim	0	2	0	2
Tamil Nadu	2	86	7	95
Telangana	0	34	5	39
Tripura	0	6	0	6
Uttar Pradesh	11	72	6	89
Uttarakhand	0	15	3	18
West Bengal	0	55	8	63
Total	**32**	**860**	**209**	**1101**

5. Conclusion

Considering the importance of blood transfusion services in the provision of medical care, maintaining standards and ensuring quality systems are vital in blood banks. From the programmatic perspective, adequate, accurate and updated information at the district, state and national level is essential for planning and implementation of blood services across the country. This assessment captured all the required information related to the structure, services, and facilities, availability of human resources, equipment, quality management system and practices in blood banks across the country. All blood banks function subject to obtaining and maintaining a licence for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and cosmetic act and rules. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services.

The 1101 NACO supported blood banks which were included in the review is approximately 39.8% of total blood banks (2760) existing in the country. However, the annual collection of these blood banks was 6,828,055 units which is approximately 60% of blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). The review also revealed that the majority of blood collection (70%) was by blood banks with component separation facility (427) compared to smaller blood banks without component separation facility (624).

This review indicated a mean score of 60.27 with variations across the category of blood banks, ownership, voluntary blood donation, EQAS participation and accreditation status. It is evident that blood banks with component separation facility performed well in most parameters. It is important to note that there is a huge variation between states and within states on several parameters included in the assessment. This suggests the need for targeted and customised approach to address the gaps and challenges faced by the blood banks in the country.

It is evident from the assessment that blood banks that focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented across the country.

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ANNEXURE-A3

51

सत्यमेव जयते

Assessment of Blood Banks in India-2016

NACO
National AIDS Control Organisation
India's voice against AIDS
Ministry of Health & Family Welfare, Government of India
www.nacoonline.org

NBTC
राष्ट्रीय रक्त संक्रमण परिषद
National Blood Transfusion Council

Ministry of Health and Family Welfare
Government of India

A Report on the "Assessment of Blood Banks in India"

National AIDS Control Organization (NACO) and
National Blood Transfusion Council (NBTC),
Ministry of Health and Family Welfare, Government of India
in collaboration with
U.S Centers for Disease Control and Prevention (HHS/CDC)
Division of Global HIV and TB (DGHT), India
Christian Medical College, Vellore
&
Christian Medical Association of India (CMAI), New Delhi

डॉ सी.वी. धर्मा राव
संयुक्त सचिव

Dr. C. V. Dharma Rao
Joint Secretary

राष्ट्रीय एड्स नियंत्रण संगठन
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India

PREFACE

Since the inception of National AIDS Control Programme in 1992 and the creation of the National Blood Transfusion Council in 1996, the Blood Transfusion Services in India have made significant advancement in the availability and access to safe and quality Blood and Blood components to even the remotest areas of the country.

Currently, the National AIDS Control Programme is in Phase IV (2012-2017) and one of the key strategies under NACP IV is strengthening the management and structure of Blood Transfusion Services together with the implementation of Quality Management Systems in Blood Transfusion Services.

The Assessment of all licensed Blood Banks was carried out with the specific objectives of reviewing the existing situation in Blood Banks in terms of collection of blood, voluntary blood donation, quality management systems, and other areas; and to categorize and grade the Blood Banks using a scoring system for implementation of phased quality improvement systems. This report highlights the key issues, gaps, challenges, and possible opportunities to the state health officials and programme officers of State Blood Transfusion Councils and State AIDS Control Societies.

The rich data generated from this exercise will also be further mined to generate state specific reports.

(Dr C.V Dharma Rao)

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Know Your HIV status, go to the nearest Government Hospital for free Voluntary Counselling and Testing

53A

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S/d

(Dr.C.V. Dharma Rao)

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सत्यमेव जयते

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ACKNOWLEDGEMENT

Blood Transfusion Services is a lifesaving intervention in the health care system. Therefore, the Blood and Blood products must be safe and of consistent quality for clinical effectiveness. Planning and implementation of Quality Management Systems in Blood Transfusion Services across the country under the National Blood Programme require updated information at District, State & National level. This country-wide assessment was one of the unique and first assessment of its kind which captured almost all the required information on all aspects of Blood Transfusion Services across the country.

It is evident from the assessment that Blood Banks focussing on Quality Management Systems performed better than others. Therefore, it is imperative that specific programmes with targeted and customized approach are developed and implemented across the country, to improve the quality systems and patient care practices in Blood Transfusion Services.

I take this opportunity to express my heartfelt gratitude to Shri N.S Kang, President NBTC/Secretary & DG, NACO and Dr. C.V. Dharma Rao, Joint Secretary, NACO for providing constant encouragement and guidance to undertake this important activity.

I also extend my sincere appreciation to all the team members of the BTS Division of respective State Blood Transfusion Councils & State AIDS Control Societies whose constant perseverance enabled timely completion of this arduous task. Thanks are due to all the Blood Bank staff, who took out time from their schedule to fill in the detailed assessment forms for timely data submission.

It is commendable to note that this time bound activity was very well co-ordinated with the concerned efforts of the BTS team in NACO/NBTC especially Dr. Shobini Rajan, ADG (BTS) NACO; Dr. Harjeet Singh, NPO (BTS) NACO; Dr. Shameo Mishra, PO (QC) NACO/NBTC; Mr. Jolly Lazarus, PO (VBD) NACO/NBTC & Mr. Benjamin Franklin, Project Associate, CMAI. I also express my sincere thanks to all the Zonal Managers who coordinated the activities at their respective zones.

The report has been principally prepared by Dr. Joy Mammen, CMC, Vellore and Dr. Edwin Sam, CMAI with inputs from their respective teams. Sincere gratitude is expressed for their patience, perseverance, and hard work. Our special thanks to Dr. Bimal Charles, CEO & General Secretary, CMAI and Dr. Sumita Upadhyaya, Senior Lab Advisor, CDC-DGHT, India for their technical inputs. Thanks are also due to US Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT) India and Christian Medical Association of India (CMAI) for supporting the completion of the assessment and developing the report.

(Dr. B.S Gupta)

54 A

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I take this opportunity to express my heartfelt gratitude to Shri N.S. Kang, President NBTC/ Secretary & DG, NACO and Dr. C.V. Dharma Rao, Joint Secretary, NACO for providing constants encouragement and guidance to undertake this important activity.

I also extend my sincere appreciation to all the team members of the BTS Division of respective State Blood Transfusion Councils & State AIDS Control Societies whose constant perseverance enabled timely completion of this arduous task. Thanks are due to all the Blood Bank Staff, who look out time from their schedule to fill in the detailed assessment forms for timely data submission.

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S/d

(Dr. R.S. Gupta)

Abbreviations

BB	-	Blood Bank
BCSU	-	Blood Component Separation Units
BTS	-	Blood Transfusion Service
CDSCO	-	Central Drug Standard Control Organisation
CHEMI	-	Chemiluminescence
DAT	-	Direct Antiglobulin Test
DCT	-	Direct Coombs Test
ELISA	-	Enzyme Linked Immuno Sorbent Assay
EQAS	-	External Quality Assessment Scheme
FFP	-	Fresh Frozen Plasma
HIV	-	Human Immunodeficiency Virus
HBV	-	Hepatitis B virus
HCV	-	Hepatitis C virus
HVPI	-	Haemovigilance Program of India
IAT	-	Indirect Antiglobulin Test
ICT	-	Indirect Coombs Test
IH	-	Immunohematology
IQC	-	Internal Quality Control
IQR	-	Interquartile Range
MoHFW	-	Ministry of Health and Family Welfare
NACO	-	National AIDS Control Organisation
NAT	-	Nucleic Acid Testing
NBTC	-	National Blood Transfusion Council
NGO	-	Non Governmental Organisation
NHP	-	National Health Portal
PSU	-	Public Sector Undertaking
QC	-	Quality Control
QM	-	Quality Manager
QMS	-	Quality Management Systems
RPR	-	Rapid Plasma Reagin
SACS	-	State AIDS Control Societies
SBTC	-	State Blood Transfusion Council
SD	-	Standard Deviation
SIMS	-	Strategic Information Management System
SOPs	-	Standard Operating Procedures
TTIs	-	Transfusion Transmitted Infection
TM	-	Technical Manager
TPHA	-	Treponema Pallidum Hemagglutination Assay
VNRBD	-	Voluntary, Non-Remunerated Blood Donation
VBD	-	Voluntary Blood Donor/Donation
WHO	-	World Health Organization

56

Table of Contents

	Preface	iii
	Acknowlegment	v
	Abbreviations	vii
	Tables and Figures	x
	Executive Summary	xiii
1.	Background	1
2.	Objectives	4
3.	Methodology	4
4.	Key Findings	7
	4.1 Basic details of blood banks	9
	4.1.1 Category of Blood Banks	9
	4.1.2 Ownership	10
	4.1.3 Organizational Attachment	11
	4.1.4 License details of blood banks	11
	4.2 Annual Blood Collection and Voluntary Blood Donation	13
	4.2.1 Annual Collection of Blood	13
	4.2.2 Voluntary blood donation	17
	4.3 Transfusion Transmitted Infections (TTIs)	20
	4.3.1 Transfusion Transmitted Infections by Category of blood banks	21
	4.4 Component Separation	24
	4.5 Quality Management Systems	26
	4.6 The current status of blood banks based on the assessment	29
	4.6.1 Assessment score by Category of blood banks	33
	4.6.2 Assessment score by Ownership	34
	4.6.3 Assessment score of Private Sector blood banks	35
	4.6.4 Assessment score by Annual collection	35
	4.6.5 Assessment score by voluntary blood donation	36
	4.6.6 Assessment score by participation in External Quality Assessment scheme	36
	4.6.7 Assessment score by Accreditation status	37
5	Conclusion	40
6	Reference	42
7	Annexures	44
	7.1 NACO/NBTC - Questionnaire for Blood Banks	44
	7.2 Scoring Pattern	56

57

Tables and Figures

Tables

Table 1 - Details of technical areas included in the assessment 5

Table 2 - Scoring details and weight 6

Table 3 - State wise description of blood banks 7

Table 4 - Basic details of blood banks 9

Table 5 - State wise list of blood banks by Ownership 10

Table 6 - Average Annual collection-State 14

Table 7 - Annual Blood Collection and percentage of VBD 15

Table 8 - Transfusion Transmitted Infections 20

Table 9 - Transfusion Transmitted Infections by category of blood banks 21

Table 10 - Total annual collection by BCSU's and percentage of component separation 24

Table 11 - Availability and adherence to quality parameters in blood banks 27

Table 12 - Mean assessment score 29

Table 13 - Mean assessment score - (NACO supported Vs. Non-NACO) 31

Table 14 - Number of blood banks scored <=35 32

Table 15 - Number of blood banks scored above 70 33

Table 16 - Mean assessment score by Category of blood banks 34

Table 17 - Mean assessment score by Ownership 35

Table 18 - Mean assessment score (Categories) by Ownership 35

Table 19 - Mean assessment score by annual collection 36

Table 20 - Mean assessment score by Voluntary Blood Donation 36

Table 21 - Mean assessment score by EQAS enrolment 37

Table 22 - Mean assessment score by Accreditation 37

Table 23 - Distribution of Blood banks by state and mean assessment score categories 38

Table 24 - Distribution of Blood banks by state and mean assessment score categories 39

Figures

Fig 1 - Availability of BBs per 1,000,000 (1 million) population 8

Fig 2 - License status 12

Fig 3 - Annual collection and Voluntary donation 13

Fig 4 - Type of blood donation (Voluntary vs. Replacement donation %) 13

Fig 5 - Annual collection per 100 population - State wise 16

Fig 6 - Annual collection per 100 population vs. BB's per 1 million- State wise 17

Fig 7 - Percentage of Voluntary Blood Donation by state (Overall) 18

Fig 8 - Percentage of Voluntary Blood Donation by state (NACO supported) 18

Fig 9 - Percentage of Voluntary Blood Donation by state (Non-NACO) 19

Fig 10 - Transfusion Transmitted Infections (%) Jan-Dec 2015 20

Fig 11 - HIV seropositivity – By state (%) 21

Fig 12 - HCV seropositivity – By state (%) 22

Fig 13 - HBV seropositivity – By state (%) 22

Fig 14 - Syphilis seropositivity- By State (%) 23

Fig 15 - Malaria Positivity– By state (%) 23

Fig 16 - Total blood collection and component separation. 24

Fig 17 - Percentage of component separation – By state (All BBs) 25

Fig 18 - Percentage of component separation – By state (NACO supported) 26

Fig 19 - Categorisation of blood banks 29

Fig 20 - Categorisation of blood banks - NACO supported blood banks 30

Fig 21 - Categorisation of blood banks – Non-NACO blood banks 30

Fig 22 - Mean assessment score - By state (All BBs) 30

Fig 23 - BBs with component -Score 31

Fig 24 - BBs without component -Score 31

Executive Summary

Blood Banks in India

According to Central Drugs Standard Control Organization (CDSCO), there were 2,760 blood banks in the country in 2015. The assessment exercise identified 2,626 functional blood banks across the country excluding 46 military blood banks. Of the 2,626 blood banks, 1,131(43%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 1,495 were Non-NACO blood banks.

Maharashtra (308) had the highest number of blood banks followed by Tamil Nadu (265), Uttar Pradesh (248), Karnataka (185), Kerala (166), Telangana (153), Gujarat (134), Madhya Pradesh (133), Andhra Pradesh (125), West Bengal (115) and Rajasthan (102).

Around 61% (1,592) of all the blood banks(n=2,626) in the country were in 8 states that are, Maharashtra (11.7%), Tamil Nadu (10.1%), Uttar Pradesh (9.4%), Karnataka (7%), Kerala (6.3%), Telangana (5.8%), Gujarat (5.1%), and Madhya Pradesh (5%).

Considering the number of blood banks per one million population, states such as Bihar (0.7 blood banks), Jharkhand (1.2), Uttar Pradesh (1.2), West Bengal (1.3), Rajasthan(1.5), Madhya Pradesh (1.8), Manipur (1.8), Odisha(1.9), Assam (2), Nagaland(2), Meghalaya(2) and Chhattisgarh(2) recorded less than the national average of 2.2 blood banks per 1,000, 000 (one million) population.

In this assessment, 2,493 blood banks (1,119 NACO supported - 98.9% and 1,374 Non-NACO - 91.9%) that submitted the assessment forms in complete were included in the analysis.

Description of blood banks (n=2,493)

- Around 51% (1,271) of the blood banks in the country had component separation facility.
- The public and not-for-profit sector each owned 38% of the blood banks in the country and the private sector owned approximately 24% (598) of blood banks.
- The majority (876; 78.3%) of NACO supported blood banks were owned by the public sector and the remaining 21.7% (243) were run by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc.

- The majority of the blood banks (77%; 1919) were attached to hospitals, 1% (23) were attached to laboratories and the remaining 551 (22.1%) were standalone blood banks.

- The majority of the blood banks (65.7%) had valid and current licenses while the remaining 34.3% (860) had applied for renewal. Around 55% (617) of NACO supported and 74.3% (1,021) of Non-NACO supported blood banks had a valid and active license.

Annual Collection and Voluntary Blood Donation

- During January to December 2015, the annual blood collection from all the blood banks that reported was 11,645,791 of which 71.9% (8,378,692) units were through voluntary blood donations and the remaining were from replacement donations.

- The average annual collection of blood units of all the blood banks in the country was 4789 units. The average annual collection of NACO supported blood banks was found to be higher than (6,219 units) the Non-NACO blood banks (3,583 units).

- The blood banks with component separation units recorded a higher average collection (7,035 units) compared to blood banks without component separation units (2,432 units).

- The NACO supported Blood banks collected 59.4% (6,915,963 units) of the total collection, of which 80.5% (5,568,143) units were through voluntary blood donation. The Non-NACO Blood banks collected 4,729,828 (40.5%) units of which only 59.4% (2,810,549) units were through voluntary blood donation.

Transfusion Transmitted Infections

- HIV positivity among blood donors was found to be 0.14%, Hepatitis C 0.34%, Hepatitis-B 0.87%, Syphilis 0.17% and Malaria 0.06%. However, there is a huge variation between different states.

Component Separation

- Around 71% of blood units collected by blood banks with component separation facilities, were used for component separation in India.

- The percentage component separation was higher (75.4%) in Non-NACO blood banks compared to NACO supported blood banks (67.3%).

Quality Management Systems

- 91.5% of the blood banks reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by less than 50% of the blood banks in the country. Around 42% of NACO supported blood banks and 55% of Non-NACO blood banks reported they had a document control system.
- More than 95% of blood banks reported havingstandard operating procedures (SOPs) for technical processes.
- Internal quality control (IQC) for Immunohematology was reported by 78% of the blood banks and IQC for TTIs was reported by 52% of all the blood banks, with slight variation between NACO supported and Non-NACO blood banks.
- Around 86% of the blood banks reported carrying out quality control for kits, reagents and blood bags.
- Only 12.6% and 11.2% of the blood banks in India have enrolled themselves in External Quality Control Systems (EQAS) by recognized providers for immunohematology and TTIs respectively.
- Only 73 (2.9%) blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).
- Designated and trained Quality Managers and trained Technical managers were available only in 37.9% and 48.2% of the blood banks respectively.
- More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 89% reported that they calibrate the equipment as per requirement.

The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the country was 62 (SD: 11.19). The Non-NACO blood banks scored slightly higher (62.68; SD: 10.63) than the NACO supported blood banks.
- Around 78% of all the blood banks under NACO supported were in public sector and present across sub-divisional and divisional/district hospitals catering to all segments of the population including rural areas. Whereas, the majority (95%) of the Non-NACO blood banks were in the private and not-for-profit sector.

- At the national level, the majority of blood banks (77%) scored between 35 to 70 followed by 21% which scored above 70 and 2% scored less than or equal to 35.

- An equal proportion of 77% of NACO supported and Non-NACO blood banks scored between 35 to 70. Around 21% of NACO supported blood banks and 22% of Non-NACO blood banks scored more than 70.

- Most of the blood banks that scored less than or equal to 35 were in Uttar Pradesh (13; 5% of all blood banks), followed by Bihar (6; 8% of all blood banks) and Odisha (3; 4% of all blood banks).

- Of the 530 blood banks that scored more than 70, 297 (56%) were Non-NACO blood banks. The majority of blood banks that scored above 70 were from Maharashtra (90), followed by Gujarat (60), Karnataka (55), Tamil Nadu (53), Kerala (42), Delhi (34) and Rajasthan (22). These 6 States constitute 50% of the total blood banks that scored more than 70.

- The mean score of blood banks with component facilities was found to be higher (64.69; SD: 10.84) than the mean score of blood banks without component facilities (59.22; SD: 10.87). No significant differences were observed between NACO and Non-NACO Blood banks.

- The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (64.18; SD: 10.52) was found to be higher than the public sector blood banks (59.16; SD: 11.30).

- However, NACO supported blood banks run by not-for-profit sector had scored higher (67.30; SD: 11.27) as compared to Non-NACO blood banks run by NGO/Trust/Charitable institutions (63.11; SD: 10.03).

- The mean assessment score of blood banks that collected more than 5000 blood units (66.98; SD: 11.20) was found to be higher than those that collected between 3001 to 5000 (63.31; SD: 9.45) and those that collected less than 3000 blood units (59.39; SD: 10.48).

- The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score.

- The mean score was found to be higher among the blood banks that were part of EQAS for immunohematology (75.35; SD: 8.92) compared to those which were not enrolled (60.08; SD: 10.12). The similar situation was found among those blood banks that were part of EQAS for Transfusion-transmitted Infections (76.32; SD: 8.34) as compared to those which were not enrolled (60.20; SD: 10.15).

- The mean score was found to be higher among those blood banks that were accredited by National Accreditation Board of Hospitals and Health Care providers (NABH) compared to those that were not accredited.

It is evident from the assessment that those blood banks which focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented across the country.

Assessment of Blood Banks in India

1. Background

Blood Transfusion Service (BTS) is an essential part of modern health care system without which medical care is impossible (Pal, Kar, Zaman, & Pal, 2011). Adequate measures to ensure blood safety play a major role in preventing the transmission of HIV, Hepatitis and other bloodborne pathogens in health care settings. The blood and its products must not only be safe but must be clinically effective, and of appropriate and consistent quality (WHO, 2012). Ensuring the safety and availability of blood and blood products is an essential public health responsibility which is primarily the responsibility of the government or the appropriate national health authority of each country (Ramani, Mavalankar, & Govil, 2007). Therefore, it is important to establish a sustainable national blood system that should be supported by a national blood policy, strategic plan, and appropriate legal instruments (WHO, 2011). The Twenty-eighth World Health Assembly resolution number WHA 28.72 of 1975 urged member countries to promote the development of national blood services based on voluntary non-remunerated blood donation (VNRBD); to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products (WHO, 1975).

However, provision of safe and quality blood for a country like India involves a highly complex operation involving various stakeholders, and the magnitude and complexity of issues raise several challenges(GOI, 2003). This requires a holistic and comprehensive approach to planning, designing and operationalizing the BTS. It is important to ensure coordination between blood transfusion services, health services and hospitals, educational institutes, religious, social and industrial organizations, mass media, and other stakeholders including the general public. The system should ensure adequate resources and inputs into the legislative, regulatory, technical, social, and cultural aspects of making this life-saving product accessible and safe.

The need for blood is paramount and universal. However, millions of patients requiring transfusion do not have timely access to safe blood, and there is a major imbalance between developing and industrialized countries in access to safe blood (WHO, 2009). There is a huge inequity in the availability of blood within countries, with the urban areas having more access to the majority of blood available. Even if sufficient blood is available, many are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. In order to ensure universal access to safe and quality blood, achieve 100% voluntary blood donation and quality-assured testing of donated blood, strengthening the blood transfusion services with evidence-based, innovative and result-oriented strategies are essential. It is also imperative to optimize blood usage, develop quality systems in the transfusion chain, strengthen the workforce, adopt new developments, and build effective partnerships(WHO, 2008).

The National AIDS Control Organization(NACO), under the Ministry of Health and Family Welfare, and the National Blood Transfusion Council (NBTC), which is the apex policy making body, are the prime bodies responsible for the functioning of blood transfusion services and blood safety in India at the national level. At the state level, the respective state AIDS Control societies(SACS) and State Blood Transfusion Councils(SBTCs) are responsible for the smooth functioning of blood transfusion services. As blood and blood products are considered as drugs, the Central Drug Standard Control Organisation(CDSCO) and State Drug Control Organisations play a vital role in key aspects such as, approval of licenses, and enforcement of standard transfusion practices to ensure safe, quality and efficacious blood and blood components in clinical practices.

Several directions, guidelines, and legal measures during the last two decades facilitated the significant improvement of blood transfusion services in the country. The Supreme Court verdict in 1996 directed the government to improve the blood transfusion services that resulted in establishing the National and State Blood Transfusion Councils. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993, as a result of which the licensing of blood banks was brought under the dual authority of the state and central government (MoHFW, 2013). The state licensing authority issues the license, while the Drug Controller General (India) is the central license approving authority. In 2002, the WHO Guidelines on the Clinical Use of Blood was adopted by NACO. In the same year, the Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007a).

In 2007, the National AIDS Control Organization developed standards for blood banks and blood transfusion services. This clearly spelled out the need for mandatory licensing and compliance to all regulatory norms; compliance to policies/ guidelines of NBTC; donor selection/ recruitment/ retention/ counseling based on voluntary non-remunerated regular repeat blood donors; appropriate blood collection procedures; mandatory testing of all donated Blood units for HIV, HBV, HCV, Syphilis and Malaria; transportation of blood and blood components ensuring cold chain maintenance; manpower requirements; maintenance of quality assurance system; regular maintenance and calibration of equipment; biosafety; waste disposal mechanisms; documentation, record keeping and regular reporting under the national programme(NACO, 2007b).

Since the inception of the National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization has been making significant strides towards ensuring access to safe, and quality blood and blood products to all those who are in need of a transfusion. The goals and objectives of the programme are to ensure provision of safe and quality blood even to the most remote areas of the country. NACO has been taking continuous steps to strengthen the blood banks across the country by providing equipment, consumables, manpower and capacity building. The efforts to modernizing blood-banks, establishing model blood banks, and setting up blood storage centres in rural areas have improved the quality of blood transfusion services in the country. The current phase of the NACP IV (2012 -2017) focuses on blood safety that aims to support 1,300 blood banks, and achieve 90,00,000 blood units from NACO supported Blood Banks and 95% Voluntary

Blood Donation in 2016-17. The key strategies under NACP IV are strengthening management structures of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services, and developing new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

Due to the continuous efforts in India, the availability of safe blood increased from 44 lakh units in 2007 to 100 lakh units by 2014-15; during this time HIV seroreactivity also declined from 1.2% to 0.2%, and Voluntary Blood Donation increased substantially (NACO, 2016). Currently, India has 2,760 blood banks of which 1,131 blood banks are supported by NACO, Ministry of Health and Family Welfare (MoHFW). NACO has been providing technical and operational support to improve the efficiency and effectiveness of these blood banks, thereby, increasing the availability and accessibility of safe and quality blood and blood products to those who are in need. Though there has been a substantial improvement in BTS in India over a period of time, there are still gaps in ensuring access to quality blood and blood products that needs to be addressed at the district, state and regional levels through an evidence-based approach.

In order to have evidence-based programmes, and policies, accurate and updated information at the district, state and national level is an essential prerequisite. Lack of updated information is one of the key barriers affecting the planning and implementation of blood transfusion services across the country. Though current programmes emphasize Quality Management Systems (QMS) including EQAS and accreditation in blood banks, not much information is available related to this area. In particular, information on the existing practices of blood banks, their potential, and willingness to get involved in the programmes on QMS are critical factors that will facilitate developing appropriate strategies and programmes related to QMS at the National level.

Therefore, facility-wise updated information on structural and programmatic components, the gaps, and challenges are required which will not only facilitate in developing better programmes and policies in BTS, but also serve as a baseline for specific programmes that are being, and will be implemented at the district, state, regional, and national levels. Considering the above factors, a nationwide assessment of all the Blood Banks was conducted.

(68)

2. Objectives

The overall purpose of this assessment was to understand the current situation of blood banks, in terms of facilities, services, practices, performance, gaps, and challenges.

The specific objectives were:

- To review the existing situation in blood banks in terms of collection of blood, voluntary blood donation, quality management systems, and other programme areas.
- To categorize and grade the blood banks using a scoring system, for implementation of phased quality improvement systems.
- To provide evidence for the formulation of evidence-based policies and programs for blood transfusion services in India.
- To develop an updated database with basic essential details of blood banks in the country.

3. Methodology

This assessment was a cross-sectional survey that captured the current situation of all the blood banks that are owned by the government, private, non-profit and not-for-profit organizations in the country. In order to create a comprehensive and accurate list of functional blood banks in the country, data (list of blood banks) from multiple sources were obtained which included NACO, NBTC, CDSCO, state drugs control organizations, SACS, and SBTCs. These were further reviewed for duplication, errors in name and other necessary details, and triangulated to arrive at a comprehensive list of state wise functional blood banks.

Following this, an assessment tool was designed as a web-based survey tool in REDCap Software - Version 6.11.2 which was developed by an informatics core at Vanderbilt University with support from National Center for Research Resources (NCRR) and National Institute of Health (NIH) grants. An exclusive online survey link for each blood bank, generated from REDCap, was sent to all the blood banks. This online link was linked to the email ID of the blood bank and Unique IDs created for each blood bank. Since many blood banks did not have adequate internet facility, a paper format was also developed which was sent to all the blood banks by post with a pre-stamped and self-addressed envelope. The data from the completed paper forms were then entered into REDCap.

Tool: A self-assessment questionnaire that included all the below-mentioned components was developed in consultation with programme officials and experts from the areas of public health, epidemiology, bio-statistics, and transfusion medicine.

The review focused on the following components:

Table -1 - Details of technical areas included in the assessment

S No	Component	Description
1	General	Basic details, Ownership, Category, License, etc.
2	Collection and VBD	Annual Collection, VNRBD and donor management
3	Technical – IH, TTIs, components	Methods, Performances
4	Quality Management System	Check for compliance to guidelines and standards
5	HR, Training, and Equipment	Availability and Participation

Data Handling and Analysis Management: The database for this study was developed and maintained by Clinical Data Management Centre (CDMC), Department of Biostatistics, Christian Medical College, Vellore, India. In-built validation checks were incorporated in the system to confirm that all study related parameters are captured completely and accurately.

Data were analyzed using SPSS Version 21 for Windows. The data were screened for outliers and extreme values using histograms, frequency distribution and Box plots. To summarize the whole data, frequency distributions and bar/pie charts were done for qualitative (categorical) variables such as ownership, type of blood banks etc., and descriptive statistics like mean, standard deviation (SD), median, interquartile range(IQR), minimum, and maximum were done for quantitative variables such as annual collection, voluntary blood donation, etc. Comparison of the means of different variables was done using an independent t-test or ANOVA, if the distribution was normal. Mann-Whitney or Kruskal-Wallis test was done if the data was not normally distributed.

Categorisation of blood banks and scoring: In order to study variables that impact quality, the blood banks have been categorized into two groups based on the availability of component separation facility. The first category comprises of blood banks with component separation facility that includes Model Blood Banks and Blood Component Separation Units (BCSU) in NACO supported blood banks. Model blood banks collect more than 10,000 units and BCSUs collect between 5,000 to 10,000 units of blood annually. The second category includes blood banks without component separation facility that covers major blood banks and District Level blood banks (DLBB) in NACO supported blood banks. Major blood banks collect between 3,000 to 5,000 units and district level blood banks collect up to 3,000 units annually.

Each component of the tool was given a weight based on the programmatic and quality priorities. The maximum achievable sum of all weighted scores under each component totaled 100 marks.

Table 2 - Scoring details and weight

Details	With Components	Without Components
Licence	3	3
Annual Collection, VBD, Repeat donation and Counselling	11	16
Technical - IH, TTI and Component separation	43	38
Quality Management Systems	35	35
Reporting	8	8
TOTAL	100	100

The scoring pattern was different based on the category of blood banks that are: 1. Blood banks with component separation facility (n=1,271) and, 2. Blood banks without component separation facility (n=1,222). Scores were allocated to each indicator under specific components based on the expected level of performance by these two categories of blood banks.

The blood banks were categorized based on the scores obtained by each blood bank that are, less than and equal to 35 (Red); 36 to 70 (Yellow) and above 70 (Green).

4. Key Findings

According to CDSCO, there were 2,760 blood banks in the country in 2015 (CDSCO, 2015). However, the assessment exercise identified 2,626 functional blood banks across the country excluding 46 military blood banks. Of the 2,626 blood banks, 1,131(43%) were supported by National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India and the remaining 1,495 were Non-NACO blood banks. There is an addition of five blood banks to the 1,126 NACO supported blood banks, recorded in the preliminary assessment of NACO supported blood banks in July 2016, as they have recently reported as being NACO supported. Of the total functional blood banks, 2,493 blood banks (1,119 NACO supported - 98.9% and 1,374 Non-NACO- 91.9%) which have submitted the assessment forms in complete were included in the analysis.

Table - 3 indicates the state wise details of all the blood banks in the country, including the description of NACO supported and Non-NACO blood banks. Maharashtra (308) had the highest number of blood banks followed by Tamil Nadu (265), Uttar Pradesh (248), Karnataka (185), Kerala (166), Telangana (153), Gujarat (134), Madhya Pradesh (133), Andhra Pradesh (125), West Bengal (115) and Rajasthan (102). In terms of NACO supported blood banks, Maharashtra (122) had the highest number of blood banks, followed by Tamil Nadu (95), Uttar Pradesh (89), Gujarat (77), Karnataka (66), West Bengal (63), Madhya Pradesh (62), Andhra Pradesh (61), Odisha (58), and Rajasthan (50).

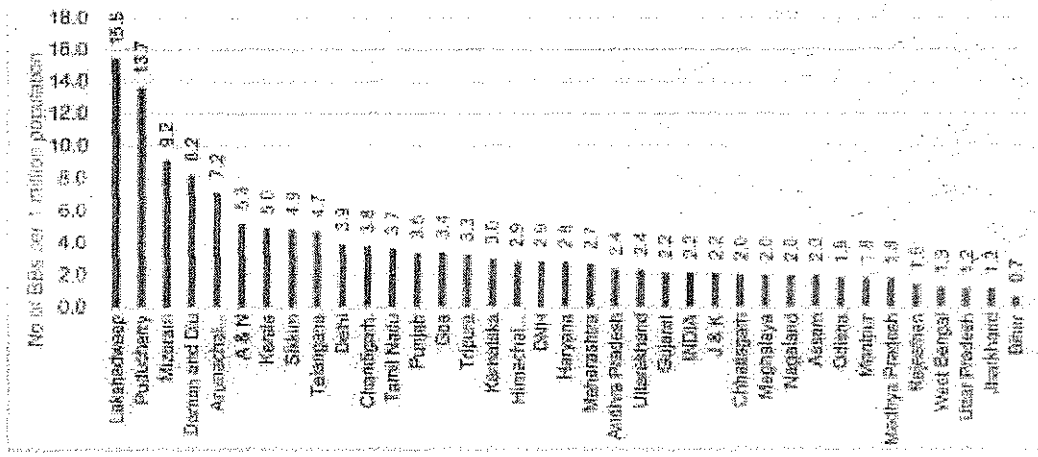
Around 61% (1,592) of all the blood banks(n=2,626) in the country were in 8 states that are, Maharashtra (11.7%), Tamil Nadu (10.1%), Uttar Pradesh (9.4%), Karnataka (7%), Kerala (6.3%), Telangana (5.8%), Gujarat (5.1%), and Madhya Pradesh (5%).

Table -3 State wise description of blood banks

State	NACO Supported	%	Non-NACO	%	Total
A & N	1	50.0	1	50.0	2
Andhra Pradesh	61	48.8	64	51.2	125
Arunachal Pradesh	8	80.0	2	20.0	10
Assam	26	41.9	36	58.1	62
Bihar	39	54.2	33	45.8	72
Chandigarh	4	100.0	0	0.0	4
Chhattisgarh	16	30.8	36	69.2	52
DNH	1	100.0	0	0.0	1
Daman and Diu	2	100.0	0	0.0	2
Delhi	20	30.3	46	69.7	66
Goa	3	60.0	2	40.0	5
Gujarat	77	57.5	57	42.5	134
Haryana	24	33.3	48	66.7	72
Himachal Pradesh	14	70.0	6	30.0	20

Jammu & Kashmir	23	85.2	4	14.8	27
Jharkhand	23	59.0	16	41.0	39
Karnataka	66	35.7	119	64.3	185
Kerala	45	27.1	121	72.9	166
Lakshadweep	0	0.0	1	100.0	1
Madhya Pradesh	62	46.6	71	53.4	133
Maharashtra	122	39.6	186	60.4	308
Manipur	3	60.0	2	40.0	5
Meghalaya	6	100.0	0	0.0	6
Mizoram	10	100.0	0	0.0	10
Nagaland	3	75.0	1	25.0	4
Odisha	58	72.5	22	27.5	80
Puducherry	5	29.4	12	70.6	17
Punjab	43	44.8	53	55.2	96
Rajasthan	50	49.0	52	51.0	102
Sikkim	2	66.7	1	33.3	3
Tamil Nadu	95	35.8	170	64.2	265
Telangana	43	28.1	110	71.9	153
Tripura	6	50.0	6	50.0	12
Uttar Pradesh	89	35.9	159	64.1	248
Uttarakhand	18	75.0	6	25.0	24
West Bengal	63	54.8	52	45.2	115
INDIA	1,131	43.1	1,495	56.9	2,626

Fig-1 Availability of BBs per 1,000,000 (1 million) population



Considering the number of blood banks per one million population, states such as, Bihar (0.7 blood banks), Jharkhand (1.2), Uttar Pradesh (1.2), West Bengal (1.3), Rajasthan(1.5), Madhya Pradesh (1.8), Manipur (1.8), Odisha (1.9), Assam (2), Nagaland(2), Meghalaya(2) and Chhattisgarh(2) recorded less than the national average of 2.2 blood banks per 1,000, 000 (one million) population.

4.1 Basic details of blood banks (n=2,493)

As indicated earlier, 2,493 blood banks (1,119 NACO supported and 1,374 Non-NACO) that submitted the assessment forms were included in the analysis.

4.1.1 Category of Blood Banks: Around 51% (1,271) of the blood banks in the country had component separation facility, of which, 431 (33.9%) were NACO supported blood banks. Of the 1,222 blood banks that were without component separation facility, 56.3% (688) were NACO supported blood banks.

Table-4 Basic details of blood banks

Specifics	Description	NACO Supported	Non-NACO	Total
Type of BB	With components	431 (38.5%)	840 (61.1%)	1271 (51.0%)
	Without components	688 (61.5%)	534 (38.9%)	1222 (49%)
Ownership	NGO/Trust/Charitable	243 (21.7%)	704 (51.2%)	947 (38%)
	Private	0 (0%)	597 (43.4%)	597 (23.9%)
	Public	876 (78.3%)	73 (5.3%)	949 (38.1%)
Licence	Valid	617 (55.1%)	1021(74.3%)	1638 (65.7%)
	Under Renewal	502 (44.9 %)	353 (25.7%)	855 (34.3%)
Attachment	Attached to Hospital	964 (86.1%)	955 (69.5%)	1919(77%)
	Attached to lab	0	23 (1.7%)	23(0.9%)
	Stand alone	155(13.9%)	396(28.8%)	551(22.1%)

At the state level, Delhi had the highest percentage of blood component separation units (60; 91%), followed by Maharashtra (240, 81.4%), Chandigarh (3; 75%), Karnataka (120; 65.9%), Puducherry (10; 58.8%), Uttar Pradesh (140; 56.7%), Andhra Pradesh(65; 55.1%), Haryana (34; 55.7%), Telangana (68; 55.3%), Rajasthan (53; 53.5%), Chhattisgarh (22; 53.7%).

Larger states like Jharkhand (13.5%), Odisha (17.1%), Bihar (19.4%), Assam (21.8%), Madhya Pradesh (28%), Uttarakhand (33.3%), West Bengal (41.4%), and Tamil Nadu (43%) had a low percentage of blood component separation facility. Dadra and Nagar Haveli had one blood bank that had component separation facility.

4.1.2 Ownership: The public and not-for-profit sector owned each 38% of the blood banks in the country and private sector owned around 24% (598) of blood banks. The majority (876; 78.3%) of NACO supported blood banks were owned by the public sector and the remaining 21.7% (243) were owned by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. The not-for-profit sector had a higher proportion (47.9%) of blood component separation facility than the public (23.2%) and private sector (28.9%). Among the NACO supported blood banks, the not-for-profit sector had a higher (61.3%) proportion of component separation facilities compared to the public sector (32.2%).

Around 55% of all the not-for-profit blood banks (n=947) were clustered in five states which are Maharashtra (21.2%), Tamil Nadu (9.7%), Gujarat (8.7%), Karnataka (7.8%), and Uttar Pradesh (7.6%). Around 50% of all the public owned blood banks were clustered in seven states which are Tamil Nadu (9.7%), Uttar Pradesh (9.5%), Maharashtra (7.9%), West Bengal (7.8%), Madhya Pradesh (6.2%), Rajasthan (5.1%), and Odisha (4.7%). Similarly, 58% of all the private owned blood banks were in six states which are Uttar Pradesh (14.2%), Karnataka (10.9%), Kerala (9.7%), Tamil Nadu (9.7%), Telangana (7.2%), and Madhya Pradesh (6.4%). (Refer Table - 5)

Table-5 State wise list of blood banks by Ownership

State	Public	%	Not-for-profit	%	Private	%	Total
A & N	1	50.0	1	50.0	0	0.0	2
Andhra Pradesh	35	29.7	62	52.5	21	17.8	118
Arunachal Pradesh	8	88.9	1	11.1	0	0.0	9
Assam	30	54.5	9	16.4	16	29.1	55
Bihar	34	47.2	22	30.6	16	22.2	72
Chandigarh	3	75.0	1	25.0	0	0.0	4
Chhattisgarh	18	43.9	14	34.1	9	22.0	41
DNH0	0.0	1	100.0	0	0.0	1	
Daman and Diu	2	100.0	0	0.0	0	0.0	2
Delhi	22	33.3	20	30.3	24	36.4	66
Goa	3	60.0	0	0.0	2	40.0	5
Gujarat	27	20.5	82	62.1	23	17.4	132
Haryana	23	37.7	12	19.7	26	42.6	61
Himachal Pradesh	17	85.0	2	10.0	1	5.0	20
Jammu & Kashmir	24	88.9	2	7.4	1	3.7	27
Jharkhand	20	54.1	5	13.5	12	32.4	37
Karnataka	43	23.6	74	40.7	65	35.7	182
Kerala	35	21.5	70	42.9	58	35.6	163
Madhya Pradesh	59	44.7	35	26.5	38	28.8	132
Maharashtra	75	25.4	201	68.1	19	6.4	295

Manipur	4	80.0	1	20.0	0	0.0	5
Meghalaya	4	66.7	2	33.3	0	0.0	6
Mizoram	7	70.0	3	30.0	0	0.0	10
Nagaland	3	100.0	0	0.0	0	0.0	3
Odisha	45	64.3	20	28.6	5	7.1	70
Puducherry	5	29.4	6	35.3	6	35.3	17
Punjab	43	44.7	25	26.0	28	29.2	96
Rajasthan	48	48.5	37	37.4	14	14.1	99
Sikkim	2	66.7	0	0.0	1	33.3	3
Tamil Nadu	92	38.0	92	38.0	58	24.0	242
Telangana	27	22.0	53	43.1	43	35.0	123
Tripura	10	83.3	0	0.0	2	16.7	12
Uttar Pradesh	90	36.4	72	29.1	85	34.4	247
Uttarakhand	16	66.7	4	16.7	4	16.7	24
West Bengal	74	66.1	18	16.1	20	17.9	112
INDIA	949	38.1	947	38.0	597	23.9	2493

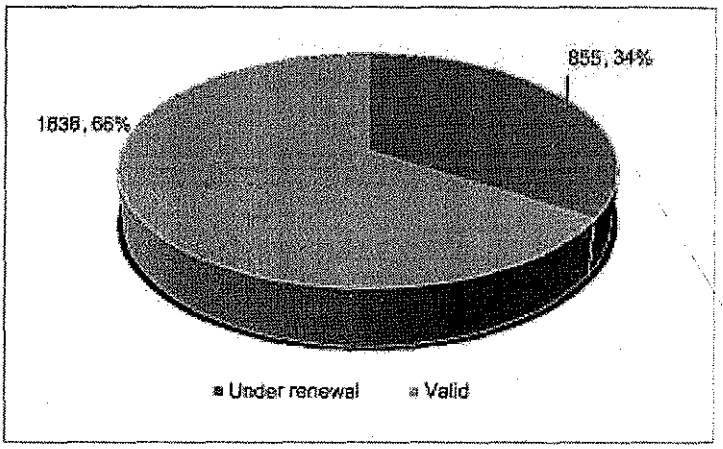
4.1.3 Organizational Attachment: The majority of the blood banks (1919; 77%)) were attached to hospitals, 1% (23) were attached to laboratories and the remaining 551 (22.1%) were standalone blood banks.

The majority of the NACO supported blood banks (964; 86.1%) were attached to hospitals and only 13.9% (155) were standalone blood banks. Though 69.5% (955) of the Non-NACO supported blood banks were attached to hospitals, a significant number (396; 28.8%) of Non-NACO supported blood banks were standalone and 23 (1.7%) were attached to laboratories. Further analysis indicated that 98.6% (936) of the blood banks in the public sector, 52.8 % (500) of the blood banks in the not-for-profit sector, and 80.9%(483) of the blood banks in the private sector were attached to hospitals. In the not-for-profit sector 46.3% (438) of the blood banks are standalone.

4.1.4 License details of blood banks: The license status was categorized as "valid" which means that the blood bank has current and active license; and "deemed renewal" which means that the blood bank had applied for renewal which is pending.

The majority of the blood banks (65.7%) had a valid and current license, and the remaining 34.3% had applied for renewal. Around 55% (617) of NACO supported and 74.3% (1,021) of Non-NACO supported blood banks had a valid and active license. Similarly, 74.2% (443) of the private blood banks, 72.4% (686) of the not-for-profit blood banks, and 53.6% (509) of the public blood banks had a valid and active license.

Fig-2 License status (n=2,493)



The majority of those blood banks (66.9%) which have reported as "deemed renewal" had their last inspection by licencing authority during the last one year; 17% had their inspection between the last 1 to 2 years, 6.2% had between 2 to 3 years, 2.3% had between 3 to 4 years and 4.7% had their inspection before 4 years.

4.2 Annual Blood Collection and Voluntary Blood Donation

According to WHO, it is estimated that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2016b), which means that India currently needs around 12.8 million units of blood.

4.2.1 Annual Collection of Blood: During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 11,645,791 of which 71.9% (8,378,692) units were through voluntary blood donations and the remaining were from replacement donations.

Fig-3 Annual collection and Voluntary donation

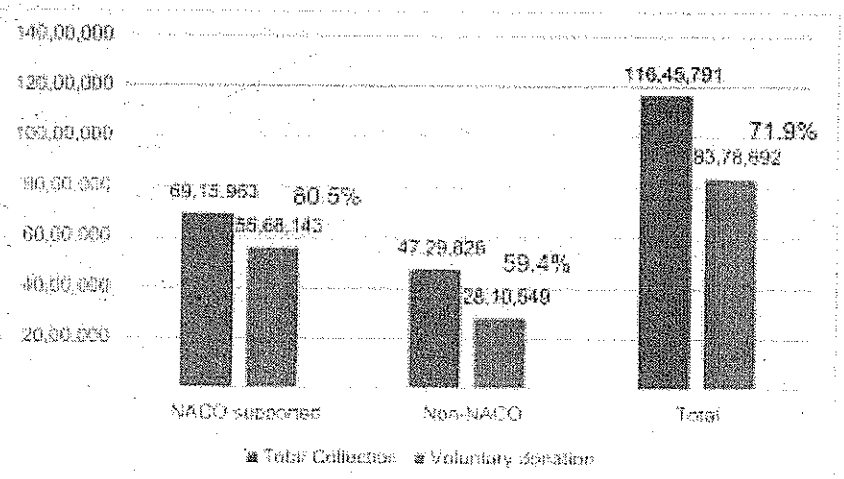
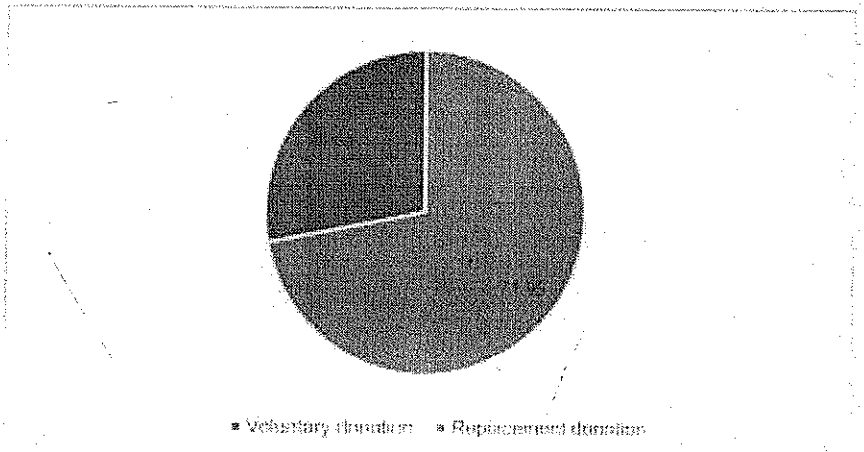


Fig-4 Type of blood donation (Voluntary vs Replacement donation %)



The average annual collection of blood units of all the blood banks in the country was 4789 units. The average annual collection of NACO supported blood banks was found to be higher (6,219 units) than the Non-NACO blood banks (3,583 units).

Table-6 Average Annual Collection

State	NACO supported	Non-NACO	All BBs
A & N	3765.0	330.0	2047.5
Andhra Pradesh	4742.7	3640.3	4210.8
Arunachal Pradesh	619.5	77.0	559.2
Assam	5542.7	2470.9	3923.0
Bihar	2838.4	2044.9	2487.0
Chandigarh	22299.8	NA	22299.8
Chhattisgarh	5781.6	4669.8	5086.7
DNH	7497.0	NA	7497.0
Daman and Diu	849.0	NA	849.0
Delhi	15402.1	5173.3	8273.0
Goa	6479.7	187.0	4906.5
Gujarat	7943.2	3714.2	6219.0
Haryana	7228.8	4516.4	5601.4
Himachal Pradesh	2700.0	757.7	2086.6
J & K	3451.0	1031.5	3092.6
Jharkhand	5786.9	2440.9	4430.4
Karnataka	6211.7	3434.6	4434.4
Kerala	6286.2	1737.6	3008.9
Madhya Pradesh	5138.6	3008.0	4056.4
Maharashtra	6864.9	4090.5	5226.8
Manipur	6548.7	1222.0	4418.0
Meghalaya	2256.0	NA	2256.0
Mizoram	2465.8	NA	2465.8
Nagaland	3018.3	-	3018.3
Odisha	6459.8	2449.4	5587.9
Puducherry	6418.3	1269.9	2642.8
Punjab	4899.0	3807.9	4296.6
Rajasthan	8780.8	4822.2	6801.5
Sikkim	2113.5	2195.0	2140.7
Tamil Nadu	4102.0	3189.7	3550.0
Telangana	4511.5	3145.1	3635.6
Tripura	4734.8	1720.5	3981.3
Uttar Pradesh	5889.8	3762.0	4564.4
Uttarakhand	5797.6	2019.8	4812.1
West Bengal	11170.7	8316.8	9951.3
INDIA	6219.3	3,583.2	4,788.6

Similarly, the blood banks with component separation units recorded a higher average collection of 7,035 units compared to blood banks without blood component separation units which was 2,432 units. However, the variation in the collection was found to be very high across and within districts and states.

The NACO supported blood banks collected 59.4% (6,915,963 units) of the total collection, of which 80.5% (5,568,143) units were through voluntary blood donation. The Non-NACO supported blood banks collected 4,729,828 (40.5%) units of which 59.4% (2,810,549) units were through voluntary blood donation. Blood Banks with component separation facility collected the majority (75.2%) of blood units (87,589,98) and the remaining (2,886,793) were collected by blood banks without the component facility. Similarly, blood banks owned by public sector collected 43.5% (5,053,320) of the total collection followed by the not-for-profit sector 39% (4,542,790) and private sector blood banks (17.5%, 2,049,681).

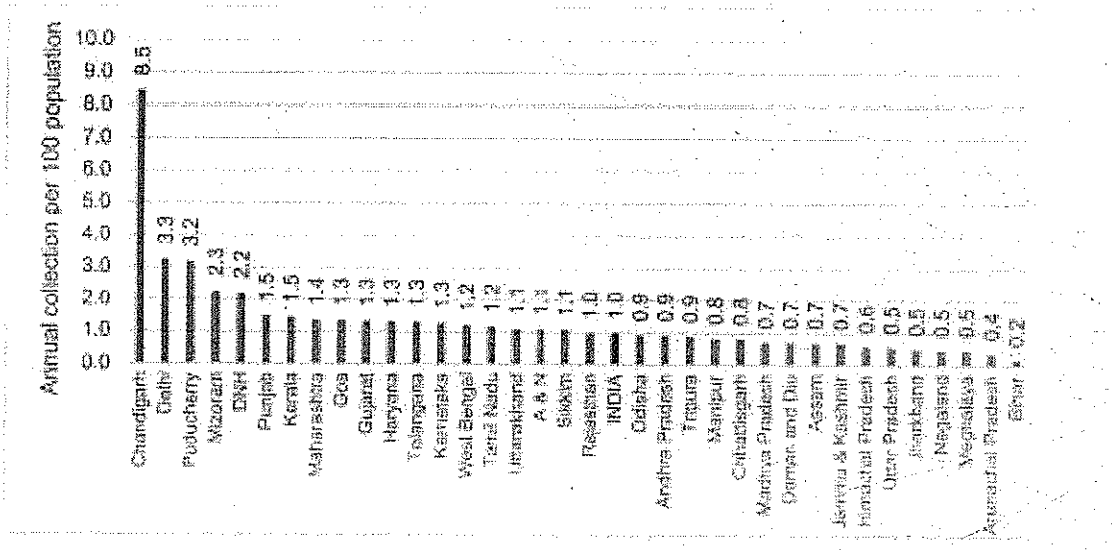
Table-7 indicates the state-wise details of the total annual collection, voluntary and replacement donation in the country.

Table -7 Annual blood collection and percentage of VBD

States	Total Voluntary donation	Replacement donation	Annual Collection	VBD %
A & N	3371	724	4095	82.3
Andhra Pradesh	335376	144657	480033	69.9
Arunachal Pradesh	5021	12	5033	99.8
Assam	103435	112331	215766	47.9
Bihar	88241	85850	174091	50.7
Chandigarh	76778	12421	89199	86.1
Chhattisgarh	90335	113133	203468	44.4
DNH	7497	0	7497	100.0
Daman and Diu	1576	122	1698	92.8
Delhi	243596	302420	546016	44.6
Goa	15333	4293	19626	78.1
Gujarat	627156	181318	808474	77.6
Haryana	229561	106520	336081	68.3
Himachal Pradesh	32260	7386	39646	81.4
Jammu & Kashmir	47643	35856	83499	57.1
Jharkhand	83659	80266	163925	51.0
Karnataka	565844	210173	776017	72.9
Kerala	400473	83964	484437	82.7
Madhya Pradesh	378906	132199	511105	74.1
Maharashtra	1481484	49962	1531446	96.7

Manipur	9060	13030	22090	41.0
Meghalaya	5178	8358	13536	38.3
Mizoram	18543	6115	24658	75.2
Nagaland	7038	2017	9055	77.7
Odisha	277932	107636	385568	72.1
Puducherry	20745	18897	39642	52.3
Punjab	277166	135312	412478	67.2
Rajasthan	436800	229748	666548	65.5
Sikkim	4212	2210	6422	65.6
Tamil Nadu	786626	58282	844908	93.1
Telangana	265857	159507	425364	62.5
Tripura	30304	1546	31850	95.1
Uttar Pradesh	416965	660231	1077196	38.7
Uttarakhand	97352	13327	110679	88.0
West Bengal	907369	187276	1094645	82.9
INDIA	8,378,692	3,267,099	11,645,791	71.9

Fig-5 Annual collection per 100 population - State wise

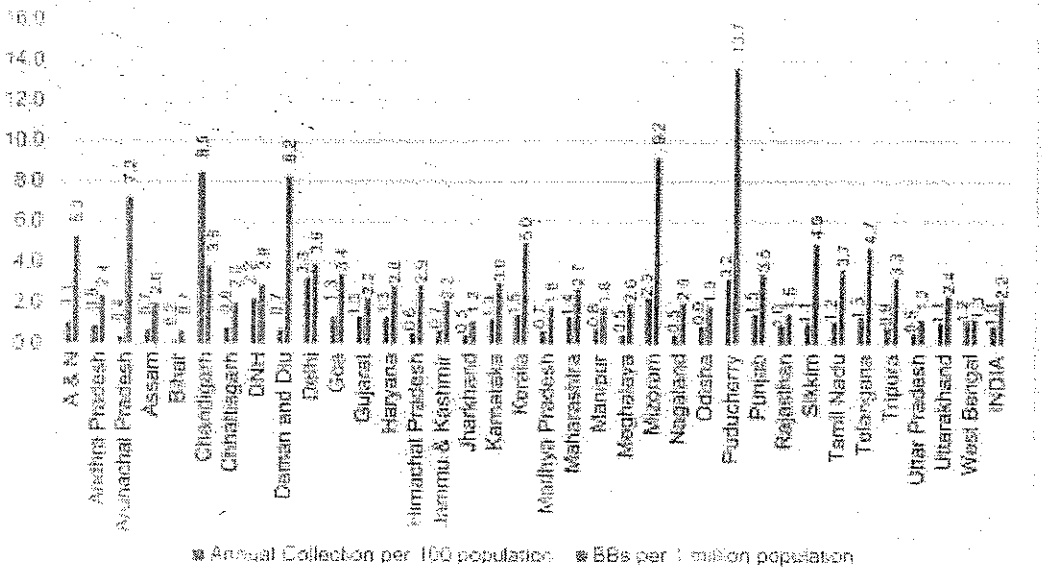


The annual collection of blood units per 100 individuals was found to be around 1% in the country, which is meeting the WHO suggested requirement that 1% of the population can meet a nation's most basic requirements for blood. However, there is a huge disparity in the collection of blood between states. Bihar state collected only 0.2 units of blood per 100 population followed by Arunachal Pradesh (0.4), Meghalaya (0.5), Nagaland (0.5),

Jharkhand (0.5), and Uttar Pradesh (0.5). Nineteen states in the country recorded an annual collection of more than 1 unit per 100 population. (Refer Fig-5)

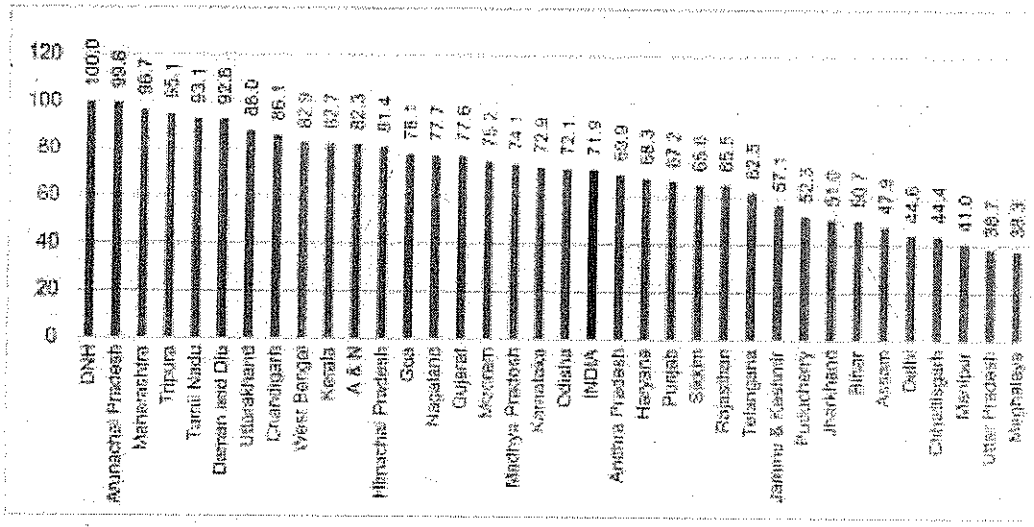
Figure 6 illustrates the state wise comparative information of annual collection per 100 population and number of blood banks per one million population. This indicates that the country had around 2.2 blood banks per million population that collected around one unit per 100 population at the ratio of 2.2 BB: 1 blood unit. The ratio was much higher in Chandigarh which was 3.8:8.5 which indicates that the state collected relatively more blood with less number of blood banks proportionate to the population. The ratio in Puducherry state had more blood banks but relatively less collection that indicates that the state collected less proportionate to the population.

Fig 6- Annual collection per 100 population Vs BBs per 1 million- State wise



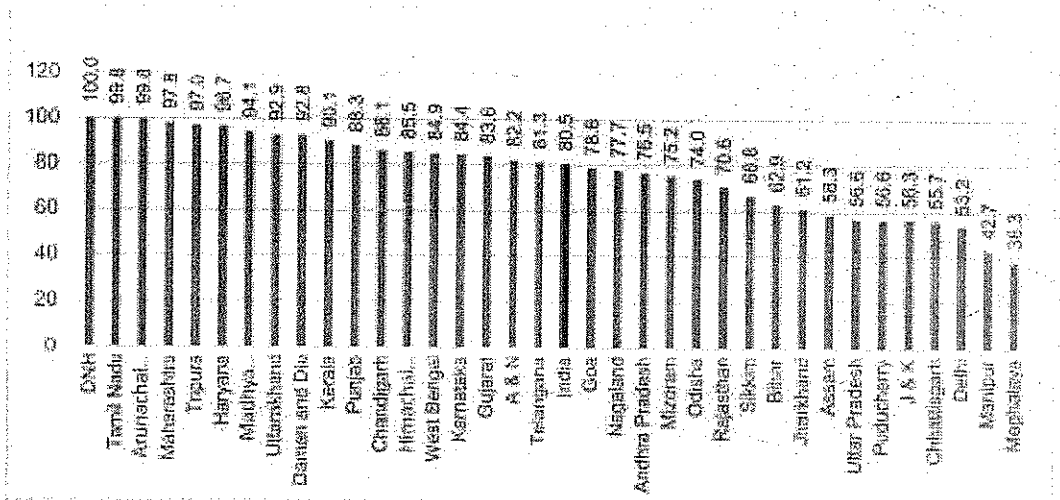
4.2.2 Voluntary blood donation: As depicted in Figure-7, nineteen states have recorded more than the national average of 71.9%. States such as Dadra and Nagar Haveli, Arunachal Pradesh, Maharashtra, Tripura, Tamil Nadu, Daman and Diu, Uttarakhand, Chandigarh, West Bengal, Kerala, Andaman and Nicobar, and Himachal Pradesh reported more than 80% voluntary blood donation. States such as Meghalaya, Uttar Pradesh, Manipur, Chhattisgarh, Delhi, Assam, Bihar, Jharkhand, Puducherry, and Jammu &Kashmir reported less than 60% of voluntary blood donation during January to December 2015.

Fig-7 Percentage of voluntary blood donation by state (Overall)



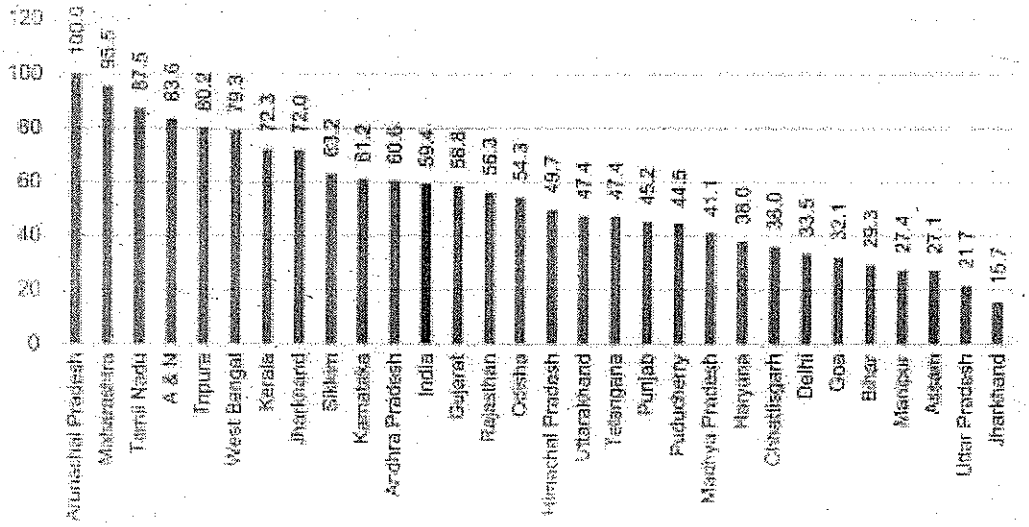
In terms of NACO supported blood banks, eighteen states have recorded a higher proportion of voluntary donation which is above the national average of 80.5%. Dadra and Nagar Haveli, Tamil Nadu, Arunachal Pradesh, Maharashtra, Tripura, Haryana, Madhya Pradesh, Uttarakhand, Daman and Diu, and Kerala reported more than 90% voluntary blood donation. States such as Assam, Uttar Pradesh , Puducherry , Jammu and Kashmir, Chhatisgarh, Delhi, Manipur, and Meghalaya reported less than 60% of voluntary donation during January to December 2015.

Fig-8 Percentage of voluntary blood donation by state (NACO supported)



Among Non-NACO blood banks, only five states recorded more than 80% of voluntary donation - Arunachal Pradesh, Maharashtra, Tamil Nadu, Andaman and Nicobar, and Tripura. However, states such as Himachal Pradesh, Uttarakhand, Telangana, Punjab, Puducherry, Madhya Pradesh, Haryana, Chhattisgarh, Delhi, Goa, Bihar, Manipur, Assam, Uttar Pradesh, and Jharkhand reported less than 50% of voluntary blood donation during January to December 2015.

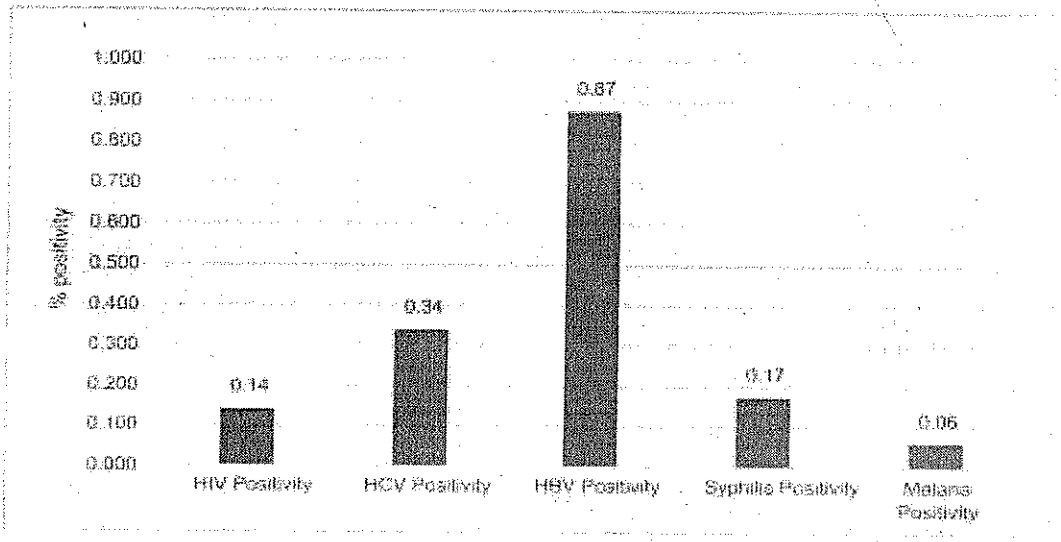
Fig-9 Percentage of voluntary blood donation by state (Non-NACO)



4.3 Transfusion Transmitted Infections (TTIs)

Transfusion-Transmitted Infections (TTIs) are major problems associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Screening for TTIs such as HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria, and Syphilis is mandatory in India. Due to the concerted and active efforts, the seropositivity percentage of TTIs has come down significantly over the years.

Fig-10 Transfusion Transmitted Infections (%) - Jan-Dec 2015



The seropositivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV positivity was found to be 0.14%, Hepatitis C was 0.34%, Hepatitis-B 0.87%, Syphilis 0.17% and Malaria 0.06%. However, there is a huge variation between states.

Though HIV and HCV positivity rates did not indicate much difference between NACO and Non-NACO blood banks. The HBV positivity was found to be higher in NACO supported blood banks. Syphilis and Malaria positivity rates were recorded higher in Non-NACO blood banks.

Table-8 Transfusion Transmitted Infections (%)

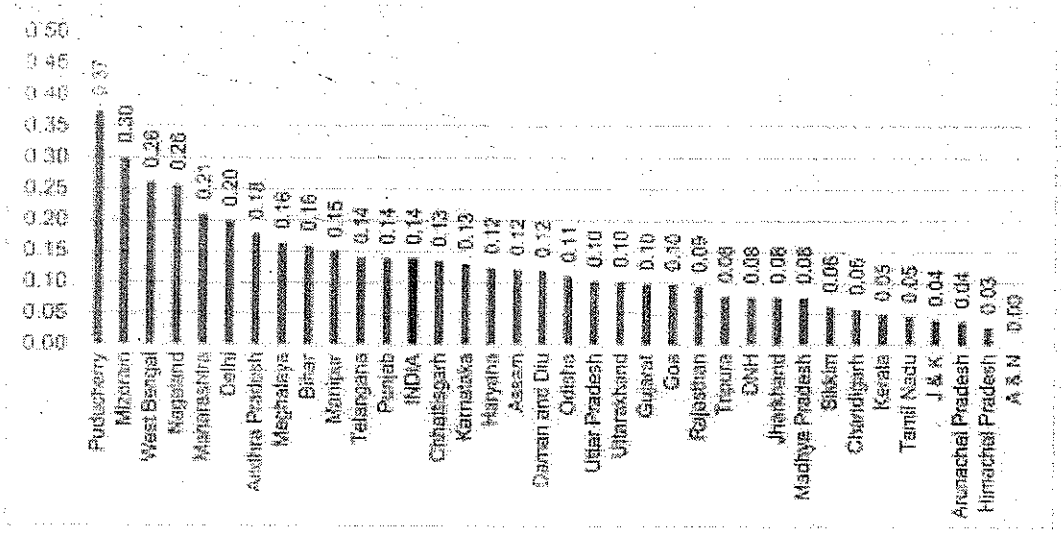
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported BBs	0.14	0.32	0.93	0.14	0.04
Non-NACO	0.14	0.36	0.79	0.22	0.09
Overall	0.14	0.34	0.87	0.17	0.06

4.3.1 Transfusion Transmitted Infections by Category of blood banks: The blood banks with component facility indicated a higher positivity of HIV (0.15%), HCV (0.37%) and HBV (0.91%). However, Syphilis (0.18%) and Malaria (0.17) were found to be higher in blood banks without component facility compared to blood banks with the component facility.

Table-9 Transfusion Transmitted Infections by category of blood banks

Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.15	0.37	0.91	0.17	0.02
BBs without component facility	0.11	0.23	0.75	0.18	0.17
Overall	0.14	0.34	0.87	0.17	0.06

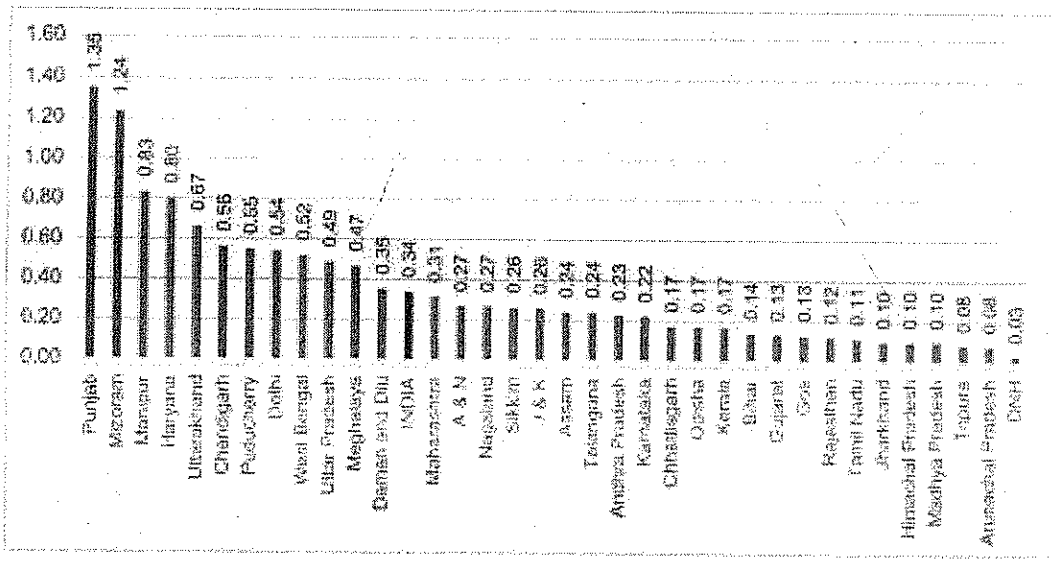
Fig-11 HIV seropositivity – By state (%)



The majority of states indicated lower HIV positivity than the national HIV positivity level of 0.14%. However, Puducherry(0.37%), Mizoram(0.30%), West Bengal(0.26%), Nagaland(0.26%), Maharastra(0.21%), Delhi (0.2%), Andhra Pradesh(0.18%), Meghalaya(0.16%), Bihar (0.16%), and Manipur(0.15%) recorded a higher positivity than national average. States like, Himachal Pradesh, Arunachal Pradesh, Jammu and Kashmir, Tamil Nadu, Kerala, Chandigarh, Sikkim, Madhya Pradesh, Jharkhand, Dadra and Nagar Haveli, Tripura, and Rajasthan recorded less than 0.1% HIV positivity.

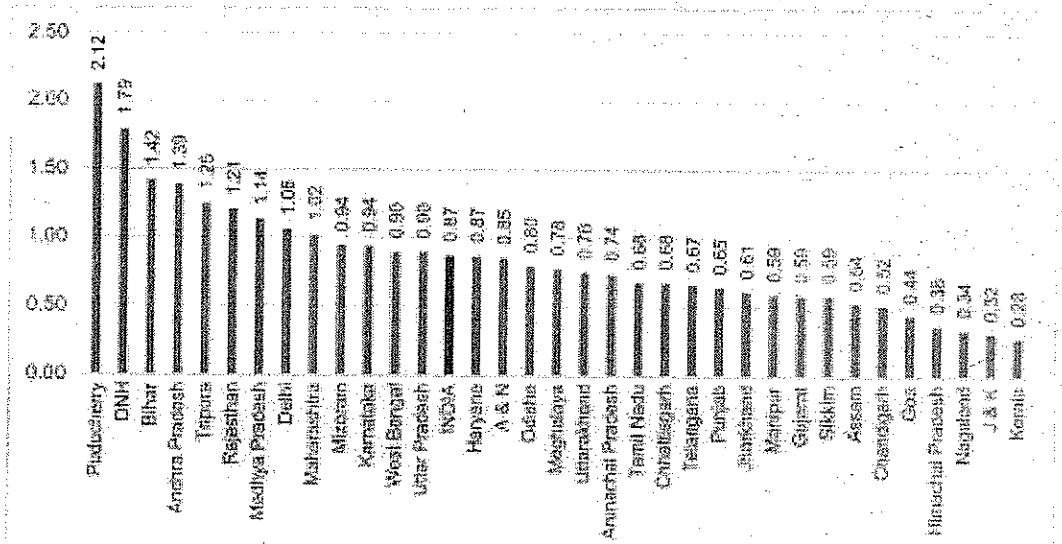
When considering Hepatitis C infection, states like Punjab (1.35%), Mizoram (1.24%), Manipur (0.83%), Haryana (0.80%), Uttarakhand (0.67%), Chandigarh (0.56%), Puducherry (0.55%), Delhi (0.54%), West Bengal (0.52%), Uttar Pradesh (0.49%), Meghalaya (0.47%), and Daman and Diu (0.35%) recorded a positivity level higher than the national average of 0.34%.

Fig-12 HCV seropositivity – By state (%)



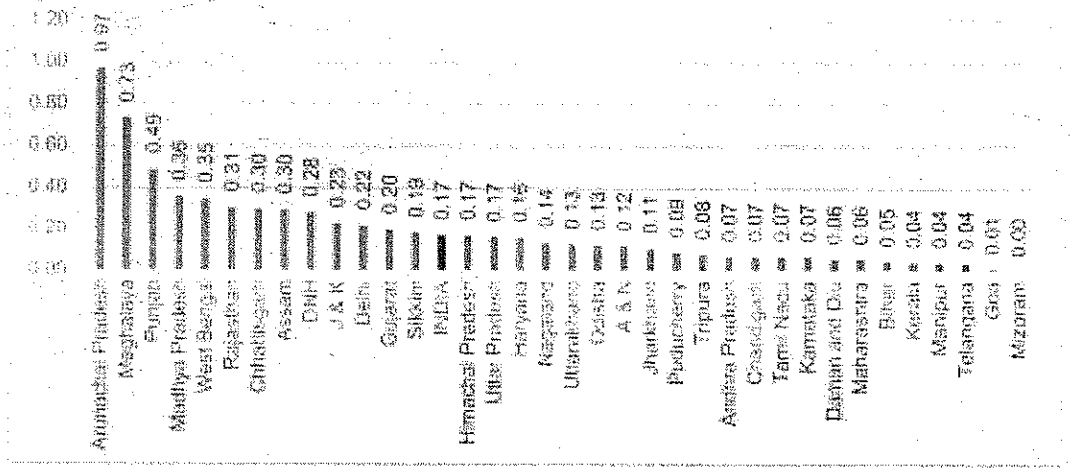
Hepatitis B was found to be higher than the national average of 0.87% in states like Puducherry (2.12%), Dadra and Nagar Haveli(1.79%), Bihar(1.42%),Andhra Pradesh(1.39%), Tripura(1.25%), Rajasthan(1.21%), Madhya Pradesh(1.14%), Delhi(1.06%), Maharashtra(1.02%), Mizoram (0.94%), Karnataka (0.94%), West Bengal (0.90%), and Uttar Pradesh (0.90%). Twenty states have recorded a positivity level less than the national average of 0.87%. Specifically, Kerala, Jammu and Kashmir, Nagaland, and Goa recorded less than 0.50%.

Fig-13 HBV seropositivity – By state (%)



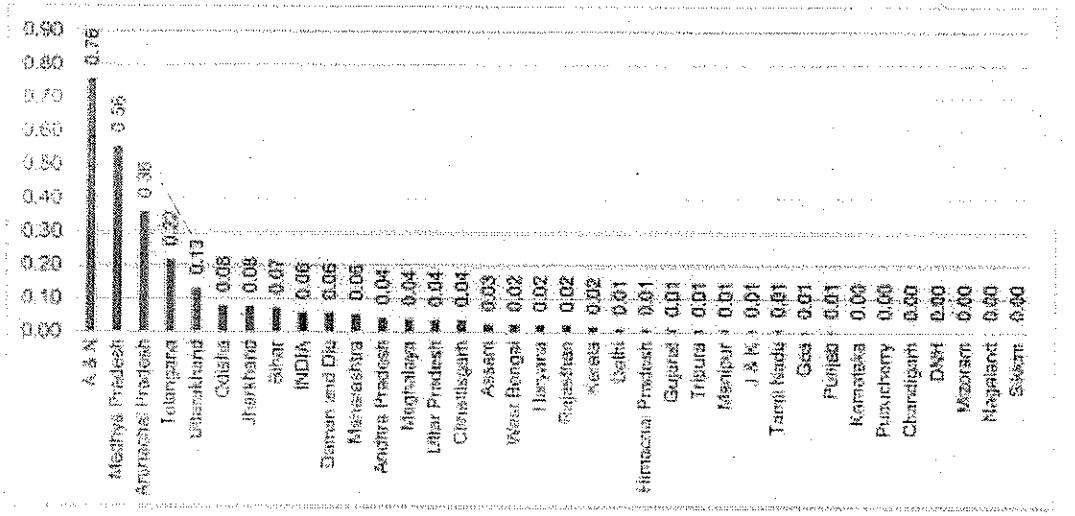
Syphilis seropositivity was found to be higher than the national average of 0.17% in states like Arunachal Pradesh(0.97%), Meghalaya(0.73%), Punjab(0.49%), Madhya Pradesh(0.36%), West Bengal (0.35%), Rajasthan(0.31%), Chhattisgarh(0.30%), Assam(0.30%), Dadra and Nagar Haveli(0.28%), Jammu and Kashmir(0.23%), Delhi (0.22%), Gujarat(0.20%)and Sikkim (0.19%). Twenty one states recorded less than the national average.

Fig-14 Syphilis seropositivity- By State (%)



The majority of the states indicated a lower positivity of Malaria than the national positivity of 0.06% whereas states like Andaman and Nicobar Islands, Arunachal Pradesh, Madhya Pradesh, Telangana, Uttarakhand, Odisha, Jharkhand, and Bihar recorded a higher positivity than the national average.

Fig-15 Malaria Positivity– By state (%)



4.4 Component Separation

As depicted in Figure -16, around 71% of blood units collected by blood banks with component separation facilities, were used for component separation in India. The percentage of component separation was higher (75.4%) in Non-NACO blood banks compared to NACO supported blood banks (67.3%).

Fig-16 Total blood collection and component separation

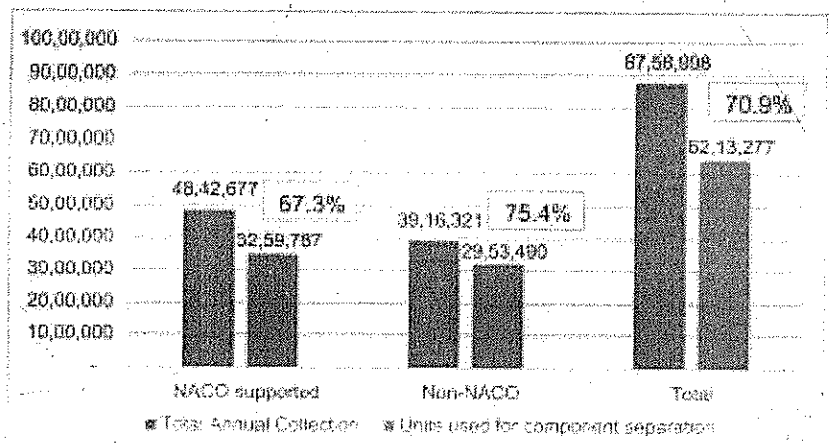


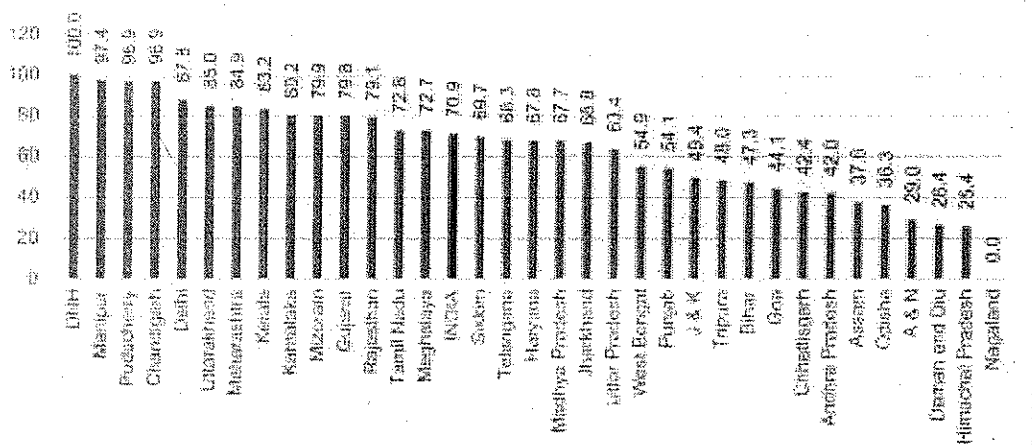
Table -10 Total annual collection by BCSUs and Percentage of component separation

State	Total Annual Collection	Total annual collection by BCSUs	Percentage of component separation
A & N	4095	3765	29.0
Andhra Pradesh	480033	376355	42.0
Arunachal Pradesh	5033	0	0
Assam	215766	107608	37.6
Bihar	174091	85325	47.3
Chandigarh	89199	84984	96.9
Chhattisgarh	203468	136447	42.4
DNH	7497	7497	100
Daman and Diu	1698	1568	26.4
Delhi	546016	536181	87.8
Goa	19626	16249	44.1
Gujarat	808474	633787	79.8
Haryana	336081	223907	67.8
Himachal Pradesh	39646	23154	25.4
J & K	83499	63985	49.4
Jharkhand	163925	92756	66.8

Karnataka	776017	704560	80.2
Kerala	484437	415748	83.2
Madhya Pradesh	511105	235200	67.7
Maharashtra	1531446	1395065	84.9
Manipur	22090	14670	97.4
Meghalaya	13536	8326	72.7
Mizoram	24658	16321	79.9
Nagaland	9055	6462	0.0
Odisha	385568	171528	36.3
Puducherry	39642	34733	96.9
Punjab	412478	298146	54.1
Rajasthan	666548	471405	79.1
Sikkim	6422	2195	69.7
Tamil Nadu	844908	570309	72.8
Telangana	425364	340840	68.3
Tripura	31850	16423	48.0
Uttar Pradesh	1077196	896693	63.4
Uttarakhand	110679	74137	85.0
West Bengal	1094645	692669	54.9
INDIA	11,645,791	8,758,998	70.9

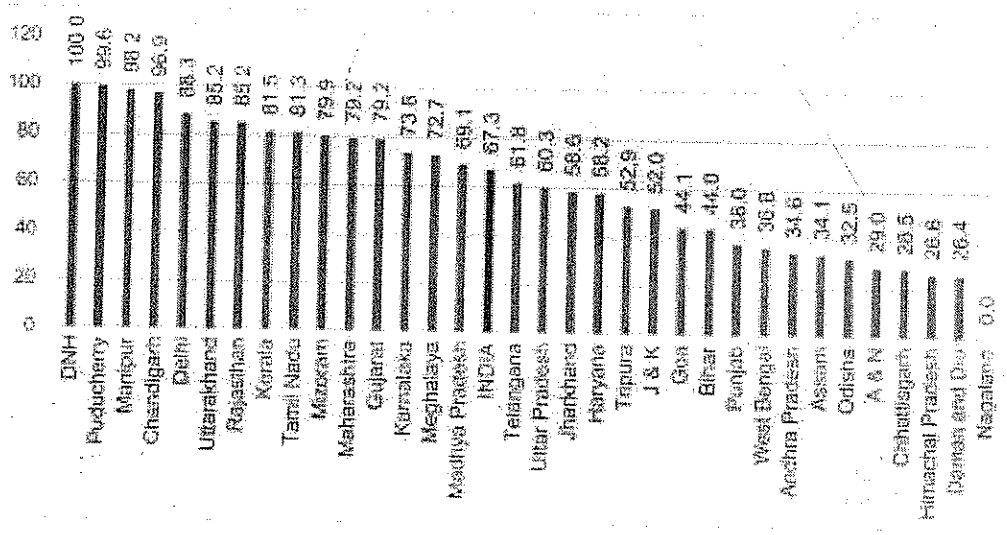
The percentage of component separation out of the total collection was more than 80% in Dadra and Nagar Haveli, Manipur, Puducherry, Chandigarh, Delhi, Uttarakhand, Maharashtra, Kerala, and Karnataka. This was reported less than 50% in states like Nagaland, Himachal Pradesh, Daman and Diu, Andaman and Nicobar, Odisha, Assam, Andhra Pradesh, Chhattisgarh, Goa, Bihar and Tripura.

Fig-17 Percentage of component separation – By state (All BBs)



The percentage of component separation in NACO supported blood banks is illustrated in Figure-18 which indicates 9 states recording more than 80% and 11 states reporting less than 50% of component separation.

Fig-18 Percentage of component separation – By state (NACO supported)



States such as Sikkim and Arunachal Pradesh did not have any NACO supported blood banks with component separation facility.

4.5 Quality Management Systems

Quality is defined as the totality of characteristics of an entity that bears on its ability to satisfy the stated and implied needs (Schlickman, 1998). It is a spectrum of activities and processes that shape the characteristics of a product or service. Quality systems are defined as the organizational structure, resources, processes, and procedures needed to implement quality management (ISO-8402, 1994) and Quality Management System is the sum total of all business policies, processes and procedures required for the execution of production, development or service of an organization.

Blood transfusion is a multi-step process with the risk of error in each process from selecting donors, collecting and processing donations, testing of donor and patient samples, issue of compatible blood, to transfusing the patient (WHO, 2016a). An effectively planned and implemented quality system that includes internal quality assessment, external quality assessment, and education and training of staff can significantly reduce the risk associated with blood transfusion.

The assessment captured several parameters that influence the quality of service provision. Some of the key parameters are mentioned in Table -11. The majority of blood banks (91.5%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by less than 50% of the blood banks in

the country. Around 42% of NACO supported blood banks and 55% of Non-NACO blood banks reported they had a document control system. In terms of Standard Operating Procedures (SOPs) for technical processes, more than 95% reported that they had SOPs.

Table -11 Availability of quality parameters in blood banks

Quality Parameters	NACO/NON-NACO		All Blood Banks
	NACO supported	Non-NACO	
Compliance with NBTC guidelines	1050	1231	2281
	93.8%	89.6%	91.5%
Availability of Documental Control System (DCS)	467	756	1223
	41.7%	55.0%	49.1%
SOPs for Technical Processes	1055	1345	2400
	94.3%	97.9%	96.3%
IQC for IH	794	1149	1943
	71.0%	83.6%	77.9%
IQC for TTI	609	690	1299
	54.4%	50.2%	52.1%
QC for kits, reagents and blood bags	882	1268	2150
	78.8%	92.3%	86.2%
EQAS for IH	79	236	315
	7.1%	17.2%	12.6%
EQAS for TTI	88	192	280
	7.9%	14.0%	11.2%
NABH accreditation for blood banks	25	48	73
	2.2%	3.5%	2.9%
Availability of designated and trained Quality Manager	243	702	945
	21.7%	51.1%	37.9%
Availability of designated and trained Technical Manager	308	894	1202
	27.5%	65.1%	48.2%
Programme for regular Equipment maintenance	834	1319	2153
	74.5%	96.0%	86.4%
Equipment calibration as per regulatory requirement	874	1335	2209
	78.1%	97.2%	88.6%
Total no of blood banks	1,119	1,374	2,493
	100.0%	100.0%	100.0%

At the national level, Internal Quality Control (IQC) for Immunohematology was reported by 78% of the blood banks and IQC for TTIs was reported by 52% of the blood banks, with slight variation between NACO supported and Non-NACO blood banks. Around 86% of the blood banks reported carrying out quality control for kits, reagents and blood bags. The percentage of blood banks enrolled in EQAS by recognized providers was found to be only 12.6% for immunohematology and 11.2% for TTIs. Only 73 (2.9%) blood banks out of the total 2493 blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Designated and trained Quality Managers and Technical managers were available only in 37.9% and 48.2% of the blood banks respectively.

More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 89% reported that they calibrate the equipment as per requirement.

4.6. The current status of blood banks based on the assessment

As mentioned in the methodology section, the blood banks were assessed and categorized based on the scores obtained. Though the assessment captured all the aspects of blood transfusion services in blood banks, adequate importance and weightage were given to the technical aspects and adherence to quality management systems.

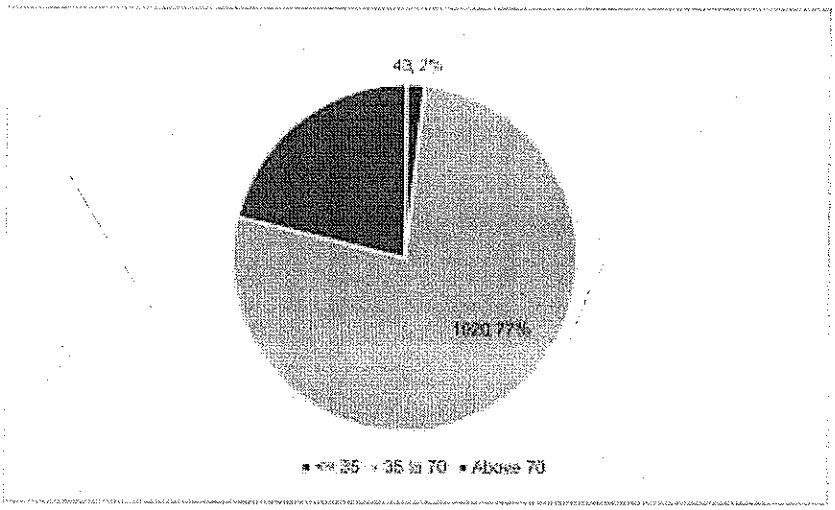
The mean assessment score of blood banks in the country was 62 (SD: 11.19). The Non-NACO supported blood banks scored slightly higher (62.68; SD: 10.63) than the NACO supported blood banks (Refer Table - 12). It is important to understand that around 78% of all the blood banks under NACO supported were in the public sector and present across sub-divisional and divisional/district hospitals catering all segments of the population including rural areas. Whereas, the majority (95%) of the Non-NACO blood banks were in the private and not-for-profit sector. Essentially all the private sector blood banks were coming under the Non-NACO category which could be a reason for the minor difference in the score.

Table-12 Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	1119	61.18	11.79
Non-NACO	1374	62.68	10.63
Total	2493	62.00	11.19

At the national level, the majority of blood banks (1920; 77%) scored between 35 to 70, followed by 21% (530) which scored above 70, and 2% (43) scored less than or equal to 35.

Fig-19 Categorisation of blood banks (n=2493)



An equal proportion of 77% of NACO supported and Non-NACO blood banks scored between 35 and 70. Around, 21% of NACO supported blood banks and 22% of Non-NACO blood banks scored more than 70 Score or Percentage? (Refer Figure 20; Figure 21)

Fig-20 Categorisation of NACO supported \BBs (n=1119)

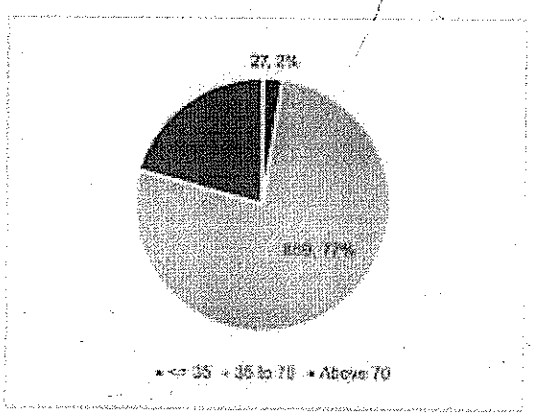
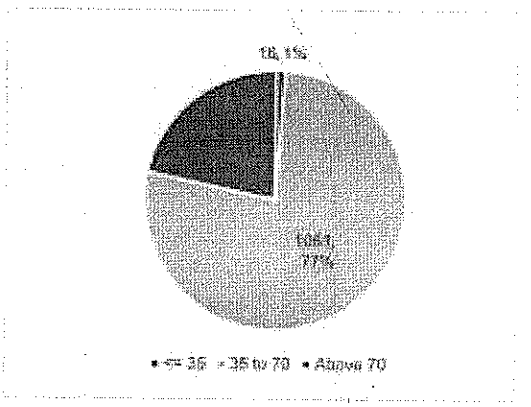
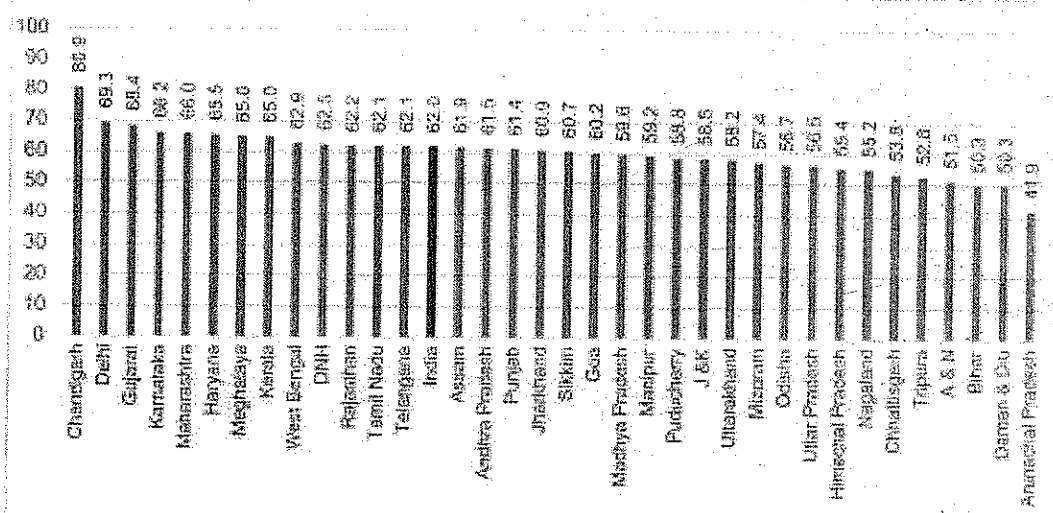


Fig-21 Categorisation of Non-NACO BBs (n=1374)



Among the states, Chandigarh (80.9) scored the highest and Arunachal Pradesh (41.9) scored the least. Excluding Chandigarh and Arunachal Pradesh, the mean scores of all the other states ranged from 69.3 to 50.3 with relatively less variations between states. Although only 13 had mean scores over the national average, a majority (59.6%) of the blood banks were located in these states/UTs.

Fig-22 Mean assessment score - By state (All BBs)



Though the difference in the mean score at the national level was only 1.5 between NACO and Non-NACO supported blood banks, the mean scores of NACO supported blood banks were higher than the Non-NACO blood banks in 15 states.

The difference in the score was more than 5 in NACO supported blood banks in states such as Goa, Haryana, Jammu & Kashmir, Sikkim, and Uttarakhand. Among the 15 states that scored higher mean score than the Non-NACO blood banks, the difference was more than 5 in states such as Bihar, Chhattisgarh, Punjab, Tamil Nadu and Uttar Pradesh.

Table -13 Mean assessment score - By state (NACO supported Vs Non-NACO)

State	NACO Supported	Non-NACO	TOTAL
Andaman & Nicobar	52.0	51.0	51.5
Andhra Pradesh	61.3	61.7	61.5
Arunachal Pradesh	41.6	44.0	41.9
Assam	59.5	64.0	61.9
Bihar	46.8	54.4	50.3
Chandigarh	80.9	NA	80.9
Chhattisgarh	49.2	56.7	53.8
DNH	62.5	NA	62.5
Daman and Diu	50.3	NA	50.3
Delhi	71.0	68.6	69.3
Goa	64.0	54.5	60.2
Gujarat	70.5	65.5	68.4
Haryana	68.6	63.4	65.5
Himachal Pradesh	54.5	57.4	55.4
Jammu & Kashmir	59.6	52.5	58.5
Jharkhand	61.2	60.6	60.9
Karnataka	67.8	65.3	66.2
Kerala	66.3	64.5	65.0
Madhya Pradesh	59.5	59.7	59.6
Maharashtra	66.7	65.5	66.0
Manipur	57.7	61.5	59.2
Meghalaya	65.0	NA	65.0
Mizoram	57.4	NA	57.4
Nagaland	55.2	NA	55.2
Odisha	56.1	58.8	56.7
Puducherry	56.9	59.6	58.8
Punjab	57.4	64.6	61.4
Rajasthan	63.9	60.5	62.2

Sikkim	62.5	57.0	60.7
Tamil Nadu	58.9	64.2	62.1
Telangana	62.1	62.1	62.1
Tripura	58.7	46.8	52.8
Uttar Pradesh	52.5	58.7	56.5
Uttarakhand	60.2	52.3	58.2
West Bengal	62.1	63.9	62.9
INDIA	61.2	62.7	62.0

The number of blood banks (by state) that scored less than or equal to 35 is mentioned in Table-14. Most of the blood banks were in Uttar Pradesh (13; 5% of all blood banks), followed by Bihar (6; 8% of all blood banks) and Odisha (3; 4% of all blood banks).

Table-14 Number of blood banks scored <=35

State	NACO supported	Non-NACO	Total
Uttar Pradesh	10	3	13
Bihar	4	2	6
Odisha	3	-	3
Arunachal Pradesh	2	-	2
Punjab	2	-	2
Gujarat	-	2	2
Karnataka	-	2	2
Andhra Pradesh	1	-	1
Chhattisgarh	1	-	1
Jharkhand	1	-	1
Madhya Pradesh	1	1	2
Maharashtra	1	-	1
Rajasthan	1	-	1
Tamil Nadu	-	1	1
Haryana	-	1	1
Kerala	-	1	1
Telangana	-	1	1
Tripura	-	1	1
Uttarakhand	-	1	1
TOTAL	27	16	43

The number of blood banks (by state) that scored more than 70 is mentioned in Table-15. Of the 530 blood banks that scored more than 70 score, 297 (56%) were Non-NACO supported blood banks. The majority of

blood banks that scored above 70 were from Maharashtra (90) followed by Gujarat (60), Karnataka (55), Tamil Nadu (53), Kerala (42), Delhi (34), and Rajasthan (22). These 6 States constitute 50% of the total blood banks that scored more than 70.

Among these states, the proportion of NACO supported blood banks that scored above 70 were relatively higher in Delhi (65%) and Gujarat (54.5%).

Table-15 Number of blood banks scored above 70 – by state

State	NACO Supported	Non-NACO	TOTAL
Maharashtra	44	46	90
Gujarat	42	18	60
Karnataka	22	33	55
Tamil Nadu	8	45	53
Kerala	12	30	42
Delhi	13	21	34
Rajasthan	13	9	22
West Bengal	11	11	22
Uttar Pradesh	6	15	21
Punjab	5	14	19
Haryana	10	8	18
Telangana	6	12	18
Madhya Pradesh	9	8	17
Andhra Pradesh	6	10	16
Assam	3	9	12
Jharkhand	6	1	7
Odisha	5	2	7
Uttarakhand	5	1	6
Chandigarh	4	-	4
J & K	2	-	2
Puducherry	-	2	2
Bihar	-	1	1
Manipur	-	1	1
Meghalaya	1	-	1
TOTAL	233	297	530

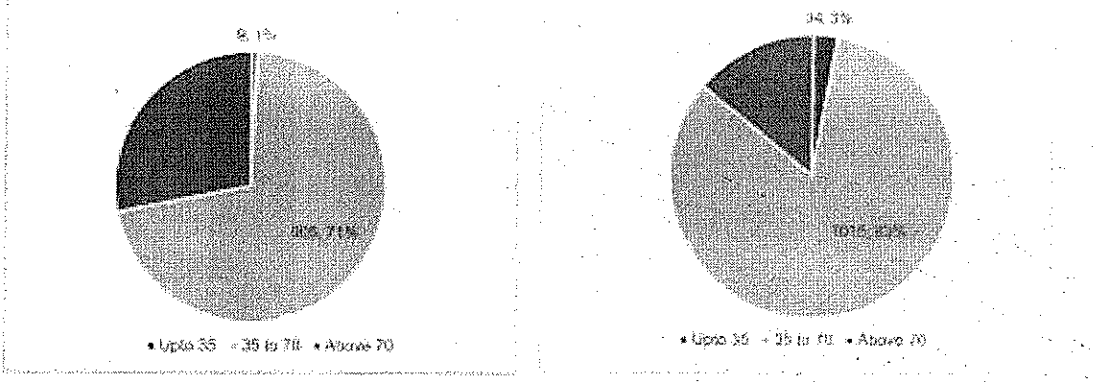
4.6.1 Assessment score by Category of blood banks: The mean score of blood banks with component facilities was found to be higher (64.69; SD: 10.84) than the mean score of those without component facilities (59.22; SD: 10.87). No significant differences are observed between NACO and Non-NACO supported Blood banks.

Table-16 Mean assessment score by category of blood banks

Type of BBs	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Blood Component Separation Units	431	64.58	11.70	840	64.75	10.38	1271	64.69	10.84
Without Components separation facility	688	59.05	11.35	534	59.43	10.22	1222	59.22	10.87

Among blood banks that scored <=35, the majority were without blood component separation facility (34), as compared to only 9 blood banks with component separation facility (Refer figure 23 and 24). Blood banks with component preparation facility were twice as likely to score more than 70 as compared those without component facility.

Fig-23 BBs with component –Score (n=1271) Fig-24 BBs without component-Score (n=1222)



4.6.2 Assessment score by Ownership: The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (64.18; SD: 10.52) was found to be higher than the public sector blood banks (59.16; SD: 11.30). It was also found that there were more public sector blood banks (24 blood banks) in the less than or equal to 35 category compared to only 10 blood banks from not-for-profit owned blood banks.

However, NACO supported blood banks run by not-for-profit sector had scored higher (67.30; SD: 11.27) compared to Non-NACO supported blood banks NGO/Trust/Charitable blood banks (63.11; SD: 10.03).

Table-17 Mean assessment score by Ownership

Ownership	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
NGO/Trust/charitable	243	67.30	11.27	704	63.11	10.03	947	64.18	10.52
Private	-	-	-	597	63.09	11.11	597	63.09	11.11
Public	876	59.48	11.37	73	55.25	9.62	949	59.16	11.30

Table-18 Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	24	779	146	949
	2.5%	82.1%	15.4%	100.0%
NGO/Trust/Charitable	10	695	242	947
	1.1%	73.4%	25.6%	100.0%
Private	9	446	142	597
	1.5%	74.7%	23.8%	100.0%
Overall	43	1920	530	2493
	1.7%	77.0%	21.3%	100.0%

4.6.3 Assessment score of Private Sector blood banks: Irrespective of the NACO support status, 62% (1544) blood banks were owned by private sector, of which, 947 (61.3%) were owned by not-for-profit sector such as, NGO, Trust, and charitable organizations. The mean score of private sector owned blood banks including not-for-profit sector was 63.75 (SD: 10.76) and the mean score of public owned blood banks was 59.15 (11.29). Among the private sector, not-for-profit sector (64.18; SD: 10.51) scored slightly higher than the other private blood banks (63.09; SD: 11.11).

Nevertheless, it is also important to note that the average annual collection was higher (5,405 units) in public owned blood banks compared to private blood banks (4,404 units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (78.2%) compared to the private blood banks (67.2%). Of the total private blood banks, 976(63.2%) had component separation facility whereas only 295 (31%) of public blood banks had component separation facility.

4.6.4 Assessment score by Annual collection: The mean assessment score of blood banks that collected more than 5000 blood units (66.98; SD: 11.20) was found to be higher than those which collected between 3001 to 5000 (63.31; SD: 9.45) and less than 3000 blood units (59.39; SD: 10.48).

Table-19 Mean assessment score by annual collection

Annual Collection	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Up to 3000	57.29	11.22	60.68	9.78	59.39	10.48
3001 to 5000	60.08	9.34	65.66	8.84	63.31	9.45
Above 5000	66.14	11.51	68.34	10.58	66.98	11.20

4.6.5 Assessment score by voluntary blood donation: Table - 20 provides the mean assessment score of blood banks that have been categorized by percentage voluntary blood donation. The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score. Non-NACO supported blood banks have marginally scored higher than the NACO supported blood banks across all the categories.

Table-20 Mean assessment score by voluntary blood donation

% VBD	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Less than 25	51.93	12.68	60.78	11.02	59.69	11.60
25 to 49	59.14	11.62	61.19	9.28	60.41	10.25
50 to 74	58.95	11.61	65.03	9.51	62.20	10.95
75 to 90	59.60	11.36	62.84	9.06	61.05	10.50
Above 90	63.45	11.21	65.57	10.00	64.32	10.78

4.6.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): The mean score was found to be higher among the blood banks that were part of EQAS for immunohematology (75.35; SD: 8.92) as compared to those who were not enrolled (60.08; SD: 10.12). Similar situation was found among those blood banks that were part of EQAS for Transfusion-Transmitted Infections (76.32; SD: 8.34) as compared to those who were not enrolled (60.20; SD: 10.15).

Although more number of Non-NACO supported blood banks were enrolled in IH and TTI-EQAS, NACO supported blood banks had higher scores under IH-EQAS (78.54;SD:9.46) and TTI-EQAS (78.14;SD:8.54).

Table-21 Mean assessment score by EQAS enrolment

IH - EQAS	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	79	78.54	9.46	236	74.29	8.48	315	75.35	8.92
NO	1040	59.86	10.87	1138	60.27	9.38	2178	60.08	10.12
TTI - EQAS	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	88	78.14	8.54	192	75.49	8.14	280	76.32	8.34
NO	1031	59.73	10.87	1182	60.60	9.47	2213	60.20	10.15

4.6.7Assessment score by Accreditation status: The mean score was found to be higher among blood banks that were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH) in comparison to those that were not accredited. NACO supported blood banks accredited by NABH scored higher than Non-NACO NABH accredited blood banks.

Table-22 Mean assessment score by Accreditation

NABH	NACO Supported			Non-NACO			Total		
Accreditation	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	25	87.12	5.85	48	83.25	6.17	73	84.58	6.30
NO	1094	60.59	11.21	1326	61.94	10.00	2420	61.33	10.58

However, only 25 out of the 1,119 NACO supported blood banks and 48 out of 1,374 Non-NACO blood banks have been accredited by NABH. Maharashtra (22), Gujarat (12), and Delhi (11) had the highest number of accredited blood banks.

The list of blood banks under different categories of score is given in Table- 23

Table-23 Distribution of blood banks by state and mean assessment score categories

State	Score category			
	Up to 35	35 to 70	Above 70	TOTAL
A & N	0	2	0	2
Andhra Pradesh	1	101	16	118
Arunachal Pradesh	2	7	0	9
Assam	0	43	12	55
Bihar	6	65	1	72
Chandigarh	0	0	4	4
Chhattisgarh	1	40	0	41
DNH	0	1	0	1
Daman and Diu	0	2	0	2
Delhi	0	32	34	66
Goa	0	5	0	5
Gujarat	2	70	60	132
Haryana	1	42	18	61
Himachal Pradesh	0	20	0	20
J & K	0	25	2	27
Jharkhand	1	29	7	37
Karnataka	2	125	55	182
Kerala	1	120	42	163
Madhya Pradesh	2	113	17	132
Maharashtra	1	204	90	295
Manipur	0	4	1	5
Meghalaya	0	5	1	6
Mizoram	0	10	0	10
Nagaland	0	3	0	3
Odisha	3	60	7	70
Puducherry	0	15	2	17
Punjab	2	75	19	96
Rajasthan	1	76	22	99
Sikkim	0	3	0	3
Tamil Nadu	1	188	53	242
Telangana	1	104	18	123
Tripura	1	11	0	12
Uttar Pradesh	13	213	21	247
Uttarakhand	1	17	6	24
West Bengal	0	90	22	112
INDIA	43	1920	530	2493

Table-24 Distribution of blood banks by state and mean assessment score categories

States	Score					
	NACO supported			Non-NACO		
	Up to 35	35 to 70	Above 70	Up to 35	35 to 70	Above 70
A & N	0	1	0	0	1	0
Andhra Pradesh	1	53	6	0	48	10
Arunachal Pradesh	2	6	0	0	1	0
Assam	0	23	3	0	20	9
Bihar	4	35	0	2	30	1
Chandigarh	0	0	4	0	0	0
Chhattisgarh	1	15	0	0	25	0
DNH	0	1	0	0	0	0
Daman and Diu	0	2	0	0	0	0
Delhi	0	7	13	0	25	21
Goa	0	3	0	0	2	0
Gujarat	0	35	42	2	35	18
Haryana	0	14	10	1	28	8
J & K	0	21	2	0	4	0
Jharkhand	1	15	6	0	14	1
Karnataka	0	42	22	2	83	33
Kerala	0	33	12	1	87	30
Madhya Pradesh	1	52	9	1	61	8
Maharashtra	1	75	44	0	129	46
Manipur	0	3	0	0	1	1
Meghalaya	0	5	1	0	0	0
Mizoram	0	10	0	0	0	0
Nagaland	0	3	0	0	0	0
Odisha (Orissa)	3	46	5	0	14	2
Puducherry	0	5	0	0	10	2
Punjab	2	36	5	0	39	14
Rajasthan	1	35	13	0	41	9
Sikkim	0	2	0	0	1	0
Tamil Nadu	0	86	8	1	102	45
Telangana	0	37	6	1	67	12
Tripura	0	6	0	1	5	0
Uttar Pradesh	10	73	6	3	140	15
Uttarakhand	0	13	5	1	4	1
West Bengal	0	52	11	0	38	11
TOTAL	27	859	233	16	1061	297

5. Conclusion

Considering the importance of blood transfusion services in the provision of medical care, ensuring quality systems and standards in blood banks are vital, as the blood and its products must not only be safe but also clinically effective and of appropriate and consistent quality. From the programmatic perspective, adequate, accurate and updated information at the district, state and national level is essential for planning and implementation of quality management systems in blood transfusion services across the country. Generation of accurate and essential data from blood banks at regular intervals is imperative to effectively monitor the progress, gaps and challenges in the service provision which would not only facilitate appropriate corrective measures but also facilitate the development of evidence-based policies and programmes.

This country-wide assessment captured most of the required information related to the structure, services, facilities, availability of human resources, equipment, quality management system and practices in blood banks across the country. All blood banks in India function subject to obtaining and maintaining a license for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and Cosmetic Act 1940 and Rules 1945 there upon. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services at the state and national level.

The 1,119 NACO and 1,374 Non-NACO blood banks which were included in the review are approximately 95% of the total blood banks excluding the military blood banks existing in the country. The annual collection of these blood banks was 11.6 million (One crore and sixteen lakhs) units which is approximately 95% of blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between states that ranges from 0.2 units to 8.5 units per 100 population. Clinical demand for blood and blood products can happen only when there is a health care facility with adequate infrastructure in proximity to a blood bank. The relatively lower collection of blood in the few states could be due to the fact that there is lower demand for blood because of the gaps in availability, accessibility, and affordability of health care services.

The review also revealed that the majority of blood collection (70%) was by blood banks with the component facility compared to smaller blood banks without component facility. Though there has been an increase in the percentage of voluntary blood donation over the years (around 72% in 2015), there is still a huge variation between states that ranges from 38.3% to 100%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

It is also evident that the distribution of blood banks is skewed with 61% of the all the blood banks in the country relegated to only 8 states. Almost a third of the states (13) have less than the national average of 2.2 blood banks per million population. The potential impact of this distribution of blood banks and collection of blood on other health indices may be further studied.

Almost a third of the blood banks having their licensing status in pendency may be an indication of an opportunity to strengthen the regulatory system by modern technological modalities to ensure a standardized, timely and transparent licensing process. It is also essential to review and update the regulatory framework to keep up with recent scientific developments and modernize the transfusion practice in the country.

The provision of a blood component separation unit in the blood bank and the volume of collection apparently have a positive influence on the quality. The inequity in the distribution of component separation facilities across states and region is very evident. However, it is important to note that in the absence of reliable laboratory support, it will not be possible to ensure rational use of blood and its components. It is difficult to sustain cost-effective component production when the volume of operations is low without compromising the quality of the blood provided to the patients who access this service. Given that the provision of safe and high-quality blood in areas where access is a challenge, is still the remit of the state, it is essential to explore new cost effective innovative methods in partnership with non-governmental agencies.

For the first time, a quality score system has been created and applied to the blood banks. This review indicated a mean score of 62 with significant variations across the category of blood banks, ownership, voluntary blood donation, participation in proficiency testing (EQAS) and accreditation status. It is important to understand that there is a huge variation between states and within states on several parameters included in the assessment. This suggests the need for targeted and customized approach to address the gaps and challenges faced by the blood banks in the country. This assessment suggests that blood banks owned by trusts/charities in the private sector seemed to have performed slightly better in the quality parameters. This may be partly due to access to resources, both financial and technical, to enhance capacity and modern technology to overcome potential barriers to quality.

It is evident from the assessment that blood banks that focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented across the country.

106

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(108)

7. Annexures

7.1 NACO/NBTC - Questionnaire for Blood Banks

NACO/NBTC - Questionnaire for Blood Banks			
Data Filled by			
Mobile Phone *Number (Person filled the data)*			
Section A – GENERAL			
A1	**Basic Information**		
1	Name of the Blood Bank (as mentioned in the licence)		
2	Address 1 (Institution name)		
3	Address 2 (Door number & Street name – if applicable)		
4	Address 3 (Important land mark - if applicable)		
5	City/Town		
6	District		
7	State		
8	Pin code		
9	Blood Bank Phone number (Land line including area code)		
10	Blood bank Email ID		
11	Do you have internet facility?	Yes	
		No	
12	Name of the Blood Bank In-charge *(This should be the name of the current Medical Officer in charge)*		
13	Is the name of the Medical officer mentioned in the Licence, the current medical officer?	Yes	
		No	
14	Designation *(Please enter designation of the Medical Officer in the blood bank (e.g. Civil surgeon, or academic like Asst. Prof etc.)*		
15	Highest Qualification *(Tick only one)*	MBBS	
		MD	
		MS	
		Diploma	
16	Specify branch/Broad speciality		
17	Email ID: *(Official/Personal Email where the medical officer can be directly contacted). This is apart from the blood bank email ID provided above.*		

18	Fax number		
19	Telephone number 1 – Medical Officer *(Mobile)*		
20	Telephone number 2 – Medical Officer *(Landline including STD code)*		
21	Type of blood bank as per NACO category	Model blood Bank	
		Blood Component Separation Units	
		Major Blood Bank	
		District level blood bank	
		Others	
22	Who is the blood bank owned by?	Public (Central/State/Local government)	
		Public (Other than ministry of health e.g. PSU, Army etc.)	
		NGO/Trust/Charitable – NACO Supported	
		NGO/Trust/Charitable	
		Private - Others	
23	Is the Blood Bank attached to any of the following?	Hospital	
		Lab	
		Stand alone	
24	If attached to Private Hospital, specify level of hospital	Medical College Hospital	
		Tertiary care hospital (other than medical college)	
		Secondary care hospital	
25	If attached to public/govt. hospital, specify the level of the hospital	Sub-District hospital	
		District level hospital	
		Medical College hospital	
		Tertiary care hospital (other than Medical College)	
26	If the blood bank is attached to a hospital, please specify the number of inpatient beds available		
27	Are you permitted to conduct Blood donation camp?	Yes	
		No	
28	How many Blood storage centres are linked to your blood bank?		
29	BB working hours *(Specify hours per day)*		

A2	**License Information**	
1.	**BB License Number** *(Enter your license number. This should be exactly as is displayed in your license issued by the Drugs Controller Office and will be used for verification purposes. This is a mandatory field and should be entered regardless of the status of license - under-renewal etc.* **(You will have to submit a self-attested photocopy of the currently displayed license along with this form.)**	

2	Status of Current License	Valid	
		Under renewal	
3	Date of issue of current licence DD/MM/YYYY		
4	Last Inspection by licensing authority	< 1 year	
		1-2 years	
		2-3 years	
		3-4 years	
		>4 years	

A3	**Basic Statistics (Date of reporting from Jan-2015- Dec-2015)**	
1	Number of voluntary donations	
2	Number of replacement donations	
3	Number of autologous deposits	
4	Total Annual collection for reporting period (Jan - Dec 2015) Total Annual collections (sum of A3.1+A3.2+A3.3)	

	5. Transfusion Transmissible Infections - Annual statistics	**Number tested**	**Number positive**
	HIV(Anti-HIV I & II)		
	HCV(Anti-HCV)		
	HBV(HBs Ag)		
	Syphilis (RPR/TPHA/ELISA)		
	Positive for Malaria (Any method)		

A4.	**Reporting Summary**		
1	Are you in compliance with NBTC guidelines?	Yes	
		No	
2	Are you recovering processing charges for blood/components within NBTC/SBTC norms?	Yes	
		No	
3	Are you displaying stock position in the blood bank premises?	Yes	
		No	
4	Are you submitting statistics to the State Drugs controller?	Regular	
		Occasional	
		No	
5	Are you reporting in SIMS (strategic Information Management System- NACO)?	Regular	
		Occasional	
		No	
6	If yes to Q5. please provide your SIMS ID		

7	If you are not reporting to SIMS, would you be willing to report in the future?	Yes	
		No	
8	Are you reporting in the E-blood banking?	Regular	
		Occasional	
		No	
9	If Regular/ Occasional to 8, specify *(more than one can be selected)*	State	
		National (NHP)	
		Other(Specify	
10	Please provide E Blood banking user ID *(State)*		
11	Please provide E Blood banking user ID *(National)*		
12	If not part of e-blood banking, would you be willing to participate in future?	Yes	
		No	

SECTION B			
B1	**Blood Donor(Reporting from Jan 2015- Dec 2015)**		
Definition of VBD = Close relatives should NOT be counted as VBD			
1	Are you recruiting voluntary blood donors?	Yes	
		No	
2	Is donor selection performed as per regulatory norms?	Yes	
		No	
3	Do you maintain records of donor deferral?	Yes	
		No	
4	Is pre-donation counselling being performed for blood donors?	Regular	
		Occasional	
		No	
5	Is post donation counselling being performed for blood donors?	Regular	
		Occasional	
		No	
6	Are you conducting Blood donor drives/Blood collection camps?	Regular	
		Occasional	
		No	
7	If you conduct camps, how many have been conducted in the reporting period? *(Provide numbers of VBD camps conducted during the period January - December 2015.)*		
8	Does the blood bank have dedicated staff for the promotion of Voluntary blood donors? *(If your blood bank has dedicated staff for camps, answer yes.)*	Yes	
		No	
8 a.	If Yes to 8, select as applicable *(More than one may be selected)*	Donor Motivator	
		Public relations officer (PRO)	
		Social Worker	
9	Is there a specific budget for donor program?	Yes	
		No	
10	If Yes, Specify budget source	Central	
		State	
		Others (Specify)	

11	Is there a donor database in the blood bank *(Donor database is essential to contact donors to remind them or to call during an emergency?)*	Yes	
		No	
12	If yes to Q 11, is it in electronic format or paper based?	Electronic	
		Paper	
		Both	
13	What percentage of the voluntary blood donors are repeat blood donors? (%)		
14	Does your blood bank have a mobile blood collection facility? *(Answer yes if your Blood bank has a mobile facility (bus or van with donor couches)*	Yes	
		No	
15	Source of funds for the mobile blood collection *(Indicate the source of funding for the purchase of the mobile blood donor van.)*	State	
		Central	
		Donor	
		Others	
16	Specify, other source of funds		
17	Is there a record for donor adverse reactions?	Yes	
		No	
18	Is there a referral system for HIV sero-reactive blood donors?	Yes	
		No	
19	If yes to Q 18, please specify what is the process adopted.		

Section C
Technical – Immunohematology

		Blood Group (Tick as applicable)		Rh Type (Tick as applicable)
C1.	Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed?	Forward	Reverse	
C1.1	Slide			
C1.2	Tube			
C1.3	Micro plate			
C1.4	Column agglutination Gel/Microparticle)			
C1.5	Solid phase			
C1.6	Other Specify			

1	How do you perform RhD typing?	Monoclonal reagent	
		Polyclonal reagent	
		Both	
2	Do you perform irregular antibodies screening on blood donations and patient sample?	Yes	
		No	

3	Do you perform direct antiglobulin test (DAT/DCT)? *(If you are performing Direct Antiglobulin test (DAT)- earlier called as Direct Coombs Test (DCT), answer yes.)*		Yes	
			No	
4	If yes to previous question, please specify method	Tube		
		Column agglutination		
		Solid phase		
5	Do you perform indirect antiglobulin test (IAT/ICT)?		Yes	
			No	
6	If yes, to previous question please specify method	Tube		
		Column agglutination		
		Solid phase		
7	Number of group and type tests performed in reporting period (Jan - Dec 2015) *(Specify the number of group and type tests performed - Total of all patient and donor tests in the reporting period - January to December 2015.)*			
8	Number of compatibility testing performed in reporting period. *(Specify number of compatibility tests performed in the reporting period January to December 2015)*			
9	Total Number of DAT/DCT tests performed in the reporting period *(Specify number of DAT/DCTtests performed in the reporting period (January to December 2015)*			
10	Total Number of IAT/ICT tests performed in the reporting period *(Specify number of DAT/DCTtests performed in the reporting period (January to December 2015)*			
11	Total Number of antibody screening performed in reporting period *(If you answered YES to Q2, Specify number of antibody screening tests performed in the reporting period (January to December 2015).*			
12	Do you have automation for Immunohematology testing? *(If you have implemented any kind of automation, please indicate so.)*		Yes	
			No	
13	Do you perform Internal QC for all immunohematology tests (blood group/DAT/IAT etc.)? *(Please answer yes if you are performing internal quality control (IQC) for the immunohematology tests listed above. They include daily QC on reagents and cells.)*		Yes	
			No	
14	Do you participate in an external quality assessment program or scheme (EQAS) for immunohematology tests usually performed in your laboratory?		Yes	
			No	
15	If yes to 14, Specify name of program/provider			
16	If yes to 14, EQAS MembershipID number/ PIN#.			
17			Inter-lab	
	If yes 14, specify Highest level of EQAS program participant in		National	
			International	
18	If you are not participating in EQAS for immunohematology, will you be willing to do so in the future?		Yes	
			No	
19	If Yes to above question, will your blood bank be able to allocate financial resources (about Rs.2500 per year)?		Yes	
			No	

(114)

20	If your answer to Q 19 is NO, when do you think you will be ready for EQAS participation? (Immunohematology)	Next 6 months	
		Later than 6 month	
21	Are you a member of National Haemovigilance Program of India (HVPI)?	Yes	
		No	
22	If yes, provide HVPI ID Number		
23	If not, would you be willing to participate in HVPI in the near future?	Yes	
		No	
24	Are you reporting all adverse events to the National Haemovigilance Program of India?	Yes	
		No	
25	Number of adverse reactions recorded in the reporting period		
26	Does your hospital have regular transfusion committee meetings?	Yes	
		No	
27	What is the frequency of Transfusion committee meetings?	Annual	
		Half-yearly	
		Quarterly	
		Occasional	

Section D
Technical - Screening For Transfusion Transmissible Infections (TTI)

Does the blood bank screen the following TTIs?

	Type of Test	Platform (please tick appropriate)	Method (please tick appropriate)
1	**HIV I & II**	Rapid	
		ELISA	Manual ☐ Automated ☐
		CHEMI	Manual ☐ Automated ☐
		NAT	Manual ☐ Automated ☐
1.1	Specify % of donors tested by Rapid Test?		
2	**Hepatitis B**	Rapid	
		ELISA	Manual ☐ Automated ☐
		EM	Manual ☐ Automated ☐
		NAT	Manual ☐ Automated ☐
2.1	Specify % of donors tested by Rapid Test?		

3	**Hepatitis C**	Rapid	
		ELISA	Manual ☐ Automated ☐
		CHEM	Manual ☐ Automated ☐
		NAT	Manual ☐ Automated ☐
3.1	Specify % of donors tested by Rapid Test?		
4	**Syphills**	RPR	Manual ☐ Automated ☐
		TPHA	Manual ☐ Automated ☐
		ELISA	Manual ☐ Automated ☐
5	**Malaria**	Rapid	
		Fluorescent	Manual ☐ Automated ☐
		Slide microscopy	
		ELISA	Manual ☐ Automated ☐
6	Does the blood bank have an algorithm for units that test POSITIVE in initial screening? *(If you have a method of verifying a sample that has tested positive on the screening test please answer yes.)*		Yes ☐ No ☐
7	If yes to Q6 , Repeat testing with same test/ technique		Yes ☐ No ☐
8	If Yes to Q6, Repeat testing with different test/technique		Yes ☐ No ☐
9	If yes to Q6, Recalling donor for repeat sample		Yes ☐ No ☐
10	Do you perform independent internal QC (Third party controls) with TTI testing?		Yes ☐ No ☐
11	Do you participate in an external quality assessment program or scheme (EQAS) for TTI*(Viral Markers, Malaria, and Syphilis) testing?*		Yes ☐ No ☐
12	If yes, Specify program/provider		
13	Membership ID number (PIN)		
14	Level of EQAS		Inter-lab ☐ National ☐ International ☐
15	If you are not participating in EQAS for TTI screening, will you be willing to participate in future?		Yes ☐ No ☐

16	If Yes to Q15, will your blood bank be able to provide financial support (about Rs. 2500 per year)	Yes	
		No	
17	If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening) participation?	Next 6 months	
		Later than 6 months	

Section E
Technical - Component Preparation (Applicable only to BCSU)

1	Does your blood bank prepare components?	Yes	
		No	

If your answer to Q1 is NO, SKIP TO SECTION F

If Yes, List the components and number prepared and issued in the period Jan to December 2015

2	Number of donated blood that was used for component preparation during the period Jan- December 2015.		
		Number prepared	**No. issued (utilized)**
3	Packed red cells IP (With or without Additive)		
4	Platelet concentrate IP		
5	Fresh frozen plasma (FFP)		
6	Cryoprecipitated antihaemophilic factor IP		
7	Human plasma IP		
8	Other (specify)		
9	Do you perform apheresis for components?	Yes	
		No	
	If yes to above question, Specify the following details		
		Number prepared	**No. issued (utilized)**
10	Platelet concentrate IP		
11	Fresh frozen plasma (FFP)		
12	Granulocytes concentrates		
13	Other (specify)		
14	Do you perform QC for the components prepared? *(If you perform quality control for all components, answer yes.)*	Yes	
		No	
15	If yes to above, Are the Factor assays on Fresh Frozen plasma/Cryoprecipitate performed at your Blood Bank?	Yes	
		No	
16	If yes for above question, do you participate in external quality assessment scheme (EQAS)?	Yes	
		No	
17	If yes, to above question, Specify agency		

SECTION F
Quality Management Systems

F 1	Are you aware of quality management systems for Blood bank	Yes	
		No	

1	Is the blood bank accredited?	Yes	
		No	
2	If yes, provide Name of Accrediting Body		
3	Do you have a document control system - other than mandatory registers as D&C act?	Yes	
		No	
4	Do you have Standard Operating Procedures (SOPs) for all technical processes?	Yes	
		No	
5	Do you have written responsibilities for all levels of staff?	Yes	
		No	

How many staff are currently employed in each of the following categories and how many of them have been trained during the reporting period Jan 2015 - Dec 2015? (Questions 6 - 15)

	Staff Details	Total number of staff	Number on contract	NACO/NBTC Supported in-service training	Other National Training
6	Professor				
7	Associate Professor				
8	Assistant Professor				
9	Senior Resident/Tutor				
10	Medical Officer *(include senior/Junior)*				
11	Technical Staff				
12	Nursing staff				
13	Counsellor				
14	PRO/Donor motivator				
15	Administrative staff				
16	Support staff				
	If other staff, please specify				
Total number of staff					

17	In your opinion, does the BB have adequate staff to function optimally (24x7)? This may be decided based on the volume and duration of work hours.	Yes	
		No	
18	Do you monitor Quality indicators or Key Performance indicators?	Yes	
		No	
19	If yes to above question, please specify names of indicators		
20	Do you have a designated and trained Quality manager?	Yes	
		No	
21	Do you have a designated and trained Technical Manager?	Yes	
		No	
22	If you do not have either a trained Quality manager or Technical Manager please state reasons?		

118

23	Please specify if you have a plan for recruitment in the future?	

F2. EQUIPMENT AND SUPPLIES			
1	Does the blood bank have adequate equipment to meet regulatory requirements? *(If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)*	Yes	
		No	
2	How is equipment purchase funded?	Local bodies	
		Central or upper (state) level agencies	
		Donors	
		Others (specify)	
3	Does the blood bank have a program for regular equipment maintenance?	Yes	
		No	
4	Are all the equipment calibrated regularly as per regulatory requirement?	Yes	
		No	
5	How are consumables purchased?	Local bodies	
		Central or state level agencies	
		Donors	
		Others (specify)	
6	Do you evaluate kits at your facility prior to procurement? *(Are kits evaluated locally (at your blood bank) prior to purchase (e.g. Titre and avidity for blood group Anti Sera?))*	Yes	
		No	
7	Is quality control for kits, reagents and blood bags carried out at your blood bank? *(Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood group Anti Sera?))*	Yes	
		No	
8	Did you have a regular supply of the following items? (Jan to Dec 2015)		
8.1	Blood Bags	Yes	
		No	
8.2	TTI Screening Kits	Yes	
		No	
8.3	Blood grouping / IH reagents	Yes	
		No	
9	Number of staff vaccinated for Hepatitis B?		

EQUIPMENT LIST (Below is a summary equipment list (a subset of D&C list). Please specify the number in inventory and number in working condition? If you are using shared resources of hospital, you can mention that as well

		Number in inventory	Number in working condition
10	Donor beds/couches		

11	Any instrument for Hb Estimation *(other than CuSO4 method)*		
12	Blood collection monitor (Blood agitator)		
13	Quarantine Blood bank refrigerator to store untested units with temperature recorder		
14	Container for safe disposal of sharps		
15	Oxygen supply equipment		
16	Computer with accessories and software		
17	General lab centrifuge for samples		
18	Bench top centrifuge for serological testing		
19	Blood transportation box		
20	Emergency drugs box/Crash card		
21	Autoclave machine (shared resource should be specified)		
22	Water bath		
23	Blood bank refrigerator (storage of tested blood) with temperature recorder		
24	Automated pipettes		
25	Refrigerated centrifuge (BCSU)		
26	Blood container weighting device		
27	Serology rotator		

120

7.2 Scoring Pattern

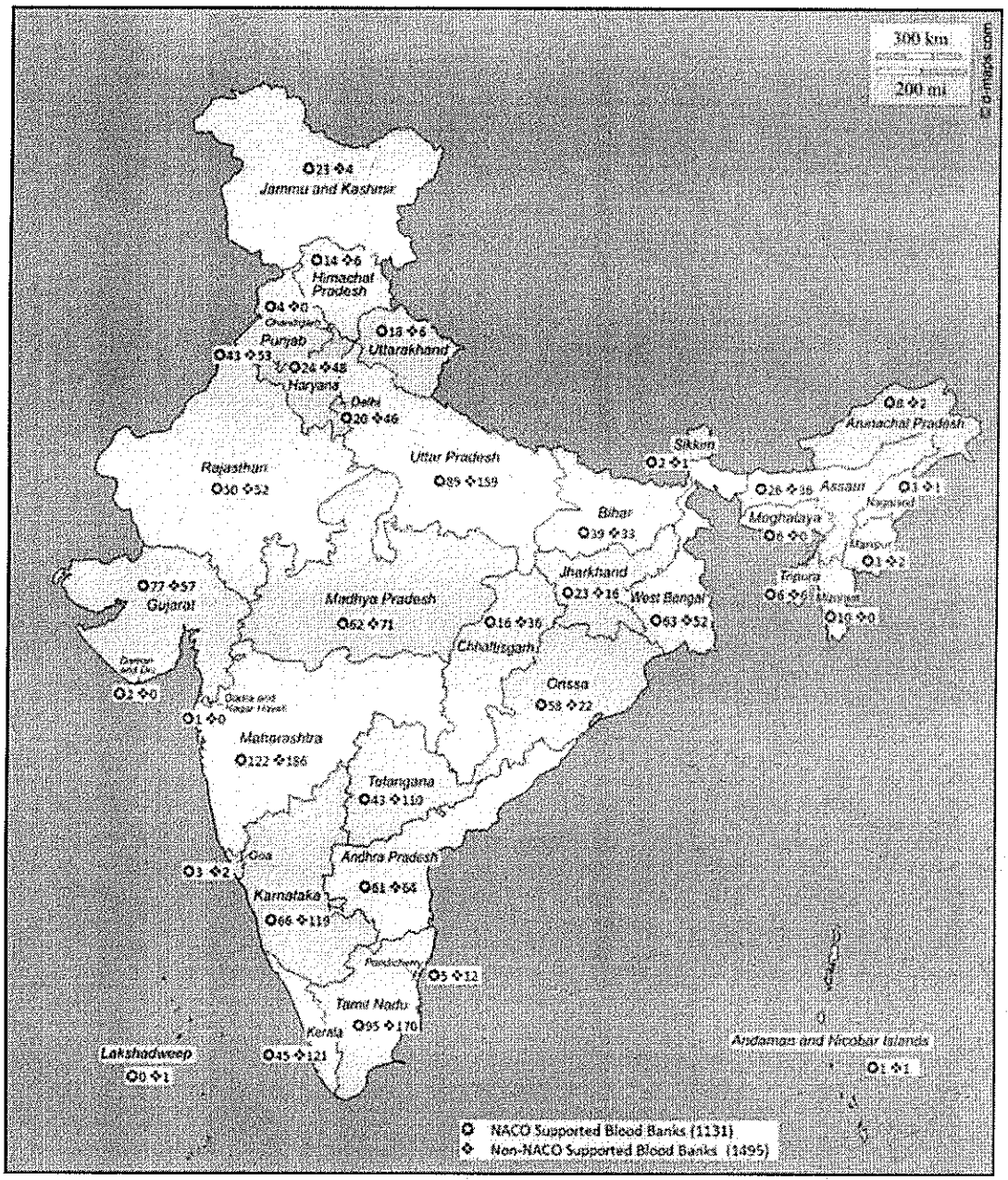
Individual Scoring Sheet - Blood Component Separation Units			
GENERAL	General Summary	**WEIGHTAGE**	**Total**
Licence	Under renewal	1	
	Valid	3	
Subtotal			**3**
Annual collection	Below 1000	0	
	1000 to 2000	0.5	
	2000 to 5000	1	
	5000 to 10000	1.5	
	Above 10,000	2	
Subtotal			**2**
VNRBD	BB by VNRBD (%)	0	
	<25%	0	
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
Counselling	Pre and post donation counselling - Regular	2	
Subtotal			**9**
TECH-IH	BB performing only slide grouping (forward typing)	0	
	BB using tube method for forward typing	2	
	BB performing reverse grouping (Serum group)	2	
	BB performing tube method for compatibility testing	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			**18**
TECH- TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	Elisa	2	
	Advanced	3	
Hep B	Rapid	1	
	Elisa	2	
	Advanced	3	

Hep C	Rapid	1	
	Elisa	2	
	Advanced	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			20
COMP			
	Component separation < 25	0	
	Component separation < 25-50%	1	
	Component separation 51 to 80%	2	
	Component separation > 80%	3	
	BB that performs component QC	2	
Subtotal			5
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Technician with NACO/NBTC training	3	
	BB with designated and trained QM	2	
	BB with designated and trained TM	2	
	BB with Document control system	4	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags carried out at blood bank with regular bags supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	Blood bank accredited	5	
Subtotal			35
GEN	BB reporting regularly on SIMS under National AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	More than 50% of the staff are vaccinated for Hep B	1	
	Compliance with NBTC norms	1	
Subtotal			8
SCORES	TOTAL		100

122

Individual Scoring Sheet - Without Blood Component Separation Units			
GENERAL	General Summary	WEIGHTAGE	Total
Licence	Under renewal	2	
	Valid	3	**3**
Subtotal			
Annual collection			
	500 - 1000	1	
	1001 to 2000	2	
	2001 to 3000	3	
	3001 - 5000	4	
	>5000	5	
Subtotal			**5**
VNRBD	BB by VNRBD (%)		
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
	pre donation counselling - regular	2	
Counselling	post donation counselling - regular	2	
Subtotal			**11**
TECH-IH	BB performing slide ONLY for forward grouping	1	
	BB performing TUBE for forward grouping	2	
	BB performing reverse grouping (Serum group)	2	
	Compatibility testing with tube	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			**18**
TECH- TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	ELISA	3	

Hep B	Rapid	**1**	
	ELISA	3	
Hep C	Rapid	**1**	
	ELISA	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			**20**
COMP	*Not applicable*		
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Lab technician with NACO/NBTC training	3	
	BB with designated TM/QM	2	
	BB with SOPs	2	
	BB with Document control system	2	
	BB with more than 75% equipment functional	2	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags carried out at blood bank with regular supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	Blood bank accredited by NABH	5	
Subtotal			**35**
GEN	BB reporting regularly on SIMS underNational AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	Compliance with NBTC norms	1	
	More than 50% of the staff are vaccinated for Hep B	1	
Subtotal			**8**
SCORES	**TOTAL**		**100**



Disclaimer

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(125)

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Ministry of Health and Family Welfare
Government of India

ANNEXURE-A4

126

No.S.12016/08/2016 - NACO (NBTC)
Government of India
Ministry of Health & Family Welfare
National AIDS Control Organization
(National Blood Transfusion Council)

9th Floor, Chanderlok Building,
36, Janpath, New Delhi – 110 001
Dated 19th June 2017

Office Memorandum

Subject: Minutes of 26th meeting of Governing Body of National Blood Transfusion Council (NBTC)-reg.

This is to inform you that 26th Meeting of Governing Body of NBTC was held on 1st June, 2017 at 3.00 P.M. in the Committee Room of NACO, 6th Floor, Chanderlok Building, 36, Janpath, New Delhi under the Chairpersonship of Additional Secretary, NACO (as President National Blood Transfusion Council). Minutes of the meeting are enclosed for reference and necessary action.

This issues with the approval of President, NBTC.

(Dr. Shobini Rajan)
ADG (Blood Safety) &Director (NBTC)

To

All member of Governing Body of NBTC.

Copy for information to:

1. PPS to Secy(H).
2. PPS to DGHS.
3. PPS to Additional Secretary (NACO).
4. PS to Joint Secretary (Policy).

(127)

Minutes of the 26th Governing Body Meeting of National Blood Transfusion Council

The 26th Meeting of Governing Body of the National Blood Transfusion Council was held on 1st June 2017 in the Committee Room, 6th Floor, NACO, Chandralok Building, 36, Janpath, New Delhi under the Chairmanship of Additional Secretary, National AIDS Control Organization & President of National Blood Transfusion Council.

The following members attended the meeting:

1. Dr Arun Kumar Panda, Additional Secretary, National AIDS Control Organization & President, National Blood Transfusion Council New Delhi – in Chair
2. Shri Alok Saxena, Joint Secretary NACO
3. Ms.Vandana Jain, Director IFD, Representing Ms Vijaya Srivastava, Additional Secretary & Financial Advisor, Ministry of Health and Family Welfare, Nirman Bhawan, Delhi
4. Prof A. K. Gadpayle, Addl. Director General and Medical Superintendent Dr RML Hospital, Directorate General of Health Services, Nirman Bhawan, Delhi
5. Dr.Joy Mammen, Professor, Department of Transfusion Medicine and Haematology, Christian Medical College, Vellore
6. Dr.R. N. Makroo, Director Deptt. of Transfusion Medicine, Apollo Hospital, Delhi
7. Dr Nagesh NS, Director, Institute of Gastroenterology Sciences and Organ Transplant, Victoria Hospital, Bangalore
8. Mr Biswaroop Biswas, Secretary, Federation of Indian Blood Donor Organizations, Kolkata
9. Dr K K Aggarwal, President Indian Medical Association
10. Dr.V. G. Somani. Joint Drugs Controller, representating DCG(I), Delhi
11. Ms Vinita Srivastava, National Consultant Blood Cell representing Mr Manoj Jhalani, Joint Secretary (Policy), National Health Mission
12. Dr Alok Ahuja, Member Executive Committee MCI representing Dr. Jayashreeben Mehta, President, Medical Council of India, New Delhi
13. Col.Umesh Kapoor, CO and Head of Armed Forces Transfusion Centre, New Delhi representing DG Armed Forces Medical Services
14. Dr R Sreelatha, Professor and HOD, IHBT Department, Victoria Hospital and BMCRI, BangaloreDelhi
15. Dr.Shobini Rajan, ADG (Blood Safety) NACO, Delhi & Director and Member Secretary NBTC

Attendees/ Invitees from Blood Transfusion Services Division, NACO, CMAI, NIB and CDSCO included

1. Sh. M K Diwaker, Asst. Director, NBTC & Section Officer (BS), NACO Delhi
2. Dr. Shanoo Mishra, PO (QC), NBTC, Delhi
3. Mr Jolly Lazarus, PO (VBD), NBTC Delhi
4. Dr Sunita Upadhyaya, Senior Laboratory Advisor, CDC
5. Mr Lokesh S, Technical Advisor, CMAI
6. Sh. Navneet Pratap Singh, Asstt. Drug Controller, CDSCO, Delhi
7. Dr Akanksha Bisht, Scientist III and Officer I/C Hemovigilance, NIB

The following members could not attend the Meeting or depute any representative for the same:

1. Dr.Neelam Marwah, HOD, Department of Transfusion Medicine, PGIMER, Chandigarh
2. Dr.Bharat Singh, Director, State Blood Transfusion Council, Delhi
3. Dr M Gajjar, HOD, Department of IHBT, BJ Medical College, Ahmedabad
4. Joint Secretary, Indian Red Cross Society, Delhi

The Addl. Secretary, NACO and President of the Governing Body extended a warm welcome to all new members of the Governing Body of NBTC. A power point presentation was made to apprise members of the progress made in strengthening blood transfusion services of India as per approved action plan for 2015-17, also touching on activities conducted through support of CDC CMAI QMBB Project.

The agenda-wise discussions were held and the following decisions were taken in the meeting:

Agenda Item No. 1: Approval of minutes of the 25th meeting of the Governing Body of National Blood Transfusion Council held at New Delhi on 20th January 2014;

The minutes of the 25th Governing Body meeting of NBTC held on 5th August 2015 were approved by the Governing Body.

Agenda Item No. 2: Action Taken Report on proceedings of the 25th Governing Body of NBTC

The Action Taken Report on the minutes of the 25th meeting of the Governing Body of NBTC was noted and accepted by the Governing Body.

Agenda No. 3: Agenda Items for consideration and approval:
The decisions taken on the various agenda items by the Governing Body are as follows:

Agenda Item No. 3.1: Approval of Audit Report 2014-15

The Audited accounts of the Society for 2014-15 were approved.

Agenda Item No. 3.2: Approval of Audit Report for 2015-16

The Audited accounts of the Society for 2015-16 were approved.

Agenda Item No.3.3: Extension of term of existing auditors for FY 2016-17

It was informed that approval of President, NBTC has been accorded for continuing with the existing auditors to carry out the audit work of NBTC for FY 2016-17 as detailed below

1. M/s N. C. Mittal & Co. For Statutory Audit of NBTC @ Rs. 20,000/- per annum (Excl. Of applicable Service tax)
2. M/s L. K. Dhingra & Co. for Internal Audit of NBTC @ Rs. 30,000/- per annum (Incl. Of applicable service tax)

This decision was ratified by the Governing Body.

Agenda Item No.3.4: Financial powers of Director NBTC

The existing financial powers of Director to sanction expenditure of a miscellaneous or contingent nature up to an amount not exceeding Rs 500/- in each case were **enhanced to Rs 50,000** (Rupees Fifty thousand only) with the approval of Governing Body. The rules may be amended accordingly.

Agenda Item No.3.5: Action Plan for NBTC (2017-18 and 2018-19)

The activities proposed as part of the Annual Action Plan (2017 to 2019) were approved by the Governing Body. A total budget of **2000 Lakhs** was projected for the activities as per detailed Work Plan with budget breakup is at ***Annexure 1***

It was informed that the actual activities would be tailored to the availability of funds.

Agenda Item No.3.6: Unification and Organizational role allocation of work of Blood Safety and BTS within MoHFW

Members of the Governing Body perused through the agenda notes and the following documents.

1. White paper by a group of experts on "Improving Blood Transfusion Services in India: A Concept Paper on Strengthening National Blood Programme- Way forward" presented to the National Transfusion Services Core Coordination Committee on 29th September 2016.
2. Report of the Mid Term Appraisal (MTA) of NACP IV
3. Recommendations of the High Level Committee (HLC) constituted by the Ministry of Health and Family Welfare on consolidation of the AIDS response based on the Mid Term Appraisal (MTA) of NACP IV

It was decided that there should be there should be a single focal point in the Ministry of Health for all matters pertaining to Blood Transfusion Service and all other entities must work under the overall ambit of National policy guidelines.

It was also informed that the JS (Policy) in NHM has been co-opted as a member in Governing Body of NBTC GB and approval of Hon'ble HFM has been obtained for amendments in the R&R of NBTC.

There was overall agreement towards the recommendation of High Level Committee for take-over of all activities for BTS by NHM including NBTC in a phased manner.

In light of several shortcomings and malpractices continuing in Blood Banks despite regulation and mandatory licensing, the National Blood Policy must be reviewed and its legislation considered with creation of a single authority on lines of NOTTO/SOTTO at National and State level.

As an interim measure, roles and responsibilities of various stakeholders (NBTC/ NACO/ NHM) were demarcated to facilitate the transition of NBTC into NHM and circulated among all members. No comments were received on the document till 15th June 2017. These were deemed approved as detailed in ***Annexure 2.***

Agenda Item No. 3.7: Roles of different committees and expert groups constituted under NBTC (GB, EC, Core Committee, Technical Resource Group, Technical Expert Groups, Technical Working Groups)

After review of the composition and TORs of existing committees and expert groups for Blood Transfusion services under NACO and NBTC, the following decisions were taken

1.) All Bodies/ Committees for Blood Transfusion Services would be **under aegis of NBTC.**

2.) **Governing Body** would be the final authority to take policy decisions on all matters pertaining to Blood Transfusion Services.

3.) **Standing Committee** is to be constituted under chairpersonship of Joint Secretary Policy (NHM) to replace the Executive Committee and Core coordination committee with representation from all stakeholders, including few State representatives. This committee would review the functioning of Blood Transfusion Services and Blood Banks every quarter through an online dashboard enabled through e Rakt Kosh and would appraise and inform the Governing Body of NBTC.

4.) Matters would be referred for **Technical examination to DGHS or Technical Resource Group** by the Standing Committee as and when required, obviating the need for re-constitution of a separate Technical Resource Group.

This would serve to simplify and make effective the functioning of NBTC.

Agenda Item No. 3.8: Proceedings of the 3rd NTSCCC meeting

The minutes of the Third meeting of National Transfusion Services Core Coordination Committee held on 29th September 2016 under the chairmanship of DGHS were circulated to all the Governing Board members as an attachment for the aforesaid agenda item. During discussion, no objections were raised and the recommendations agreed upon. NBTC stance on Unbanked directed Blood Transfusion is in agreement to the recommendations of NTSCCC.

Agenda Item No. 3.9: Proceedings of the VBD Consultation and way forward for 100% VBD by 2020

National Stakeholder Consultation towards 100% Voluntary Blood Donation by 2020 Workshop was held on 28th January 2016 in Tamarind Hall, India Habitat Center, New Delhi under the Chairpersonship of Shri. N. S. Kang, AS & DG, NACO and proceedings shared with members of Governing Body of NBTC for their information.

The further initiatives taken by NBTC to support Voluntary Blood Donation and creating blood access were also apprised.

- An amendment has been issued to the Drugs and Cosmetics Rules dated 3rd April 2017 indicating that private hospital associated blood banks can conduct blood donation camps, there is no captive consumption clause for set

up of blood storage centres and bulk transfer of blood between blood banks is permitted.

- A proposal has been sent to DoPT to extend the provision of Special Casual Leave for Voluntary Blood Donation to apheresis and enhance the provision to 6 times a year.
- A National Consultative Workshop for development of Communication Strategy for IEC in BTS and material development for 100% VBD by 2020 was held in Vishakhapatnam on 8th and 9th May 2017. It is proposed to develop the requisite materials and launch them on 1st October 2017 on the occasion of National Voluntary Blood Donation Day through a National event.

Agenda Item No. 3.10: Proceedings of review meeting of SBTC and way forward

Review meeting of all State SBTC Directors and SACS representatives was held on 29th of Jan 2016 at India Habitat Center, Delhi under the Chairpersonship of Sh. N.S. Kang, Additional Secretary, NACO & President (NBTC). The meeting was presided over by Prof. Dr.Jagdish Prasad, Director General Health Services, GOI. Proceedings were shared with the members of Governing Body along with a copy of the Compendium of NBTC policy and guidelines disseminated during the meeting for reference and information.

Agenda Item No. 3.11: Approval on Policy and Guidelines for Referral linkages of TTI reactive Blood Donors

National Blood Policy 2002 states that result seeking blood donors shall be referred to a blood testing centre for post donation information and counselling. Action Plan on Blood Safety 2003 describes the process of revealing the status of Transfusion Transmitted Infection status of blood donors.

The policy and guidelines for referral linkages of TTI reactive blood donors were deliberated in a Technical Expert Group meeting held on 5th January 2016 at NACO under Chairpersonship of Dr Neelam Marwaha, HOD Transfusion Medicine, PGIMER Chandigarh. Proceedings of this meeting were shared with the members of NBTC and it was agreed upon that it is desirable to operationalize and strengthen the donor referral linkages for all donors who test sero-reactive for HIV, HBV, HCV, Malaria and Syphilis and that such donors are to be recalled and referred to appropriate facility for confirmation and management.

The guidelines for the same are detailed at ***Annexure 3*** and summarized below:

1. It is not the primary duty of the Blood Bank or Blood Transfusion Services to confirm the diagnosis of any of the TTI screened for.

2. All initial reactive blood units must continue to be discarded as per protocol.
3. Consent of the Blood Donor is to be obtained for performing the screening tests and to be informed of the results thereof at the time of blood donation.
4. Blood Bank must 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.
5. All initial sero-reactive donors must be recalled, offered post donation counselling and referred to appropriate facility for further counselling, confirmation and management.
6. A standard referral format for the same must be used and Blood Bank must maintain all records of recall and referral.
7. Signatures of the blood donor must also 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.

Matter had already been seen and approved by President NBTC on 5th August 2016, but as per directions of present President NBTC, the guidelines were shared on mail with all the members and no comments were received till 15th June 2017, hence considered approved for circulation to all States and Blood Banks for compliance.

Agenda Item No. 3.12.: NBTC stance on mandatory use of IV generation testing technology for all licensed blood banks

Members of Governing Body went through the minutes of meeting of Technical Resource Group for ICTC held at NACO on 22nd and 23rd December 2015 and Technical Expert Group for Blood Transfusion Services held under chairpersonship of Dr Neelam Marwaha, HOD Transfusion Medicine, PGIMER, Chandigarh on 5th January 2016.

There was a recommendation for use of IV generation assay (Ag/Ab) for screening for HIV in blood banks as it offers a distinct advantage of sero-conversion sensitivity.

National Transfusion Services Core Coordination Committee in its meeting held on 29th September 2016 had also reiterated the stance and recommended for the use of IV Generation ELISA tests for screening blood units at all licensed Blood Banks for HIV, HBV and HCV.

There were discussions and deliberations over the relative merits and advantages with enhancing the technology for screening for TTI at blood banks beyond the mandatory third generation ELISA/Rapid. While it was agreed that NAT and IV generation ELISA offer distinct advantage of reduction of window period vis-à-vis third generation ELISA, but it was not considered appropriate that they be made mandatory at first instance.

The consensus was arrived at

1. NBTC would encourage for the use of IV generation ELISA and NAT to enhance the window of safety of blood for transfusion.
2. NAT would however continue to remain an add on test in addition to performance of ELISA.
3. ICTC would not give out a negative result for HIV with one negative test for initial sero-reactive donors referred from blood banks, but would report it as inconclusive and repeat the test after two weeks to look for sero-conversion.
4. All donors receiving a HIV positive report from the ICTC must be counseled to permanently defer themselves from donating blood or organs.

Agenda Item No. 3.13: NBTC stance on Isolated Plasmapheresis

Permission for Isolated Plasmapheresis for 'Source Plasma' was requested by Plasma Fractionators to fulfil the domestic need for Plasma Derived Medicines and had been deliberated extensively in a multi-stakeholder National Consultation Meeting held under chairpersonship of DGHS on 18th July 2016.

Members of Governing Body after going through the proceedings of this meeting agreed to the following stance, which had also been reiterated in the third meeting of National Transfusion Services Core Coordination Committee held on 29th September 2016.

1. Recovered plasma would continue to remain the main source of raw material for plasma fractionation.
2. While Plasmapheresis is required in our country, it should not be encouraged as 'Standalone plasma collection centers' but 'in collaboration with blood banks with blood component separation units or apheresis'. Piloting could be done with Govt or Pvt Sectors in this regard.
3. Blood donation is a voluntary activity. Plasma donation shall be promoted only through non-remunerated voluntary blood donors. No modality for financial compensation/ recognition beyond what is acceptable by the NBTC in form of badges/ tokens etc shall be admissible.

Agenda Item No. 3.14: NBTC stance on BTS TRG recommendations

It was informed to the Governing Body that all activities being undertaken by NBTC were guided by recommendations of various technical experts and Technical Resource Group for BTS. These activities include conduction of baseline assessment of blood banks of India, roll out of capacity building trainings for blood donor counseling and strengthening Quality Management Systems through a standardized curriculum, assessment of PT providers and plan to roll out of EQAS, study of estimation of blood requirement in India.

Proceedings of BTS TRG meeting held on 19th January 2017 were shared with the members of Governing Body of NBTC wherein the donor selection criteria for the country have been reviewed and standardized for adoption by all the licensed blood banks of the country.

These criteria detailed at ***Annexure 4*** were approved by the Governing Body. A standard guideline document for Donor selection and Donor Referral prepared by NBTC should be referenced in the Drugs and Cosmetics Act and Rules for compliance by all blood banks.

Agenda Item No. 3.14: Matters for discussion and deliberation

1. Previously approved processing charges for Blood and Blood Components to remain valid for one year (till 31st May 2018), during which time, NBTC would work on revision.
2. NBTC would recommend to the MoHFW for creation of teaching/ non teaching positions for Specialists in Transfusion Medicine through an amendment in CHS Rules.
3. President accorded approval to create a list of NBTC empanelled experts in accordance to set selection criteria for use by the officials of the State FDA which conducting inspections of blood bank license renewals/ issuance. Criteria for selection would also be shared with DCG(I) for use in case of non-availability of NBTC empanelled experts.
4. NBTC requested MCI to remove the anomaly of having differing nomenclature for MD courses having the same curriculum (MD Transfusion Medicine, MD IHBT, MD IHTM). It also requested them to consider the teaching experience of Pathologists valid for starting a PG course in Transfusion Medicine.
5. Armed Forces Medical Services would submit a consolidated monthly report to NBTC for all the blood banks via hard copy, since they do not report on SIMS. They were agreeable to bulk transfer of blood and components with civilian blood banks.
6. IMA was requested to convene a meeting to discuss the course of action for partnership with NBTC for incorporation of informed consent for blood/ component transfusion, improving rational and appropriate clinical use of

blood and blood components, voluntary blood donation and counseling of blood donors and other areas for cooperation.

7. President directed NBTC to work towards a holistic five year Strategic framework for Blood Transfusion Services.

Agenda Item No. 4: Any other matter with the permission of chair

1. President NBTC directed CDSCO to immediately review the status of pendency in the licensing of blood banks across the country and submit a report within a period of 10 days. He also directed that a central dashboard be created for blood banks on the Sugam/ e Rakt Kosh platform to be accessed by policy makers and regulators for reviewing licence status and monitoring of blood banks. He also asked CDSCO to create a platform through integration of Sugam online with e Rakt Kosh/ other initiatives of CDC QMBB Project and make online reporting mandatory by all licensed blood banks.
2. The relative merits and demerits of a "Hub & Spoke" approach for BTS versus a decentralized blood collection, processing and distributions were deliberated and it was decided to take up the matter with a small group of experts including State representatives to review existing models globally and come up with a realistic approach for the country.
3. The minimum standards prescribed for Blood Banks and Blood Transfusion Services prescribed under the Drugs and Cosmetics Rules must be reviewed and their compliance facilitated and monitored across all Blood Banks to improve quality. Emphasis on and support for accreditation may be however considered for select blood banks.
4. It was pointed out that there were long standing amendments already recommended by NBTC to CDSCO to be made in the Drugs and Cosmetics Rules. Concern was however expressed regarding the long drawn process for the same. NBTC should facilitate summarizing the key bottlenecks required immediately for taking up by CDSCO.
5. NHM was directed to work on creation of a functional network of Blood Storage Units to ensure access to safe blood especially in remote, difficult terrains and along highways. The existing BSU may be mapped out and gaps identified.
6. President NBTC requested for the present status of refreshment money for blood donors through NACO and State Governments be put up to him.

The meeting ended with a vote of thanks.

137

Annexure 1

Action Plan for National Blood Transfusion Council

(2017-18 and 2018-19)

1. **Development of Guidelines and Standards:**

NACO/NBTC envisions developing and printing the following Guidelines and Standards for Blood Transfusion Services:

1.1 National Standards
1.2 Technical & Operational Guidelines
1.3 Communication Strategy for VBD
1.4 Development of National Strategic Framework
1.5 Review and revision of Transfusion Medicine Technical Manual, DGHS, 2nd Edition 2003

Technical and financial assistance would also be sought from WHO, CDC, Professional Associations for BTS like ISTM, ISBTI, AATM etc for this activity.

This would be a one-time activity and the Total financial implication for the year 2017-18 and 2018-19 for conduction of expert working group meetings will be around ***Rs. 121.00 lakhs***

2. **Training Programmes in BTS:**

2.1 Strengthening Quality Management Systems in BB-Training of designated 01 Quality Manager and 01 Technical Manager posted in Blood Banks in designated Regional Training Centres (80 batches, Rs.601.6 lakhs)

2.2 Counselling Blood Donors- Training of Counsellors posted in Blood Banks for Counselling Blood Donors at Designated Regional Training Centres (40 batches, Rs. 205.20 lakhs)

Funds would be positioned directly with the training centres for this activity.

Total financial implication during the year 2017-18 and 2018-19 for conducting Training Programmes in BTS *will be around* ***Rs. 806.80lakhs.***

3. **E-Initiatives:**

3.1 NBTC Website: Development and maintenance of NBTC Website (Rs.5.00 lakhs)

3.2 Blood Helpline: National Toll Free Blood Helpline for queries related to Blood Banks location and availability of Blood/Blood Components. (Rs. 60.00 lakhs)

Total financial implication for E-initiatives during the year 2017-18 and 2018-19 for will be around ***Rs. 65.00 lakhs***

4. **External Quality Assurance Programme (EQAP) for Blood Banks:**

4.1: Grant-in-aid towards annual subscription charges: @ Rs 4000 per blood bank for enrollment of NACO supported blood banks of the Country in the External Quality Assessment Scheme for Blood Banks in a phased manner. In the year 2017-18, 470 NACO supported Blood Banks to be enrolled in the programme and in the year 2018-19 around 500 NACO supported Blood Banks to be enrolled in the programme.

Total financial implication during the year 2017-18 and 2018-19 for (EQAP) for Blood Banks: will be around ***Rs. 38.80 lakhs.***

5. **VBD Awareness Activities:**

5.1 Observance of Blood Donation Days: Event management/ advertisement/ printing and replication of IEC material, National level activities for 14th June and 1st October each year will be conducted under the aegis of NBTC.

Support would also be extended for this occasion to the various NGOs and organizations involved in promotion of voluntary blood donation to carry out contests, competitions, development of IEC material and felicitation of blood donors, NGOs, government agencies and others supporting the cause of voluntary blood donation. (Rs.200.00 lakhs)

5.2 Round the year Awareness Programme: Awareness programme round the year through multimedia campaigning and nationwide blood drives. Regular spots on radio and TV may be developed which address the youth to volunteer themselves as voluntary blood donors. Programmes should highlight all positive aspect of voluntary blood donation and blood transfusion. These spots may be broadcast/telecast in Hindi as well as regional languages. Social media would also be leveraged (Rs. 200.00 lakhs)

5.3: Development of Standardized Communication Strategy and materials for VBD: National level workshops would be organized to generate a healthy brainstorm among

all stakeholders for VBD and help come up with a communication strategy and standardized prototypes and content for use across States and facilities. Limited quantities of the prototypes would be replicated at National level for dissemination. Thereafter, standardized prototypes would be shared with all the States for replication using their resources. This activity would be conducted with the support from CDC-CMAI QMBB project and outputs disseminated on 1st October 2017 on the occasion of NVBDD. (Rs.120 lakhs)

Total financial implication for VBD Awareness Activities *during the year 2017-18 and 2018-19 for will be around* ***Rs. 520.00 lakhs.***

6. **Meetings/ Workshops:** It is proposed to organize the following Meetings/ Workshops through NBTC support:

6.1:SBTC Review Meetings: Organizing SBTC Review meeting once every year (Preferably in April)

6.2: NBTC GB Meeting: Organizing Governing Body meeting of NBTC twice every year (preferably in June/ December)

6.3: Regional Training Centres Review Meeting: Organizing Review Meeting for regional training Centres once every year (preferably in February)

6.4: PT Providers Review Meeting: Organizing Review Meeting with PT Providers once every year (after completion of 01 PT cycle)

6.5: Other Meetings: Organizing Meetings of National Core Coordination Committee, Executive Committee, Technical Resource Group, Technical Expert Group, Working Group and any other Meeting.

6.6: Workshops/ Conferences: Organizing/ Supporting/ Attending International/ National Workshops/ Conferences for Strengthening BTS in the CountryOrganizing/ Supporting International/ National Workshops/ Conferences for Strengthening BTS in the Country.

Total financial implication during the year 2017-18 and 2018-19 for conducting Meetings/ Conferences for BTS *will be around* ***Rs. 142.00 lakhs.***

7. **Human Resource:**

7.1: Remuneration and TA/DA of NBTC officials:

Remuneration towards Salary and TA/ DA of officials posted in NBTC will be paid through NBTC fund.

Existing regular positions and additional contractual positions would be created/ filled to make the NBTC functional and independent.

A fund of ***Rs 200.00 Lakhs*** *will be needed to support staff in NBTC for year 2017-18 and 2018-19.*

8. **Contingency:**
A contingency grant of **Rs. 100.00 lakhs** is to be retained by NBTC to be used as buffer to carry out other expenditure for Legal work, Stationery, IT support and Miscellaneous Activities in the year 2017-18 and 2018-19.

A total budget of Rs. 1993.60 lakhs will be required by NBTC during the year 2017-18 and 2018-19 to carry out the above-mentioned activities as detailed below.

NATIONAL BLOOD TRANSFUSION COUNCIL AAP 2017-18/ 18-19								
S.No.	Sub-Component	Cost Head	Unit Cost (Rs. In Lakhs)	Items/ Activities	Targets			Allocation
					2017-2018	2018-2019	Total	DBS (Rs. In Lakhs)
1	**Development of Guidelines/ Standards**	**One-time**						
1.1	National Standards	One-time		Development & Printing of National Standards for Blood Banks and Blood Transfusion Services				50.00
1.2	Technical & Operational Guidelines	One-time		Development & Printing of technical & Operational Guidelines for BTS				50.00
1.3	Communication Strategy for VBD	One-time		Development of Standardized IEC material for promotion of VBD				1.00
1.4	Strategic Framework	One-time		Development & Printing of National Strategy Document (Vision Document) for BTS				20.00
2	**Training programmes in BTS**		**per Trng Prgm**		**No. of training programmes**			
2.1	Strenghthening Quality Management Systems in BB	Recurring	7.52	Training of 01 Quality Manager and 01 Technical Manager	30	50	80	601.60

2.2	Counselling Blood Donors	Recurring	5.13	Training of 01 BB Counsellor	20	20	40	205.20
3	**E-Initiatives**							
3.1	NBTC Website			Website development and maintenance				5.00
3.2	Blood Helpline			National Toll Free Blood Helpline for queries related to Blood Banks location and availablity of Blood/Blood Components				60.00
4	**External Quality Assurance Programme (EQAP) for Blood Banks**	**Recurring**	**Annual subscription**		**No. of blood banks**			
4.1	Enrolment in EQAP		0.04	Subscription Cost for enrolling Blood Banks for EQA programme	**470**	**500**	**970**	38.80
5	**VBD Awareness Activities**	**Recurring**	**Per event**		**No. of events**			
5.1	Observance of Blood Donation Days	Recurring	50	Event management/ Advertisement/ Printing and replication of IEC material/ National level activities for 14th June and 1st October	2	2	4	200.00
5.2	Round the year Awareness Programme	Recurring	100	Multimedia campaign	1	1	2	200.00
5.3	Printing of NBTC Standardized IEC material	Recurring		Printing & replication of IEC material for promotion of Voluntary blood donation as per approved Strategy for Communications				120.00
6	**Meetings/ Workshops**	**Recurring**	**for each meeting**		**No. of Meetings**			

6.1	SBTC Review Meetings	Recurring	5	Organizing SBTC Review meetings once a year (April)	1	1	2	10.00
6.2	NBTC GB Meeting	Recurring	3	Organizing NBTC Governing Body meeting twice every year (June/ December))	2	2	4	12.00
6.3	Regional Training Centres Review Meeting	Recurring	5	Organizing RTC Review Meeting once a year (February)	1	1	2	10.00
6.4	PT Providers Review Meeting	Recurring	5	Organizing Review Meeting for PT Providers once a year (after completion of 01 PT cycle)	1	1	2	10.00
6.5	Other Meeetings	Recurring		National Core Coordination Committee, Executive Committee, Technical Resource Group, Technical Expert Group,Working Group, any other Meeting				50.00
6.6	Workshops/ Conferences	Recurring		Organizing/ Supporting International/ National Workshops/ Conferences for Strengthening BTS in the Country				50.00
7	**Human Resource**							
7.1	Salary	Recurring		Salary, TA/DA for BTS Officials in NBTC	100	100	200	200.00
8	**Contingency**	**Recurring**						
				Fund for Legal work, Stationery, IT support, Miscellaneous expenditures	**50**	**50**	**100**	100.00
	NBTC (Total Allocation)				**20 crores**			**1993.60**

Annexure 2

Roles and Responsibilities of NACO/ NBTC/ NHM

- Blood Cell (NHM) and BTS Division NACO have distinct roles, but both will work in close coordination with NBTC and overall broad umbrella of NBTC
- Periodic review meetings would be conducted under the chairpersonship of President NBTC (Additional Secretary NACO) to review the progress of all agencies and ensure coordination with all stakeholders including DCG(I) and DGHS

	NACO		NHM
	NBTC	**BTS Division**	**Blood Cell**
Mandate	Policy and Technical matters Guideline formulation and ensure updation of standards for BTS and periodic amendments in law/ rules to support the regulation thereof. Coordination mechanism through National/ State Transfusion Core Coordination Committees with DCG(I) and DGHS Overall Guidance to Programmatic Strategy, implementation and Monitoring	Blood Programme under NACP (Safety, Quality)	Blood Programme under NHM (Adequacy, Availability, Access)
Purview	All licensed BB in coordination with DCG(I) through SBTC (grant of NOC for Blood Bank license, VBD Camp permission, Grant of RBTC status, Processing Charges etc)	NACO supported Blood Banks in Government and Charitable Sectors through SACS	Blood Banks and Blood Storage Centres (BSC) in Government Sector through State NHM
Responsibility			
Metro Blood Banks		Establishing Centre of Excellence in Delhi, Mumbai, Kolkata, Chennai and providing funds for the activity, taking approvals, procurement, recruitment etc.	
Plasma Fractionation		Setting up Plasma Fractionation Centre on PPP modality Providing funds for the activity, taking approvals,	

		procurement, recruitment	
Monitoring		Monthly reporting in SIMS	
E-initiatives	NBTC website, NHP and centralized helpline		e-Raktkosh and State level helplines
Capacity Building	Training for BB Staff (on BB procedure, QMS, Counselling Blood Donors and others) and Certification thereof	-	Training for BSC Staff
QMS and EQAS	Enrolling BB for EQAS, implementation and monitoring	-	-
Infrastructure Development		Metro Blood Banks, PFC, Up gradation of existing tertiary care BCSU to CoE and enhancement of component separation subject to fund allocation	Setting up Blood Banks in district without BB and Blood Storage Centres in Govt. Sector
Procurement of BB/ BSC Equipments and their Maintenance	-	Providing equipments to BCSU subject to availability of funds	Providing equipments and AMC/ CMC of the same to BB and BSC
Commodity/ Consumables Support	-	Provide Commodity support (75% of the requirement) to NACO supported BB (Blood Bags & Testing Kits) through National procurement	Provide Commodity and Consumables (100% of requirement) to BB &BSC (Reagents, Glass wares, etc)
Technical Guidelines/ Specifications for Equipments and Commodities	Defining Standard Technical Specifications for Equipments and commodities to be used in BB/BSC in coordination with DGHS	-	-
Promoting VBD Activities		Fund support to SBTC to conduct VBD Camps, provide donor refreshment, Observe National Voluntary Days and other activities	Funding support for Donor recruitment, retention and motivation
Purchase and maintenance of Blood Donation	-	POL, Maintenance of existing Blood Mobile Bus	POL, Maintenance, Recurring expenditure of Blood Collection and Blood

Vehicles			transportation vehicles and further procurement and maintenance
Human Resource		Providing Salary to SBTC staff, lab-Technicians, Counsellors, Data Manager, Lab Attendant, Drivers, Bus Attendant, Van Attendant positioned in NACO supported BB/ Blood Mobile Bus/ BTV as per current PoA	Salary to Staff of Blood Cell at National And State level, and manpower positioned in BB through NHM
Communication and IEC	Developing Standardized IEC material to augment VBD across the Country to reach the target of 100% by 2020 Observance of National level events		Printing and distribution of Standardized IEC material developed by NBTC across all BB/BSC to the lowest level of health care delivery through States
Blood Disorders& Stem Cell Registry	-	-	All matters related to Blood disorders (Thalassemia, Haemophilia, Sickle-cell anemia and any other blood disorder) and Stem Cell Registry in coordination with Non communicable Diseases programme & NOTTO
Research & Development	Assessment of Blood Banks of India, Estimation of Blood requirement, demand and supply , other Operations Research	Providing funds for R&D related to BTS in coordination with Donor partners like WHO, CDC	-
Coordination/ Review of Activities	Coordinate with DCGI, DGHS, MCI, AFMS, Other Ministries etc on all matters related to BTS	With States as per Pre-defined areas	With States as per Pre-defined areas
Miscellaneous	-	PQ, Grievances, RTI, VIP Reference, Court Cases, Media matters, NHSRC Matters	-

Annexure 3

Recall and Referral Mechanism for 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 sero-reactive result of transfusion transmitted infection (TTI).
- Donors should be provided post-donation counselling prior to referring those 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.

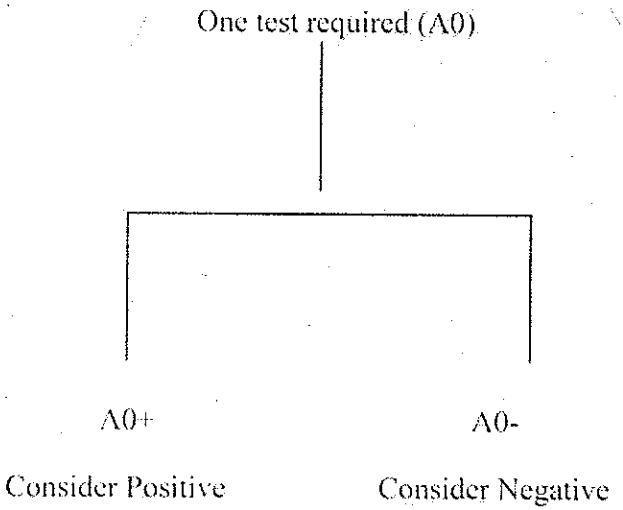
Duties of a Blood Bank:

- It is not the primary duty of the Blood Bank or Blood Transfusion Services to confirm the diagnosis of any of the TTI screened for.
- 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.
- 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.
- 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 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.

147

Referral Mechanism of HIV Sero-reactive Blood Donors to ICTC:

- 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 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 in annexure 2 and send it along with referred donor.

4. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to ICTC

- Donor shall be offered HIV pre-test counselling at the ICTC and consent taken to perform the HIV test.
- ICTC shall perform first test. 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.
- 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.

Referral Mechanism of other TTI Sero-reactive Blood Donors to clinicians:

- 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.
- 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.

1. All blood donors found to be sero-reactive at blood bank for HBV, HCV, Syphilis and Malaria shall be referredto clinicians in the Out Patient Department of associated hospitals or others for assessment and re-testing.
2. Blood bank shall fill out the referral form as per standard format in annexure 2 and send it along with referred donor.
3. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to Clinicians

- 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.

149

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: _____

Address (Res.): _____ Sex:

_____ Age:

Address (Office) _____

_____

Contact Nos : (Res.) _____ (Office) _____ (Mobile) _____

E-Mail _____

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. Are you feeling well today?
   2.2. Have you eaten anything in the last 3 hours?
   2.3. After donating blood do you have to engage in heavy work, driving heavy vehicle or work at height today? Yes No

150

3. Have you had / history 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 Blood Pressure
- 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
Mumps	Yes	No
Chicken Pox	Yes	No
Dengue	Yes	No

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

(15)

- 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 one of the above or below categories?** Yes No

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

12.2 In 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 diarrhea Yes No

12 In case of a woman:

a) Are you pregnant or have you had an abortion in the last 6 months? Yes No

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

Consent

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

b) Donation of blood or any of its 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 by 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:

152

MEDICAL ASSESSMENT	Name of Medical Officer:	Sign:
Donor's Name:		
Weight: ..... kgs Hb Level: ≥ 12.5g/dl		<12.5g/dl
History Check list	Resting well / Adequate sleep (6-8hrs) / Last meal within 1hrs Ever hospitalized Current illnesses or medications	
Examination Check List	Dehydrated / weak / pallor / icterus / alcohol smell Infected wounds / Venepuncture site lesions Pulse ..... beats/min ..... BP ..... mmHg Heart ..... lungs	
Counseling Points	Post donation instructions / motivate a regular donor Need for follow up for TTI purposes How to send for follow up purposes Re-call date / Re-phone / SMS / 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		
Check Donation No: Ok Donation records Blood Bags / Specimen Tubes		
Start time: ..... am / pm End Time of Donation		
Volume: ..... ml		
Complications: Faint Fits Drug Rx Bacteremia Others please specify		
Management:		

153

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 ICTC on _____

(Seal of ICTC /Laboratory with contact details)

Annexure 4

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. "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 Maximum age 65 years First time donor shall not be over 60 years of age, for repeat donor upper limit is 65 years. For aphaeresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of donor	350 ml- 45 kg 450ml– more than 55 kg 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. 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) After whole blood donation a plateletpheresis donor shallnot be accepted before 28 days. Apheresis platelet donor shallnot 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. 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. 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 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 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. 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. 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

157

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
40.	Convulsions and Epilepsy	Permanently defer
41.	Schizophrenia	Permanently defer
42.	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		
43.	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) - Permanently defer person requiring insulin and/or complications of Diabetes with multi organ involvement- Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks
44.	Thyroid disorders	Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, Auto Immune Hypo Thyroidism) Defer if under investigation for Thyroid Disease or thyroid status is not known Permanently defer if: 1) Thyrotoxicosis due to Graves' Disease 2) Hyper/Hypo Thyroid 3) History of malignant thyroid tumours
45.	Other endocrine disorders	Permanently defer
Liver Diseases and Hepatitis infection		
46.	Hepatitis	Known Hepatitis B, C- Permanently defer Unknown Hepatitis- Permanently defer Known hepatitis A or E; Defer for 12 months
47.	Spouse/ partner/ close contact of individual suffering with hepatitis,	Defer for 12 months

48.	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
49.	Spouse/ partner of individual receiving transfusion of blood/ components	Defer for 12 months
50.	Jaundice	Accept donor with history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in neonatal period.
51.	Chronic Liver disease/ Liver Failure	Permanently defer
	HIV Infection/AIDS	
52.	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
53.	Known HIV positive person or spouse/ partner of PLHA (person living with HIV AIDS)	Permanently defer
54.	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	
55	Syphilis (Genital sore, or generalized skin rashes)	Permanently defer
56.	Gonorrhoea	Permanently defer
	Other Infectious diseases	
57.	History of Measles , Mumps, Chickenpox	Defer for 2 weeks following full recovery
58.	Malaria	Defer for 3 months following full recovery.
59.	Typhoid	Defer for 12 Months following full recovery
60.	Dengue/ Chikungunya	In case of history of Dengue/Chikungunya: Defer for 6 Months following full recovery. Following visit to Dengue/Chikungunya endemic area: 4 weeks following return from visit to dengue endemic area if no febrile illness is noted.
61.	Zika Virus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area orZika virus outbreak zone: Defer for 4 months.
62.	Tuberculosis	Defer for 2 years following confirmation of cure

63.	Leishmaniasis	Permanently defer
64.	Leprosy	Permanently defer
	Other infections	
65.	Conjunctivitis	Defer for the period of illness and continuation of local medication.
66.	Osteomyelitis	Defer for 2 years following completion of treatment and cure.
	Kidney Disease	
67.	Acute infection of kidney (pyelonephritis)	Defer for 6 months after complete recovery and last dose of medication
68.	Acute infection of bladder (cystitis) / UTI	Defer for 2 weeks after complete recovery and last dose of medication
69.	Chronic infection of kidney/ kidney disease/ renal failure	Permanently defer
	Digestive System	
70.	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
71.	GI endoscopy	Defer for 12 months.
72.	Acid Peptic disease	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), hiatus hernia: Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding:
	Other diseases/ disorders	
73.	Autoimmune disorders like Systemic lupus erythematosis, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis	Permanently defer
74.	Polycythaemia Vera	Permanently defer
75.	Bleeding disorders and unexplained bleeding tendency	Permanently defer
76.	Malignancy	Permanently defer
77.	Severe allergic disorders	Permanently defer
78.	Haemoglobinopathies and red cell enzyme deficiencies with known history of haemolysis	Permanently defer

Vaccination and inoculation		
79.	**Non live vaccines and Toxoid:** Typhoid,Cholera,Papillomavirus, Influenza,Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	Defer for 14 days
80.	**Live attenuated vaccines:** Polio oral,Measles(rubella) Mumps, Yellow fever, Japanese encephalitis, influenza,Typhoid,Cholera,Hepatitis A	Defer for 28 days
81.	Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum	Defer for 28 days
82.	Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins	Defer for 1 year
Medications taken by prospective blood donor		
83.	Oral contraceptive	Accept
84.	Analgesics	Accept
85.	Vitamins	Accept
86.	Mild sedative and tranquillizers	Accept
87.	Allopurinol	Accept
88.	Cholesterol lowering medication	Accept
89.	Salicylates (aspirin), other NSAIDs	Defer for 3 days if blood is to be used for Platelet preparation
90.	Ketoconazole, Antihelminthic drugs including mebendazole,	Defer for 7 days after last dose if donor is well
91.	Antibiotics	Defer for 2 Weeks after last dose if donor is well
92.	Ticlopidine, clopidogrel	Defer for 2 Weeks after last dose
93.	Piroxicam, dipyridamole	Defer for 2 Weeks after last dose
94.	Etretinate, Acitretin or Isotretinoin. (Used for acne)	Defer for 1 month after the last dose
95.	Finasteride used to treat benign prostatatic hyperplasia	Defer for 1 month after the last dose
96.	Radioactive contrast material	8 weeks deferral
97.	Dutasteride used to treat benign prostatatic hyperplasia	Defer for 6 months after the last dose
98.	Any medication of unknown nature	Defer till details are available
99.	Oral anti-diabetic drugs	Accept if there is no alteration in dose within last 4 weeks.
100.	Insulin	Permanently defer

101.	Anti-arrhythmic. Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs(Digitalis)	Permanently defer
Other conditions requiring Permanent deferral		
102.	Recipients of organ, stem cell and tissue transplants Donors who have had an unexplained delayed faint or delayed faint with injury or two consecutive faints following a blood donation.	Permanently defer

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ANNEXURE-A5

(162)

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.

163

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.

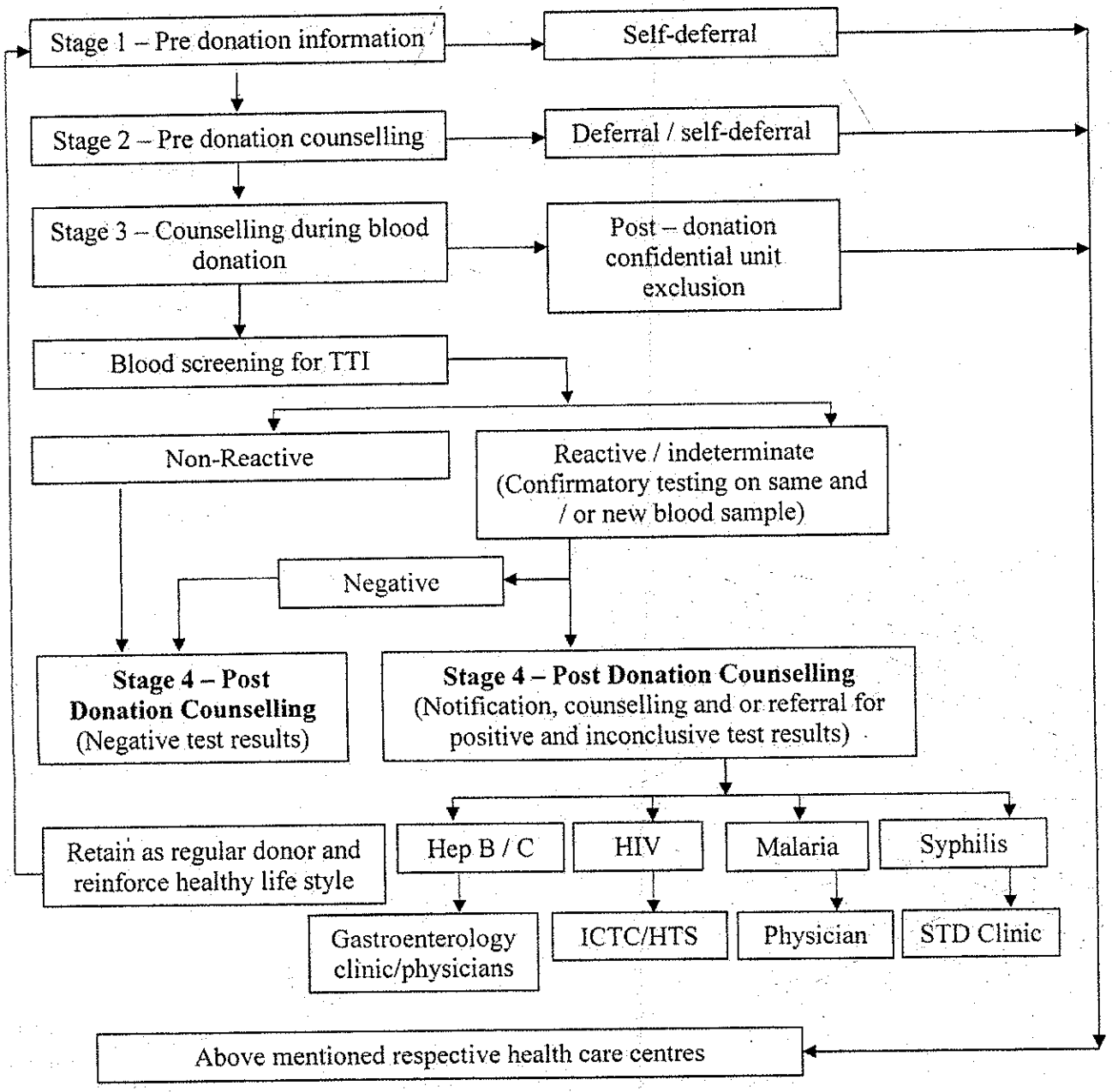
Donor Selection and Counselling

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. "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 Maximum age 65 years First time donor shall not be over 60 years of age, for repeat donor upper limit is 65 years. For aphaeresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of donor	350 ml- 45 kg 450ml– more than 55 kg 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. 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) After whole blood donation a plateletpheresis donor shall not be accepted before 28 days. 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. 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. 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 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 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. 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.
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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.
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15.	Pregnancy or recently delivered	Defer for 12 Months after delivery
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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
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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
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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
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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
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55.	Gonorrhoea	Permanently defer
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60.	Zika Virus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area or Zika virus outbreak zone: Defer for 4 months.
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74.	Bleeding disorders and unexplained bleeding tendency	Permanently defer
75.	Malignancy	Permanently defer
76.	Severe allergic disorders	Permanently defer
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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 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.

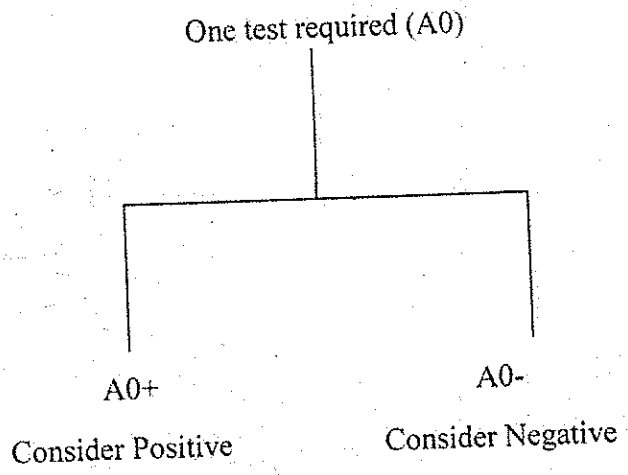
Duties of a Blood Bank:

- 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

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

11.2 In 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: _____ Weight: _____ Kgs	Hb Level: ≥ 12.5g/dl	< 12.5g/dl
History Check List	Feeling well/adequate sleep (> 5hrs) / Last meal within 4 hrs Ever Hospitalized Current illness or medications:	
Examination Check List	Unhealthy look/pallor/icterus/ alcohol smell Infected wounds/ Venepuncture site lesions Pulse: ..... beats/min BP: .....mmHg Heart: ..... Lungs:	
Counselling Points	Post donation instructions/ making a regular donor Need for follow up for TTI purposes How to contact for follow up purposes: 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 **Check Donation No**: On Donation record/ Blood Bags/ Specimen Tubes **Start time**: ..... a.m/p.m Time Taken:..... mins **Volume**: ..... ml		
Complications: Faint: Fits: Double Prick: Haematoma: Others (please specify): **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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193

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Prevalence of sexually transmitted infections among men having sex with men of urban Vadodara

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ABSTRACT

Background: Men having sex with men (MSM) are at higher risk of getting STIs, including HIV. Their role as bridge population is also very important in the spread of HIV. This study was done with the objective to study the demographic and behavioural factors of MSM and to measure the prevalence of STI among MSM using laboratory facilities of regional RTI/STI centre.
Methods: This was a cross sectional study conducted at a targeted intervention (TI) site of Vadodara city. Sixty-eight MSM were enrolled, counselled regarding HIV and other STI testing followed by an interview using a pretested semi-structured study instrument for the information regarding socio-demographic status, sexual behaviour, present and past history of STI and health seeking behaviour. Following that, clinical examination for presence of any signs of STI and sample collection [oro-pharyngeal, urethral and anorectal swab] was done in an examination room and blood samples were collected. The samples were tested for various STIs at Regional RTI/STI centre.
Results: Thirty-seven percent of MSM were bisexual. 37% MSM were not using condom consistently with 'unavailability at all the time' being the main reason. Six out of 68 MSM found positive of STI. Prevalence was maximum for Chlamydia infection followed by HSV2, HBsAg.
Conclusions: Prevalence of STI was 8.82% among MSM of Vadodara city.

Keywords: Men having sex men, Sexually transmitted infection, HIV, Prevalence, Homosexual

INTRODUCTION

Sexually transmitted infections (STI) are a major public health problem. According to World Health Organization (WHO), each year, there occur an estimated 357 million new infections; four of which are: chlamydia, gonorrhea, syphilis and trichomoniasis.[1] In India, the prevalence of STI is approximately six percent. 30 million of the total 357 million patients affected worldwide belong to India. STI causes acute illness, infertility, long term disability and death. Large numbers of sexually transmitted infections are asymptomatic and very few of those who have symptoms, seek proper testing and health care. Both symptomatic and asymptomatic infections can lead to the development of serious complications which can lead to severe consequences for the individuals and for the community. Even though passive surveillance systems exist in some countries, the data is not always reliable or complete to give the exact magnitude of the STI.[2]

Apart from being serious diseases on their own, STI intensify the transmission of sexually transmitted human immuno-deficiency virus (HIV) infections. Demographically the second largest country in the world, India has also the third largest number of people living with human immuno-deficiency virus/acquired immuno-

deficiency syndrome (AIDS). HIV Prevalence among adults (15-49 years) is 0.34% for India, whereas it is 0.41% for Gujarat state. In Gujarat (a moderate prevalence state) HIV infection is below 1% in antenatal women, but it is still 5% or more among high-risk groups [female sex workers (FSW), MSM and injecting drug users (IDU)].[3] MSM form a substantive population that is extremely vulnerable to HIV not only through their activities but also with regards to their bridging role in general population.

The prevalence of HIV among MSM in India is estimated at 6.8%, which is more than 10 times that among the general population.[4] The prevalence of sexually transmitted infections (STIs) is also high among MSM e.g., syphilis: 5.8%.[5]

As the dynamics of STI and HIV are similar and STI increases the risk of transmission of HIV, a reduction in the prevalence of STI is likely to reduce transmission, and therefore, incidence of HIV. Repeated cross-sectional STI surveys can also be a powerful tool for monitoring the effects of HIV and STI programs because they can demonstrate the combined effects of changes in risk behavior, changes in health-seeking behavior and improved quality of care while adapting to changing patterns of causation and antimicrobial susceptibility.[6]

Under the national AIDS control program, targeted interventions (TI) are being implemented for these high-risk groups. Such TI sites provide STI services to the target population which includes early diagnosis and treatment of STI, biannual syphilis screening, counselling services through TI counsellor, availability of free condoms, referral to integrated counselling and testing centre (ICTC) for HIV screening etc.[7]

This study was done to study the demographic and behavioral factors of MSM of urban Vadodara and to measure the prevalence of STI among MSM of urban Vadodara using laboratory facilities of regional RTI/STI centre.

METHODS

This was a cross sectional study conducted between February to August 2011 in Vadodara city at a non-government organization (NGO) which is identified as TI site for the MSM population of Vadodara by Gujarat state AIDS control society (GSACS). The study universe comprised of all MSM getting services from this TI site.

The MSM term is used to denote all men who have sex with other men, regardless of their sexual identity or sexual orientation. This is because a man may have sex with other men but still consider himself heterosexual or may not have any particular sexual identity at all.[8]

Twice a week visits by PI and skin and VD specialist to this NGO were scheduled. The 14 outreach workers (ORW) were informed beforehand about researcher's visits to their NGO. During each visit 3-4 ORW were asked to mobilize their key population (MSM) to the NGO. During seven months of data collection 83 MSM were brought to the NGO by ORW, out of which 15 refused to participate, thus making a total sample size of 68. As the study population is an unrevealed one, accessibility of the same could not be assured by the ORW. Before starting enrolment of the participants, necessary clearances and permissions were obtained from concerned authorities including (GSACS) and institutional ethics committee for human research (IECHR). MSM were enrolled in the study only after taking informed written consent.

The participants were counselled regarding HIV and other STI testing by counsellors of TI site. Following that, they were interviewed using a pretested semi-structured study instrument for information regarding socio-demographic status, sexual behavior, present and past history of STI and health seeking behavior. This was followed by clinical examination for presence of any signs of STI and sample collection [oro-pharyngeal, urethral and anorectal swab] which was conducted in an examination room by resident doctors from skin and VD department. Blood samples were collected by the laboratory technician of the TI site. Study instrument and laboratory requisition form had the same unique identification number for each participant.

All the collected samples were transported to regional RTI/STI centre, Vadodara, where the swabs were gram stained and serological tests (for syphilis, hepatitis B and C, chlamydia, herpes simplex virus type 2 and HIV) were performed. Individual reports were given to the participants after post-test counselling by TI counsellor. Those who tested positive for any of the STI were given appropriate treatment. Follow up was also done for these participants at tertiary care hospital and TI clinic for treatment. Privacy was ensured while taking the interview and sample collection. Data safety and confidentiality was also given due consideration. The data was entered in Microsoft Excel 2007 and analysis was done using SPSS Statistics 17.0 software.

RESULTS

Out of the 83 MSM contacted during seven months of data collection, 15 MSM refused to participate. Thus, data could be obtained from 68 MSM.

The age of MSM ranged from 18 years to 61 years, mean age being 26.94 years (SD=7.69). Majority (79%) of them were between the age of 21 to 30 years, while around 13% were below 21 years of age. Half of the MSM were unmarried and were living with their parents. Out of the 45% who were currently married, 36% lived with their spouse. Proportion of illiterates among the MSM was seven percent. Majority (70%) of MSM had reported having received primary or secondary level

education. Around 70% were earning less than 5000 rupees per month. Only four percent had an income of more than rupees 10,000. 34% MSM reported having 'no addiction' whereas 66% of MSM were addicted to tobacco, smoking or alcohol. Most of them (51%) had habit of chewing tobacco (Table 1).

Table 1: Distribution of MSM with respect to their socio demographic status (n=68).

Parameter	Number	Percentage
Age (in years)		
18-20	9	13.24
21-25	23	33.82
26-30	24	35.29
31-35	7	10.29
>35	5	7.35
Marital status		
Married	31	45.6
Never married	35	51.5
Divorced	1	1.5
Widowed	1	1.5
Addiction* (* Multiple answers possible)		
None	23	33.82
Tobacco chewing	35	51.47
Smoking	18	26.47
Alcohol	23	33.82
Drugs	1	1.47
Education		
Illiterate	5	7
Primary	23	34
Secondary	24	35
Higher Secondary	9	13
Graduation	4	6
Post-graduation	3	5
Monthly personal income (in Rs)		
<2500	16	23.52
2500-5000	32	47.06
5000-10000	17	25
10000-20000	3	4.42

With regards to sexual orientation, around 37% of the MSM were bisexual. 32% were active partners, 21% were passive partners while 10% were behaving as both active as well as passive partners (koti/panti) at times.

Table 2: Age at first sexual intercourse with male (n=68).

Age (in years)	Number	Percentage
<10	12	17.65
11-15	16	23.53
16-20	31	45.59
>20	7	10.29
No response	2	2.94

Almost 41% of the MSM had their first sexual intercourse with male before the age of 16 years. 18% had their first sexual intercourse with male before the age of 10 years (Table 2).

When asked whether they were consistently (at every intercourse in past 6 months) using condom with their male partners, 63% of the MSM responded positively. Out of 37% of the MSM, who were not using condoms consistently, 48% of them mentioned that they were aware of the importance of condom use, but sometimes because of 'unavailability of condom', failed to use it every time. 24% stated 'no pleasure' as the reason for non-consistent condom use, 'lack of awareness' and 'negligence' accounted for 12% each (Figure 1).

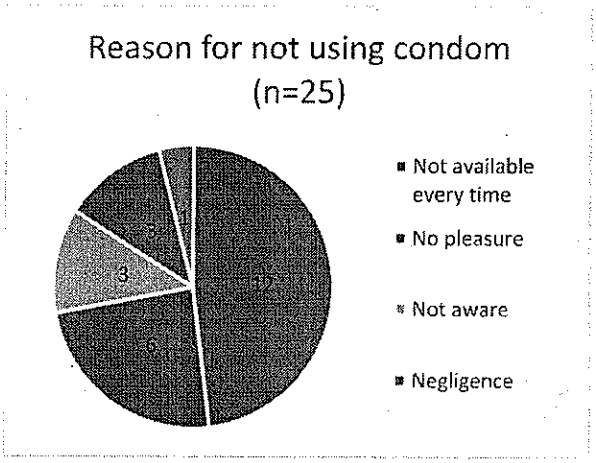

Figure 1: Reasons for not using condom.

32% had not used condom in their last intercourse with a male (Table 3).

Table 3: Condom use by MSM (n=68).

Parameter	Number	Percentage
Consistent condom use		
Yes	43	63.23
No	25	36.76
Condom use in last intercourse		
Yes	46	67.65
No	22	32.35

One or the other symptom of STI was experienced by 18% of the MSM at the time of interview. Out of them, 33% had complaint of genital ulcer while 25% had ulcer in anal region and discharge from the anal area.

Most of the MSM with symptoms of STI were already under treatment for the same; most of them had visited TI Clinic for treatment, while rest had taken advice from their peers (Table 4).

Table 4: Complaint of symptom of STI at the time of interview (n=68).

Parameter	Number	Percentage
Symptoms at present		
Present	12	17.65
Absent	56	82.35
Symptom* (n=12)		
Genital ulcer	4	33.33
Ulcer in the anal area	3	25
Discharge from the anal area	3	25
Other	5	41.67
Measures Done		
Advice from NGO clinic	10	83.33
Advice from peers	2	16.67

*Multiple answers possible

Blood samples were collected from all the 68 MSM out of which one sample was rejected due to insufficient quantity. Hence results for serological tests were available for 67 samples. Prevalence of STI was 8.82% among MSM (6 out of 68). Prevalence was maximum for Chlamydia (4.5%) followed by HSV2 (3%) and HBsAg (1.5%). None of the samples was found to be positive for syphilis, hepatitis C virus and HIV. None of the swabs was found positive for any of the STI.

All the 6 MSM who were found to be serologically positive for STI were asymptomatic at the time of examination.

DISCUSSION

Earlier studies have established the need for understanding demographics and sex work patterns to improve the effectiveness of HIV/STI prevention programs.[9,10] This study serves to identify potential vulnerabilities of MSM of urban Vadodara. Socio-demographic and sexual behavioral characteristics were examined and described for the MSM group along with the laboratory investigations for various STI.

Men accessing services at the TI site were young and most of them had at least a secondary school education, with a low prevalence of clinically diagnosed STI and HIV. Majority of the men had a predominant same sex preference, but half of the men were married to women. Being married may reflect some denial of same sex behaviour by married MSM, who might dissociate and suppress their secret lives and/or think that because they are socially perceived as heterosexual, they would be at low risk of acquiring HIV. They also may be socially isolated from other MSM and not be likely to receive community-based prevention interventions.[11]

About one third of the men expressed a bisexual behavioural preference, which was an independent predictor for having HIV/testing positive for HIV. Behaviourally, bisexual men preferred insertive anal and then vaginal sex in that order with their partners. These men may form a major bridge population between other high-risk MSM and transgender and their regular female partners or spouses, as also suggested by other studies conducted in Andhra Pradesh and Mumbai in the past.[12-14]

First sexual intercourse with male was common below the age of 16 years. Almost one fifth had their first sexual intercourse with male before the age of ten years. This might be due to sexual exploitation in their childhood. Childhood sexual abuse (CSA) is a significant global public health problem, which is associated with negative psychosocial outcomes and high-risk sexual behaviors in adults. MSM often report higher prevalence of CSA history than the general population, and CSA may play a key role in MSM's greater vulnerability to HIV.[15] More research is needed into this specific component of CSA leading to MSM or other high-risk behavior in developing countries.

The present study found high rates of unprotected sex and bisexuality among urban MSM. A study conducted in Andhra Pradesh also found that MSM reported high rates of unprotected anal sex with other men and women.[13] Another study among rural men from 5 different states in India also reported that 9.5% of single and 3.1% of married men had anal sex with other men and had greater number of male sexual partners and found high rates of unprotected anal sex with male partners.[12]

Nearly two thirds of the MSM were consistently using condom with their partner. Nearly one third of the MSM were involved in unprotected sex. That can increase the risk of acquiring STI and even transmitting them.

In this study, almost one fifth of the MSM had one or the other symptom of STI at the time of interview. But the serological tests revealed that prevalence of STI was only 8.82%. All those who had symptoms of STI at the time of interview were already under treatment for the same. Most of them visited clinic at the TI site for treatment, while rest had taken advice from their peers. This could be the reason for the low prevalence of STI being diagnosed by the laboratory tests.

A cross-sectional study of STI amongst 122 MSM attending an STI clinic in Mumbai indicated 20% STI prevalence rate.[16] In a study conducted among 831 MSM attending voluntary counselling and testing (VCT) services at the Humsafar Trust showed HIV prevalence of 12.5%, with 14% of the men reporting STD symptoms and 6.5 per cent of the men having a positive VDRL test for syphilis.[11] Prevalence of various STI was found to be 13.25% in a study done amongst MSM patients attending STI clinic at a tertiary care hospital in Chennai.[17]

CONCLUSION

Most of the MSM were between 21 to 30 years of age and married; with high rate of unprotected sex and

197

bisexuality. Prevalence of STIs was 8.82% among MSM. Prevalence was maximum for Chlamydia followed by HSV2 and HBsAg. Majority of MSM had sought treatment from the TI clinic at the NGO for episode of STI.

Recommendations

Majority of those who were positive for STI, were asymptomatic. Samples from this high-risk group should be regularly screened for presence of STI using appropriate laboratory tests and results should be correlated with HIV sero-status. Since 'inconsistent condom use' was the factor associated with the presence of STI, all MSM should be counselled through behaviour change communication regarding importance of correct and consistent condom use every time. Validation of syndromic diagnosis with laboratory diagnosis may be undertaken; so that this approach may be evaluated for screening.

Limitation of the study

As the MSM who participated in this study were recruited through their facilitators (peer educators and ORW), they may not be the representative of all the MSM, thereby, suggesting a bias towards those who are better connected with their peers

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BMC Public Health

RESEARCH Open Access

Prevalence of HIV and sexually transmitted infections among clients of female sex workers in Karnataka, India: a cross-sectional study

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Abstract

Background: Studies have demonstrated the significance of commercial sex work in the ongoing transmission of HIV and other sexually transmitted infections (STIs) in India. Clients of female sex workers (FSWs) are thought to be an important bridging population for HIV/STIs. However, there is a lack of information on basic characteristics of sex work clients. This study sought to describe the prevalence of HIV and other STIs, as well as examine the determinants of these pathogens among a sample of clients in south India.

Methods: Data were from a cross-sectional biological and behavioural survey of FSW clients from six districts in Karnataka State, India. The prevalence of HIV, syphilis, herpes simplex virus type 2 (HSV-2), chlamydia (CT) and gonorrhoea (NG) among clients was examined. Multivariable logistic regression models were used to analyse the socio-demographic, sexual behaviour and sex-work related characteristics related to the prevalence of each pathogen. Sampling weights and appropriate survey methods were utilized in regression models to account for complex sampling design.

Results: The total sample size was 2,745. The average age of clients was 30.4 (SE:0.3). Across the total sample, the prevalence of HIV, HSV-2, syphilis and CT/NG was 5.6%, 28.4%, 3.6% and 2.2%, respectively. The prevalence of HIV/STIs varied substantially across districts, reaching statistical significance for HIV (p<.0001) and CT/NG (p=.005). In multivariable models, duration of paying for commercial sex was associated with increased risk for HIV and HSV-2 (AOR: 1.1; 95%CI: 1.0-1.1, p<.0001). Clients with brothels as a main FSW solicitation site were associated with increased risk of HIV (AOR: 2.4; 95%CI: 1.2-4.7, p=.001), while those frequenting lodges were at increased risk for CT/NG (AOR: 6.3; 95%CI: 1.9-20.6, p=.03). Examining co-infections, clients with HSV-2 infections were at substantially higher risk of being HIV-positive (AOR: 10.4; 95%CI: 6.1-17.7, p<.0001).

Conclusions: This study fills in important gaps in knowledge regarding clients in southern India. The strong association between HIV and HSV-2 infections highlights the complications in designing effective prevention, intervention and management programs of this well-hidden population.

Background

Reducing the transmission of HIV and other sexually transmitted infections (STIs) remains a public health priority in India [1]. As in other parts of Asia, although HIV epidemiology is thought to be fundamentally complex [2], with elevated risk among several 'high-risk' sub-populations, such as men who have sex with men (MSM) [3-8], the predominant driver of HIV transmission in India remains sex work [8-11].

Within the context of sex work, it has been recognized that considerable variation exists in the relationships between female sex workers (FSWs) and their clients, and the behaviours and interactions between the two groups, resulting in substantial heterogeneity in the nature of risk for HIV transmission [12-16]. Ultimately, the differences in the social and structural organisation

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of sex work are manifested by variations in HIV and STI prevalence among different FSW populations [15,16].

Although high prevalence of HIV/STIs and risk behaviours associated with ongoing transmission has been observed in clients globally [17-20], with a handful of exceptions [21,22], very little is known about the prevalence and correlates of HIV/STIs among clients in India. One previous study of clients from 12 districts in India found that HIV prevalence ranged from 2% to 10%, depending on district. Although no statistically significant associations were found between HIV and factors included in their analysis, the authors found that two measures of high risk behaviour, volume of sex acts and inconsistent condom use, were positively associated with older age and having a mix of both commercial and non-commercial partners [21]. These findings align with the notion of clients as an important bridging population, with the potential to further the transmission of HIV and other STIs to both commercial and non-commercial partners, described in other localities [2,11,23,24].

Given the high rates, by Indian men, of both commercial sex partnerships and inconsistent condom use [25], and the lack of access to basic HIV prevention services [26], there is a need to describe the epidemiology of HIV and other STIs in clients from India. This study therefore sought to characterise the prevalence, and factors related to HIV and other STIs among a sample of clients. As developing interventions that are tailored for FSWs and their clients is thought to be pivotal in reducing HIV incidence further [27], the results of this study can be used to inform client-focussed prevention programmes.

Methods

Study design and sampling

Data were obtained from a cross-sectional behavioural and biological survey of clients in six districts (i.e. sub-state administrative areas, including Bagalkot, Bangalore, Belgaum, Bellary, Mysore and Shimoga) in Karnataka State, southern India. Districts were chosen purposively, based on size of high risk populations (in this case FSWs, with the rationale being large FSW populations and client populations are correlated) and the socio-cultural regions of Karnataka [16]. Clients were recruited in 2008 through a multistage cluster sampling technique, similar to that described in Subramanian et al. [21]. Briefly, selection of solicitation sites occurred in the first stage of sampling, and selection of clients in the second. Depending on place of solicitation, all clients were identified by FSWs, madams, brothel owners or through visible clues suggestive of seeking sex workers. Field supervisors would then approach and recruit clients until a target number of clients was reached. For the purposes of this study, men were included in the study if they were between 18 and 60 years of age, and reported exchanging money for sex with FSWs in the past month. Clients were truncated at age 60 to focus on those that were thought to be more sexually active. Overall response rate was 82%, with lowest response rates observed in Bangalore (70%), and highest in Bagalkot (90%).

Survey organization and methods

Men were assigned study numbers for de-identification, and interviewed individually through a structured questionnaire administered face-to-face by trained workers in the local language. As in previous studies, biological data for HIV, herpes simplex virus type 2 (HSV-2), syphilis, and chlamydial (CT) and gonorrhoeal (NG) infections were gathered using blood and urine samples [21]. Blood was tested for HIV, syphilis and HSV-2 using standard serological tests, and urine was tested with a nucleic acid amplification assay (Gen-Probe Aptima) for the detection of CT and NG. Although surveys and the results of specimens were made anonymous at collection, a mechanism was in place to notify, by study number, those who were positive for syphilis. These clients would be asked to attend a clinic for treatment. Other STIs were treated syndromically. HIV results were not notified individually, but all individuals were given vouchers for free HIV testing and counseling at government testing centres. Written, informed consent was obtained for participation in the study and the institutional review boards at the University of Manitoba in Winnipeg, Canada and St. John's University in Bangalore, India approved the study.

Measures

Respondents were compared on socio-demographic, sexual behaviour and sex-work related characteristics. Age, literacy levels, district of residence, and occupation were included as socio-demographic variables. Age at first vaginal intercourse, condom use patterns with intimate partners (i.e. regular, non-commercial partnerships) and reported anal sex with MSM or *hijras* (i.e., transgendered MSM) were used as sexual behaviour variables. Age at first paid sex, duration of paid sex, usual place of solicitation of FSWs, number of different FSWs in the last 6 months (total, and the proportion of regular and occasional FSWs), and condom use patterns with regular (i.e. FSWs whom clients seen more than once) and occasional (i.e., non-regular or casual) FSWs were used as sex work-related variables. For condom use, the following questions were asked, depending on type of partner ("Partner Type X"). First, condom use at last sex was assessed by the question: "Was a condom used the last time you had sexual intercourse with *Partner Type*

X?" Second, clients were asked "In general, how often do you use condoms with *Partner Type X*?" Clients were allowed to choose from the following: Everytime; Most of the time; Sometimes; and Never. This variable was then made dichotomous, with those answering "Never" categorized into one group, and all other remaining answers into the other group.

Statistical analysis

In bivariate analyses, chi-square tests were used to assess associations between socio-demographic, sexual behaviour and sex work-related characteristics and each pathogen under investigation. Because of the use of multiple comparisons, and as each variable was essentially tested four separate times in bivariate analyses, an association was only considered significant at the p<.0125 level (.05/4). Two sets of multivariable logistic regression analyses were conducted. First, in order to assess factors independently related to the prevalence of each specific pathogen, separate multivariable logistic regression models were constructed with each pathogen used as the outcome variable. Second, the presence of HIV was used as the outcome variable only, with all other pathogens used as predictor variables while simultaneously adjusting for the same factors in the first set of models. Because of the potential of the large sample size to detect not necessarily meaningful statistical associations, and as the main purpose of the analyses was to make comparisons *between* pathogens, the same independent variables were used for each pathogen, and for the coinfection comparisons. Thus, *a priori*, and based on a conceptual understanding of sex work in India, duration of paid sex, ability to read or write, marital status, number of FSW contacts in the last 6 months, district of residence, place of solicitation and occupation were adjusted for in multivariable models. Age and duration of paid sex were highly correlated (r^2=0.88). Given the impact of collinear variables on the precision of estimation [28], only duration of paid sex was included in multivariable analyses. As a sensitivity analysis, all multivariable models were repeated with age in place of duration. Sampling weights were utilized in multiple regression models to account for the complex sampling design, using survey methods in Stata 11 [29]. Multicollinearity in multivariable models was assessed using the variance inflation factor (VIF) and tolerance statistics, corrected for the survey methods employed [30].

Results

A total of 2757 clients were included in the study. Additional file 1 includes the socio-demographic, sexual behaviour and sex-work related characteristics of the study sample. The average age of clients was 30 years, with 46% over the age of 30 at the time of the interview. The majority of respondents were married (62%), with just under half belonging in the "Other (including Labourer)" category for occupation. Respondents from Bangalore comprised approximately 31% of the sample. The majority (66%) of respondents reported having a regular non-commercial intimate partner (including spouse), with condom usage being low among intimate partners. Approximately the same proportion of respondents reported ever having anal sex with their intimate partners (5%) as having anal sex with another man or hijra in the last 6 months (6%).

Mean age of first paid sex was 22 years, with the average duration of visiting FSWs being 9 years. Respondents were most likely to report the FSWs' home (48%) and public places (36%) as the places most frequently used to solicit FSWs. Respondents reported visiting an average of 4.3 different FSWs in the 6 months prior to their interview, with approximately 85% having had at least one contact with an occasional FSW and 42% reporting at least one contact with a regular FSW. Although practically speaking, the difference is minimal, condom use was slightly higher with occasional FSWs, with 67% of respondents reporting condom use at last sex with occasional FSWs, compared to 60% with regular FSWs.

Of the 2757 clients included in the study, 2745, 2610, 2613 and 2736 were tested for HIV, HSV-2, syphilis and CT/NG, respectively. HSV-2 was the most prevalent infection, at 28%, followed by HIV at 6%. Active syphilis was detected in 4% of the study sample who were tested for syphilis. The prevalence of CT and NG were 2% and 1%, respectively, with a prevalence of either infection being 2%.

Bivariate analyses

Additional file 2 shows the prevalence of HIV and other pathogens by socio-demographic, sexual behaviour and sex-work related characteristics; results from chi-square tests of association from bivariate analyses investigating the association between each pathogen and characteristics of interest are displayed. Age was significantly associated with HIV (p=.002) and HSV-2 (p<.0001). Similarly, marital status was significantly associated with HIV (p<.0001) and HSV-2 (p<.0001). Occupation was associated with HIV only (p<.0001), with clients employed in the service industry having the highest prevalence (9%). Literacy level was significantly associated with all four pathogens, with HIV (p<.0001), HSV-2 (p<.0001) and syphilis (p=.0006) less prevalent in those that could read or write. Bagalkot district had the highest HIV and HSV-2 prevalence, at 14% and 36%, respectively, while syphilis prevalence was highest in Bellary (6%) and CT/NG highest in Mysore (5%). Only HIV (p<.0001) and CT/NG (p=.005) differed significantly

across districts. Having an intimate partner was associated with higher levels of HSV-2 (p<.0001); HSV-2 prevalence among clients with intimate partners was 34%, while it was 18% among those without intimate partners. Condom use at last sex with an intimate partner was associated with CT/NG prevalence (p=.008).

Duration of visiting FSWs was positively associated with the prevalence of both HIV (p=.001) and HSV-2 (p<.0001). For example, HIV prevalence was 2% among respondents who had been visiting FSWs for a year or less and 8% among those with 10 or more years visiting FSWs. Place of solicitation was associated with HIV (p=.003). Clients who visited brothels had the highest HIV prevalence (9%), while those visiting lodges had the highest CT/NG prevalence (7%). Condom use was associated with the prevalence of HSV-2. Prevalence was higher among clients reporting never using condoms with their occasional (33% vs. 26%, p=.003) FSW partners.

Co-infections

Additional file 2 also shows the degree to which pathogens were related. HIV prevalence was positively and significantly related to syphilis and HSV-2 prevalence. For example, 21% of clients with syphilis were also HIV-positive, compared to 5% of clients that were not infected with syphilis (p<.0001). Similarly, elevated prevalence of HIV was seen amongst respondents who were HSV-2-positive; 16% of HSV-2-positive respondents were HIV-positive, compared to 2% of those that were not HSV-2-positive (p<.0001). Correspondingly, the prevalence of HSV-2 in those respondents who were HIV-positive was 79%, compared to 25% in HIV-negative respondents.

Multivariable models

Table 1 shows the adjusted odds ratios (AOR) and 95% confidence intervals (95%CI) from multivariable logistic regression models examining factors associated with each individual pathogen. For HIV, respondents with a longer duration of visiting FSWs were at higher odds of being HIV-positive (AOR: 1.1; 95%CI: 1.0-1.1, p<.0001), adjusted for all other factors in the model. Respondents from Bagalkot (AOR: 2.9; 95%CI: 1.7-5.1, p<.0001), those reporting "service industry" as their primary occupation (AOR: 2.8; 95%CI: 1.5-5.2, p<.01), and those

Table 1 Adjusted odds ratios (AOR) and 95% confidence intervals (95%CI) from multivariable logistic regression models, socio-demographic, sexual behaviour and sex-work related characteristics associated with pathogen prevalence, Karnataka, South India[a]

		HIV		HSV-2		SYPHILIS		CT/NG	
		AOR	95%CI	AOR	95%CI	AOR	95%CI	AOR	95%CI
Duration		1.05***	(1.03-1.07)	1.08***	(1.06-1.10)	1.03	(0.99-1.06)	0.97	(0.93-1.02)
Married									
	Not currently married	*Ref*	–	*Ref*	–	*Ref*	–	*Ref*	–
	Married	0.70	(0.43-1.16)	1.53**	(1.20-1.96)	1.14	(0.63-2.05)	1.54	(0.71-3.35)
District									
	Belgaum	*Ref*	–	*Ref*	–	*Ref*	–	*Ref*	–
	Bagalkot	2.93***	(1.68-5.10)	1.62**	(1.16-2.26)	0.42*	(0.18-0.96)	0.33	(0.05-2.25)
	Bellary	0.98	(0.48-2.02)	0.92	(0.64-1.32)	1.18	(0.57-2.61)	2.07	(0.57-7.49)
	Shimoga	0.50	(0.23-1.10)	0.79	(0.51-1.21)	0.54	(0.20-1.35)	0.92	(0.21-4.07)
	Bangalore	0.35**	(0.17-0.72)	0.87	(0.59-1.29)	0.87	(0.36-1.91)	3.26	(0.94-11.29)
	Mysore	0.87	(0.44-1.74)	1.01	(0.66-1.54)	0.58	(0.22-1.25)	7.43*	(1.52-36.25)
Occupation									
	Transport worker	*Ref*	–	*Ref*	–	*Ref*	–	*Ref*	–
	Service	2.80**	(1.51-5.19)	1.11	(0.82-1.83)	2.36	(0.80-5.89)	0.76	(0.29-1.96)
	Business	1.68	(0.83-3.41)	0.96	(0.69-1.57)	1.69	(0.53-4.67)	1.04	(0.43-2.50)
	Other	1.36	(0.81-2.29)	0.89	(0.71-1.22)	2.23	(0.96-4.72)	0.78	(0.35-1.72)
Place of solicitation									
	Public place	*Ref*	–	*Ref*	–	*Ref*	–	*Ref*	–
	Brothel	2.41**	(1.23-4.72)	1.43	(0.89-2.21)	1.11	(0.66-3.36)	2.29	(0.73-7.01)
	Home	0.98	(0.64-1.51)	1.10	(0.84-1.50)	1.09	(0.54-1.69)	2.36	(0.86-6.48)
	Lodge	0.15	(0.02-1.14)	0.77	(0.48-1.24)	0.15	(0.16-1.84)	6.28*	(1.92-20.55)
Number of FSWs (6 months)									
	1	*Ref*	–	*Ref*	–	*Ref*	–	*Ref*	–
	2-4	0.96	(0.60-1.51)	0.96	(0.71-1.30)	0.92	(0.53-2.29)	0.77	(0.26-2.23)
	5+	1.00	(0.59-1.69)	1.06	(0.77-1.45)	0.95	(0.51-2.30)	1.38	(0.42-4.49)

[a]FSWs: Female sex workers; CT: Chlamydia; NG: Gonorrhea; HIV: Human immunodeficiency virus; HSV-2: Herpes simplex virus, type 2

*p<.05; **p<.01; ***p<.0001

soliciting FSWs in brothels (AOR: 2.4; 95%CI: 1.2, 4.7, p<.01) were all at increased risk of being HIV-positive. Respondents from Bangalore (AOR: 0.4; 95%CI: 0.2-0.7, p<.01), relative to other districts were at decreased risk of HIV. For HSV-2 a longer duration of visiting FSWs (AOR: 1.1; 95%CI: 1.1-1.1, p<.001), and being from Bagalkot, relative to other districts (AOR: 1.6; 95%CI: 1.2-2.3, p<.01) were all associated with increased HIV risk. Respondents from Bagalkot were least likely to be positive for syphilis (AOR: 0.4; 95%CI: 0.2-1.0, p<.05).

Table 2 shows the results from the multivariable models examining the association between co-infection with

Table 2 Adjusted odds ratios (AOR) and 95% confidence intervals (95%CI) from logistic regression, pathogen co-infection, socio-demographic, sexual behaviour and sex-work related characteristics associated with HIV prevalence, clients of female sex workers, Karnataka, South India[a]

		AOR	95%CI
Pathogen co-infection			
	HSV-2	10.42***	(6.13-17.71)
	Syphilis	2.49*	(1.04-5.95)
	CT/NG	0.65	(0.12-3.47)
Duration married		1.01	(0.99-1.03)
	Not currently married	*Ref*	-
	Married	0.52*	(0.31-0.89)
District			
	Belgaum	*Ref*	-
	Bagalkot	2.48**	(1.35-4.56)
	Bellary	1.08	(0.45-2.58)
	Shimoga	0.55	(0.24-1.25)
	Bangalore	0.40**	(0.18-0.87)
	Mysore	0.92	(0.42-2.01)
Occupation			
	Transport Worker	*Ref*	-
	Service	2.50**	(1.26-4.94)
	Business	1.65	(0.78-3.48)
	Other	1.40	(0.79-2.46)
Place of solicitation			
	Public place	*Ref*	-
	Brothel	2.10	(0.97-4.56)
	Home	0.97	(0.60-1.55)
	Lodge	0.20	(0.03-1.29)
Number of FSWs (6 months)			
	1	*Ref*	-
	2-4	0.99	(0.59-1.64)
	5+	0.98	(0.54-1.77)

[a]FSWs: Female sex workers; CT: Chlamydia; NG: Gonorrhea; HIV: Human immunodeficiency virus; HSV-2: Herpes simplex virus, type 2
*p<.05; **p<.01; ***p<.0001

another STI and being HIV-positive. In the adjusted analysis, being positive for HSV-2 (AOR: 10.4; 95%CI: 6.1-17.7, p<.0001) and syphilis (AOR: 2.5; 95%CI: 1.0-6.0, p<.05) were both independently associated with HIV infection. It is important to note that the direction of causality of HIV, HSV-2 and syphilis cannot be determined through the cross-sectional nature of the data.

Discussion

This cross-sectional study characterised the prevalence of HIV and STIs among a sample of clients from six districts in Karnataka state, southern India. The results demonstrated substantial heterogeneity in the prevalence of HIV and other STIs, both by district and by type of pathogen. A strong and positive relationship between HIV infection and co-infection with other pathogens was detected. These results illustrate the complexity, not only in understanding the epidemiology of HIV and its interaction with other STIs [31,32], but also in the management of HIV-infected persons [31,33].

Concurrent epidemics

The prevalence of HIV, syphilis and HSV-2 in the current study was slightly lower than that observed in a previous study of clients across three states in southern India (Andhra Pradesh, Maharashtra and Tamil Nadu), where prevalence was 6%, 5% and 31%, respectively [21]. Although rates are highly variable, research from southern India has estimated much lower prevalence of HIV and HSV-2 among the general male population at under 1% [1,34] and 9% [35], respectively, underscoring the importance of characterising the epidemiology of HIV and STIs among clients of FSWs. Studies of client populations conducted in countries other than India have noted similarly high rates of HIV [18,36], as well as substantially higher rates of HSV-2 [21,37-39].

Alongside strong evidence demonstrating the link between HIV and HSV-2 [40,41], the association between HIV and HSV-2 has been observed in client populations from other settings [36]. For example, our results are consistent with a recent study of clients conducted in Haiti, where the authors found that HSV-2-positive clients were also at nine-fold the odds for HIV infection [36]. Ultimately, the co-mingling of HIV and HSV-2 has far-reaching implications for prevention and management of HIV [42], as well as understanding the trajectories of both epidemics.

Duration of sex work involvement and other heterogeneous characteristics

Although a study by Subramanian et al. provided important information regarding patterns of risk behaviour which may potentially place certain subgroups of clients at higher risk of acquiring HIV and other infections

[21], the *plausibility* of biological risk does not always necessarily translate into actual, or operationalised risk. That positivity for both HIV and HSV-2 in the present study was strongly associated with duration of paying for sex, and importantly, *not* associated with frequency of FSW contact, highlights the limitations inherent in cross-sectional data, as current behaviours do not necessarily correlate with behavioural patterns at the time of pathogen acquisition [43]. Without broader information on sexual structure, and the organization of sex work, a more complete understanding of *current* risk will remain elusive. Such information could include details on the distribution of FSWs relative to clients, the overlap of clients amongst FSWs, regular commercial and non-commercial partnerships, as well as social and sexual networks [44]. Longitudinal studies focussing on *sexual structure dynamics* examining issues such as partnership patterns, and the distribution and movement of both FSWs and clients into and out of localities over time may also be a potentially useful avenue for research [45], and may be especially salient with infections that cause ulcerative diseases as the presence (and recognition) of ulcers may cause shifts in behavioural patterns.

Although somewhat lower than what was reported by Subramanian et al. (8%), the fact that almost 6% of clients reported having anal sex with another man or hijra in the 6 months prior to their interview is of some interest. In sub-analyses by district (not shown), there was a degree of heterogeneity in reporting this sexual behaviour; prevalence was under 3% in Bagalkot (1%), Shimoga (1%), Belgaum (2%) and Bellary (3%), while highest in Mysore (6%) and Bangalore Urban (12%). Results were inconsistent when this behaviour was compared against pathogen prevalence (Table 2), with those reporting anal sex with a man/hijra having higher prevalences of HSV-2, syphilis and CT/NG, and lower HIV prevalence. However, given previously published reports of high risk behaviours amongst bisexual men [46,6], and as clients who report concurrent sex with both FSWs and other males/hijras have the potential to act as a bridging population to two disconnected networks, further research into this sub-population is warranted [6].

Finally, in multivariable models, clients who reported mostly soliciting FSWs in brothels were at over two-fold the odds of being HIV-positive, compared to clients who mostly solicited in public places. This finding is consistent with a study on FSWs from Karnataka, which found that brothel-based FSWs had the highest HIV prevalence, despite having high rates of condom use [15]. The authors concluded that higher client volume, decreased likelihood of attending sexual health clinics, and increased likelihood of travel to Mumbai (where HIV prevalence has been reported to be near 50% among FSWs) may have contributed to brothel-based FSWs being at higher risk of HIV. As demonstrated in this study, the prevalence of HIV among brothel-based clients may also be an important factor in understanding the risks posed to FSWs.

Strengths and limitations

Our study possessed a number of strengths, including the integration of biological and behavioural components. We had a large sample size from several districts in southern India, which is notable, considering the hidden nature of client populations. There were a number of limitations to the study; first and foremost, although a complex and rigorous sampling technique was used to define the sampling frame, all possible clients were not included in the sampling universe, limiting the ability to generalize our results to the total client population in each district. Notably, clients who only exchanged gifts or services (instead of money) for sex were not included in the study. Therefore, not all types of clients were included. Future studies may want to explore the possibility of using alternative sampling strategies, such as respondent-driven sampling, or snowball sampling. However, since clients represent a loosely-defined, highly heterogeneous and disconnected group, the application of these alternative strategies may prove challenging. Expanding the definition of clients to include those that exchange sex for non-monetary transactions should be explored in future studies. Second, all responses were self-reported, and the possibility of social desirability bias cannot be discounted. Third, data were cross-sectional, and thus causality could not be inferred from our study.

Conclusions

In conclusion, this study presented a comprehensive description of HIV and other STIs among clients from six districts in southern India. Our results demonstrate a remarkable degree of heterogeneity, with respect to pathogen prevalence within this hidden and important bridging population. Importantly, HIV and HSV-2 were highly associated with a longer duration of involvement with sex workers, and this finding, along with the association found between infection with HIV, HSV-2 and syphilis highlights the complexity in understanding the exact determinants of pathogen prevalence. As noted by Lowndes et al. [19,20], targeting of clients by intervention programs is a necessary component of a comprehensive response to HIV. Thus, this study can serve as a useful platform to inform present initiatives, as well as future research into client-FSW partnerships and interactions, and how they evolve over time. Given the higher rates of HIV in clients that solicit sex work in brothels, aligning with previously published work on the

higher risk of HIV amongst brothel-based FSWs, improved strategies to engage with both clients and FSWs in brothels may be essential. At the same time, because present behaviours do not necessarily correlate with behaviours at the time of pathogen acquisition, more research is needed in understanding the trajectory of clients in seeking sex workers. A more nuanced understanding of when risk shifts from *acquisition* of HIV and other pathogens, to *transmission* to sex partners would likely inform the design, timing, and placement of effective and broad-based intervention programming.

List of abbreviations used

HIV: human immunodeficiency virus; STI: sexually transmitted infections; FSW: female sex workers; HSV2: herpes simplex virus type 2; CT: Chlamydia; NG: gonorrhoea; SE: standard error; AOR: adjusted odds ratios; 95% CI: 95% confidence intervals; MSM: men who have sex with men; VIF: variance inflation factor.

Additional material

Additional file 1: Distribution of socio-demographic, sexual behaviour and sex-work related characteristics, clients of female sex worker, Karnataka, South India

Additional file 2: Pathogen prevalence, by socio-demographic, sexual behaviour and sex-work related characteristics, clients of female sex workers, Karnataka, South India.

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Authors' contributions

SYS was responsible for conducting the analysis, interpretation of results and writing of the manuscript; KND made substantial contributions to data analysis and interpretation and revised the manuscript critically and made important intellectual contributions to the manuscript; SRP, SI, and BMR contributed to the project's conception, design, implementation and progress, and provided extensive feedback and edits; SM and JFB were extensively involved in the conception, methodology, and organization of the project, and provided extensive intellectual guidance and substantial feedback for the manuscript.

Competing interests

The authors declare they have no competing interests.

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207

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Geographic and behavioral differences associated with sexually transmitted infection prevalence among Indian men who have sex with men in Chennai and Mumbai

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Abstract

India has one of the largest numbers of men who have sex with men (MSM) globally; however, geographic data on sexually transmitted infection (STI) prevalence and associations with sexual behavior are limited. Six-hundred and eight MSM in Chennai and Mumbai underwent screening for a behavioral trial and were assessed for bacterial STIs (syphilis, chlamydia, gonorrhea), HIV, and past-month self-reported condomless anal sex (CAS). Mumbai (37.8%) had a greater prevalence of any STI than Chennai (27.6%) (prevalence ratio [PR] = 1.37, 95% CI: 1.09, 1.73). This pattern also emerged for gonorrhea and chlamydia separately but not syphilis. Conversely, Mumbai MSM reported lower rates of CAS (mean = 2.2) compared to Chennai MSM (mean = 14.0) (mean difference = −11.8, 95% CI: −14.6, −9.1). The interaction of city by CAS on any STI prevalence (PR = 2.09, 95% CI: 1.45, 3.01, $p < .0001$) revealed that in Chennai, higher rates of CAS were not associated with STI prevalence, but in Mumbai they were (PR = 2.49, 95% CI: 1.65, 3.76, $p < .0001$). The higher prevalence of bacterial STIs but lower frequency of CAS in Mumbai (versus Chennai), along with the significant interaction of CAS with city on STI rates, suggests that there are either differences in disease burden or differences by city with respect to self-reported assessment of CAS. Regardless, the high prevalence rates of untreated STIs and condomless sex among MSM suggest the need for additional prevention intervention efforts for MSM in urban India.

Keywords

Gay men, sexual behavior, chlamydia infection, gonorrhea, syphilis

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Background

In India, men who have sex with men (MSM) are disproportionally affected by HIV and by sexually transmitted infections (STIs),[1] which cause morbidity and can potentiate HIV spread.[2,3] Accordingly, the HIV sentinel surveillance report issued by India's National AIDS Control Organization (NACO) found that, for 2017, MSM constituted the third largest core group of people living with HIV (PLHIV) in India (with 2.7% prevalence), compared to Hijra/Transgender people (3.1%) and persons who inject drugs (6.3%).[1] Studies from different Indian states have also found high rates of STIs – including genital warts (Delhi) and human papillomavirus (Maharashtra, Tamil Nadu),[4–6] syphilis (Delhi, Maharashtra, Telangana, Tamil Nadu),[7–9] herpes simplex virus-2 (Tamil Nadu),[9] chronic hepatitis B (Tamil Nadu),[9] gonorrhea (Delhi, Maharashtra, Telangana),[6,10] and chlamydia (Maharashtra, Telangana)[10] – among MSM in India. With the second largest population in the world,[11] India has one of the largest concentrations of MSM, and hence studies of prevalence, transmission risk, and associated variables are of high public health significance.

Self-reported HIV risk behavior, even when done via computerized assessment, can be limited by potential social desirability.[12,13] Although HIV and STIs are transmitted by similar risk behaviors (e.g. condomless anal sex [CAS]) among MSM,[14] there are other behaviors that transmit STIs that do not efficiently transmit HIV (e.g. oral sex),[15] and other STIs may be more easily transmitted than HIV, with bacterial STIs being generally more prevalent and having higher incidence rates than HIV.[16]

Given the overall size of India, both in terms of population and geography, as well as cultural differences across states, HIV and STI rates may differ widely across the country. If the background prevalence of STIs in the risk pool is different in different locations, the effects of behavioral interventions on STIs and HIV acquisition may differ, which could affect estimates of the efficacy of prevention interventions. India's NACO provides HIV prevalence estimates by state, for example, and the state of Maharashtra, which includes the city of Mumbai, has higher estimates (4.69%) of HIV among MSM than Tamil Nadu, which houses the city of Chennai (1.02%).[1] The purpose of the present study was twofold. First, we sought to examine whether the prevalence of HIV/STIs and self-reported transmission risk behaviors (CAS) differed among high-risk MSM in two major urban areas in India: Mumbai, and Chennai, with different HIV prevalence rates in MSM (4.7 and 1.0%, respectively, per NACO estimates). These two cities were chosen because they were participating in an efficacy trial for the target population, and are example cities in India representing two different regions, from different states.[17] Second, we sought to examine whether the association of CAS with bacterial STI prevalence differed among high-risk MSM in these two regions.

Methods

All procedures were reviewed and approved by the IRB at Partners HealthCare (Massachusetts General Hospital), Boston, Massachusetts, and the Ethics Committees at the National Institute for Research in Tuberculosis, Chennai, India, and the Humsafar Trust, Mumbai, India.

Participants

Participants were 608 MSM recruited for a psychosocial intervention trial focused on strengthening self-acceptance and reducing HIV risk among MSM in India.[17] MSM-identified peer recruiters with years of recruiting experience from HST in Mumbai (an NGO for MSM and TGS) and Sahodaran (a Chennai-based CBO for MSM and TGW) assisted in recruiting study participants. This was done primarily from the community through visits to the cruising sites which they frequented and some through virtual platforms. This included location-based apps/platforms used by communities for seeking partners and social media pages frequently visited by MSM communities. Data for the present analysis are from the baseline visit only. Inclusion criteria were (1) being MSM, (2) being 18 years old or older, and (3) having evidence for HIV acquisition risk defined by any of the following: (a) anal sex with four or more male partners (with or without condoms), (b) a diagnosis of an STI, (c) history of transactional sex activity, or (d) CAS with a man who was HIV unknown-status or serodiscordant. In India, there are various culturally recognized subgroups of MSM, and for this study, *Kothi* (feminine acting/appearing, predominately receptive partners in anal sex), *Double Decker* (both insertive and receptive in anal sex), or gay (identity was fluid, however, and sometimes changed between screening and baseline; some participants identified themselves as gay which aligns with Double Decker but they ultimately preferred to call themselves gay). Individuals also had to speak English or Tamil (in Chennai) or Hindi (in Mumbai) fluently.[18–20] In addition, those unable or unwilling to provide informed consent, and those with active untreated, unstable, major mental illness (i.e. untreated psychosis or mania) that would interfere with participation were excluded.

Assessments

All self-reported data were collected through the CommCare application[21] and entered directly into tablets connected to a secure server. All measures were interviewer-administered with the exception of sexual behaviors, which was self-administered through audio computer assisted self-interview (ACASI).

Covariates. Demographics included city of recruitment (Chennai, Mumbai), age, MSM subtype (Kothi, Double Decker, gay), education level (no formal, primary, middle, secondary, higher secondary, college, graduate), employment status (full-time, part-time, unemployed), and religion (Hindu, Christian, Muslim, Other/none). Participants also reported on participation in an HIV prevention intervention.

Sexual behavior. Participants completed a 7-item questionnaire that we developed based on our pilot work.[4] The items include number of male partners, number of times they had anal sex with male partners, and condom use with male partners. For the present analysis, we focus on behaviors that would place one at risk for an STI; as such, we calculated and report the number of CAS acts with a male partner in the past month.

HIV and STI testing

Participants underwent standard voluntary counseling and testing for HIV and STIs. Serological testing for HIV was performed using the Retroquic HIV Rapid card test (Qualpro Diagnostics, Goa, India). All the reactive samples were further tested using HIV Tri dot kit (J. Mitra & Co., New Delhi, India) for confirmation. Both the tests used have a reported sensitivity and specificity of 100%. Screening for syphilis was performed using the quantitative serologic test (rapid plasma reagin test) (Arkray Health care Private Ltd, Surat, India), and all reactive samples were retested using the *Treponema pallidum* hemagglutination assay/TPHA (Syphicheck-WB, Qualpro Diagnostics, Goa, India) having a sensitivity of 95.3% and specificity of 93.7% for confirmation of results. To test for chlamydia and gonorrhea, participants provided a small urine sample and a lab staff member/trained clinician took an oropharyngeal sample and a rectal swab in Abbott multi-collect tubes (Abbott Molecular, Illinois, USA). *Chlamydia trachomatis* and *Neisseria gonorrheae* (CT and NG) testing was performed using a nucleic acid amplification test (NAAT): the Abbott Real Time CT/NG Kit (Abbott Molecular, Illinois, USA). The samples were not pooled and the pharyngeal and rectal swabs and urine sample were tested separately. The assay was performed in accordance with the Abbott RealTime CT/NG testing protocol, on the Abbott *m*2000 system, consisting of the *m*2000*sp* instrument for sample preparation and the *m*2000*rt* instrument for amplification and detection. All participants with a diagnosed STI received treatment, and anyone who tested positive for HIV was referred to government HIV/AIDS program clinics where treatment was provided free of charge.

Data analysis

Means (for continuous variables) and proportions (for categorical variables) were calculated for all covariates. T-tests and Chi square tests examined differences in covariates by recruitment city. Proportions were calculated for each STI, for bacterial STIs and HIV overall and stratified by recruitment city. Differences in proportions were examined with Chi square tests. A series of regression models – specifying a Poisson regression with a log link and robust variance – were used to estimate prevalence ratios to examine relative differences in prevalence of STIs: (1) by city alone, (2) accounting for number of CAS acts, and (3) accounting for all covariates. Additional regression models assessed whether the associations between CAS and STIs were modified by recruitment city using interaction terms. To further describe significant interactions, regressions stratified by city were conducted. For ease of interpretation, CAS was standardized so that the prevalence ratio equals the relative difference in the prevalence associated with a one standard deviation increase in number of CAS acts with male partners. Because the self-report sexual behavior questions focused on CAS and not oral sex, we conducted sensitivity analyses excluding oropharyngeal STIs. All analyses were conducted in SPSS 25.

Results

Table 1 presents demographics and psychosocial data overall and by city. Statistically significant covariates were included in adjusted models. The mean age of participants was 26.2 years (SD = 6.3). Forty-five and a half percent identified as Kothi, 33.3% as Double Decker, and 21.2% as gay. Nine and three-tenths percent of participants reported having been tested for an STI in the prior four months, 3.3% reported being diagnosed with an STI, and 23.4% reported symptoms associated with an STI.

Table 2 presents the prevalence of STIs, HIV, and CAS overall and by city. Baseline STIs overall ranged from 9.5% for HIV to 15.5% for syphilis. Nearly one-third (32.7%) of participants had at least one bacterial STI diagnosed at their initial visit. Mean number of self-reported CAS acts in the past month was significantly lower in Mumbai compared to Chennai (mean difference = −11.8, 95% CI = −14.6 to −9.1, $p < .0001$). Conversely,

Table 1. Demographics and psychosocial factors, overall and by city.

	Mean (SD)			
	Total (n = 608)	Chennai (n = 304)	Mumbai (n = 304)	p-value
Age, in years	26.2 (6.3)	27.1 (6.8)	25.5 (5.6)	0.001
Number of male partners	11.9 (46.3)	18.4 (64.5)	5.5 (7.8)	0.001
Number of times CAS with male partners	8.1 (18.3)	14.0 (24.2)	2.2 (3.7)	<0.0001
	%			
MSM subpopulation identity				<0.0001
Kothi	44.5	71.3	17.8	
Double Decker	33.3	27.1	39.5	
Gay	21.2	0.7	41.8	
Other	1.0	1.0	1.0	
Religion				<0.0001
Hindu	72.7	78.6	66.4	
Christian	9.4	6.3	19.7	
Muslim	13.0	14.8	3.9	
Other/Agnostic/Atheist	4.8	0.3	9.9	
Education				<0.0001
Graduate or professional degree	14.1	19.7	8.6	
College degree	24.0	24.0	24.0	
Higher secondary	24.2	14.8	33.6	
Secondary	20.1	20.4	19.7	
Middle	12.5	15.5	9.5	
Primary	3.6	4.3	3.0	
No formal education	1.5	1.3	1.6	
Employment status				<0.0001
Full-time	48.4	36.8	59.9	
Part-time	16.1	25.0	7.2	
Unemployed	28.5	3712	19.7	
Other	7.1	1.0	13.2	
Participation in any HIV prevention interventions, past year				<0.0001
Yes	51.3	8.3	94.4	
No	48.7	91.7	5.6	
HIV positive				0.053
Yes	9.5	7.2	11.8	
No	90.5	92.8	88.2	
STI test, past four months				0.789
Yes	9.3	9.6	9.0	
No	90.7	90.4	91.0	
STI diagnosis, past four months				0.069
Yes	3.3	2.0	4.6	
No	96.7	98.0	95.4	
STI symptoms, past four months				<0.0001
Yes	23.4	31.9	14.8	
No	76.6	68.1	85.2	
HIV test, ever				<0.0001
Yes	64.0	52.0	76.0	
No	36.0	48.0	24.0	

CAS: condomless anal sex, reported for the past month; MSM: men who have sex with men; STI: sexually transmitted infection.

however, prevalence of HIV, all bacterial STIs combined, gonorrhea, and chlamydia were significantly higher in Mumbai compared to Chennai; syphilis did not differ by city (p = .654). We also looked at prevalence by anatomical site. For chlamydia, there was a 2.0% (12 infections) prevalence for urethral, 12.1% (73 infections) prevalence for rectal, and 1.7% prevalence for oral (10 infections). For gonorrhea, there was a 1.0% (6 infections) prevalence for urethral, 7.1% (43 infections) prevalence for rectal, and 7.9% prevalence for oral (48 infections).

Table 3 presents the prevalence ratios for STIs by CAS and city. Notably, after controlling for number of

Table 2. Baseline STI positivity and sexual risk behaviors,[a] overall and by site.

	Mean (SD)				
	Overall N = 608	Mumbai n = 304	Chennai n = 304	Mean difference (95% CI)	p-value
Number of times CAS	8.1 (18.3)	2.2 (3.7)	14.0 (24.2)	−11.8 (−14.6 to −9.1)	<0.0001
	N (Prevalence %, 95% CI)			Prevalence ratio[b] (95% CI)	p-value
CHL	88 (14.7, 11.9–17.5)	54 (18.2, 13.8–22.6)	34 (11.3, 7.7–14.8)	1.62 (1.09–2.41)	.018
GON	73 (12.1, 9.5, 14.7)	48 (16.0, 11.9–20.1)	25 (8.3, 5.2–11.4)	1.93 (1.23–3.05)	.005
SYP	94 (15.5, 12.6, 18.3)	45 (14.8, 10.8–18.8)	49 (16.1, 12.0–20.3)	0.92 (0.63–1.33)	.654
Any BAC[c]	199 (32.7, 29.0, 36.5)	115 (37.8, 32.4–43.3)	84 (27.6, 22.6–32.7)	1.37 (1.09–1.73)	.008
HIV[d]	58 (9.5, 7.2–11.9)	36 (11.8, 8.2–15.5)	22 (7.2, 4.3–10.1)	1.64 (0.99–2.71)	.056

CAS: condomless anal sex; CHL: chlamydia; GON: gonorrhea; STI: sexually transmitted infection; SYP: syphilis.
[a]Self-reported sexual behavior in the past month.
[b]Estimated using Poisson regression, log link, robust variance.
[c]BAC = presence of one or more sexually transmitted bacterial infections
[d]Human Immunodeficiency Virus.

Table 3. Prevalence ratio of STIs by site and condomless anal sex (standardized) with male partners (CAS).

	Models A (no covariates/interaction)		Models B (+ covariates)		Models C (+ interaction)	
	Prevalence ratio[a] (95% CI)	p-value	Prevalence ratio[a] (95% CI)	p-value	Prevalence ratio[a] (95% CI)	p-value
CHL						
Mumbai Site	1.76 (1.16–2.67)	.008	1.33 (0.58–3.03)	.497	1.47 (0.66–3.29)	.344
Std_CAS, times	1.12 (0.98–1.28)	.096	1.09 (0.97–1.23)	.154	1.08 (0.95–1.22)	.230
Mumbai Site* Std_CAS					1.63 (0.92–2.89)	.097
GON						
Mumbai Site	2.18 (1.36–3.50)	.001	3.50 (1.55–7.89)	.003	3.26 (1.42–7.48)	.005
Std_CAS, times	1.16 (1.01–1.33)	.035	1.19 (1.03–1.38)	.019	1.20 (1.03–1.38)	.016
Mumbai Site* Std_CAS					0.73 (0.24–2.29)	.594
SYP						
Mumbai Site	0.91 (0.62–1.34)	.629	0.91 (0.41–2.02)	.821	1.09 (0.51–2.32)	.827
Std_CAS, times	0.98 (0.84–1.15)	.829	1.01 (0.87–1.17)	.952	0.98 (0.82–1.16)	.789
Mumbai Site* Std_CAS					2.26 (0.98–5.20)	.056
Any BAC[b]						
Mumbai Site	1.43 (1.12–1.83)	.004	1.32 (0.81–2.15)	.267	1.54 (0.98–2.44)	.064
Std_CAS, times	1.07 (0.97–1.18)	.210	1.07 (0.98–1.17)	.156	1.04 (0.95–1.15)	.372
Mumbai Site* Std_CAS					2.09 (1.45–3.01)	<.0001
HIV						
Mumbai Site	1.35 (0.78–2.34)	.290	1.65 (0.69–3.94)	.258	1.72 (0.65–4.53)	.276
Std_CAS, times	0.66 (0.37–1.17)	.156	0.66 (0.37–1.15)	.144	0.64 (0.34–1.20)	.168
Mumbai Site* Std_CAS					1.16 (0.29–4.72)	.834

CAS: condomless anal sex; CHL: chlamydia; GON: gonorrhea; STI: sexually transmitted infection; SYP: syphilis.
Covariates include age, sexual identity, religion, education, employment status, past behavioral intervention.
[a]Estimated using Poisson regression, log link, robust variance.
[b]BAC = presence of one or more sexually transmitted bacterial infection.

CAS acts, city differences remained for any bacterial STI, chlamydia, and gonorrhea, but CAS was only associated with prevalence of gonorrhea (PR = 1.16, 95% CI = 1.01–1.33, p = .035) and was borderline associated with prevalence of chlamydia (PR = 1.12, 95% CI = 0.98–1.28, p = .096).

In multivariable regressions adjusting for covariates (Models B in Table 3), prevalence of gonorrhea was associated with living in Mumbai (PR = 3.50, 95% CI = 1.55–7.89, p = .003) and increased number of CAS acts (PR = 1.19, 95% CI = 1.03–1.38, p = .019). Neither city nor CAS acts were associated with

prevalence of chlamydia, syphilis, any bacterial infection combined, or HIV (all p-values > .10).

We examined interactions of the effects of CAS acts and city on STI prevalence (Table 3, Models C). The effects of CAS acts on the prevalence of any bacterial STI were moderated by city, as evidenced by the significant interaction term ($p < 0.0001$). The interaction terms were borderline significant for chlamydia ($p = 0.097$) and syphilis ($p = 0.056$), and not significant for gonorrhea and HIV.

To further explore the interactions, we stratified analyses by city where significant or marginally significant (Table 4). Accordingly, in Mumbai greater CAS acts were significantly associated with being diagnosed with any bacterial STI (PR = 2.49, 95% CI = 1.65–3.76, $p < 0.0001$), chlamydia (PR = 2.09, 95% CI = 1.06–4.13, $p = 0.033$), and syphilis (PR = 2.43, 95% CI = 1.04–5.71, $p < 0.0001$), but in Chennai CAS acts were not associated with STI prevalence (all $p > 0.300$).

Across analyses, the sensitivity analyses excluding oropharyngeal STIs revealed the same pattern of results with respect to statistical significance.

Discussion

In this sample of MSM from two major Indian cities (Mumbai and Chennai), nearly one-third (Table 2) had at least one previously undiagnosed bacterial STI. This is higher than the rates found in other studies with Indian MSM (e.g. Aggarwal et al.[6] and Garg et al.[7]) and substantially higher than the national average.[22] Additionally (Table 1), substantial percentages of participants, particularly in Mumbai, reported having participated in an HIV prevention program. Accordingly, additional efforts to screen for, diagnose, and treat STIs in this population in these settings are urgently needed. Additionally, there may be room for improvement in the potency and effectiveness of existing HIV prevention programs (they may be limited to outreach messaging and condom distribution) that these men report they have participated in.

While Mumbai had higher STI prevalence compared to Chennai, levels of self-reported CAS acts in Mumbai were lower than Chennai (Table 2), and in Chennai, unlike Mumbai, CAS acts were not associated with STI prevalence (Tables 3 and 4). This pattern might reflect a higher disease burden in Mumbai, so that any new partner was more likely to transmit an STI than in Chennai. But, given the sensitivity which still exists around self-reporting of sexual acts, the higher reporting of CAS in Chennai cities could be attributed to the fact that participants in the Mumbai site were recruited directly by a local NGO (Humsafar Trust) and the assessments were done in the same site where MSM could be accessing other services. This could have resulted in the fears around privacy which could have led to more socially desirable responses. In Chennai, recruitment was done through a community-based organization, which referred participants to a research site (NIRT) in a different location, and assessments were done by investigators from the institution where the research was conducted. In this case, there was potentially more opportunity for anonymity.

The current study documented a high prevalence of asymptomatic bacterial STIs in a population of Indian MSM who were either living with HIV at rates greatly exceeding national averages or were at high risk for acquiring HIV (Table 2). National guidelines for STI management in MSM focus on presumptive treatment of symptomatic infection, which would not be sufficient for the MSM in this study, given that the majority of diagnosed infections were extragenital, similar to MSM cohorts in other parts of the world.[16,23,24] These findings suggest that the routine testing of extragenital sites for STIs using NAATs is indicated in order to decrease STI transmission and acquisition in this high risk population. The NACO program for testing and monitoring PLHIV and MSM at risk of HIV includes recommendations for syphilis testing twice a year, but does not address screening for gonorrhea and chlamydia. The high rates of asymptomatic genital and extragenital infection in this population suggest that this policy needs to be reconsidered, given the documented potential of STIs to facilitate

Table 4. Prevalence ratio of STIs by condomless anal sex (standardized) with male partners (CAS), stratified by site.

		Mumbai		Chennai	
		Prevalence ratio[a] (95% CI)	p-value	Prevalence ratio[a] (95% CI)	p-value
CHL	Std_CAS, times	2.09 (1.06–4.13)	0.033	1.03 (0.90–1.18)	.659
SYP	Std_CAS, times	2.43 (1.04–5.71)	.041	1.01 (0.87–1.18)	.890
ANY BAC[b]	Std_CAS, times	2.49 (1.65–3.76)	<0.0001	1.05 (0.95–1.16)	.348

CAS: condomless anal sex; CHL: chlamydia; STI: sexually transmitted infection; SYP: syphilis.
Covariates include age, sexual identity, religion, education, employment status, past behavioral intervention.
[a]Estimated using Poisson regression, log link, robust variance.
[b]BAC = presence of one or more sexually transmitted bacterial infections.

HIV transmission and acquisition. A reframing of HIV prevention programs to a broader concept of promoting sexual health may lead to increasing testing, diagnoses, treatment, and better control of the bacterial STIs and HIV epidemics among Indian MSM.

Lastly, over the past decade the use of antiretroviral pre-exposure prophylaxis (PrEP) has been shown to decrease HIV incidence among at-risk MSM.[25–28] Unfortunately, PrEP uptake has been limited in India to date, with no demonstration project yet underway for Indian MSM, despite their increased HIV risk.[29] Guidance from the WHO and US CDC recommend PrEP for MSM who report CAS and bacterial STIs, so a significant number of the participants in the current study would be appropriate PrEP candidates. Wider STI testing among Indian MSM could help address the Indian HIV epidemic by identifying appropriate candidates for this evidence-based HIV prevention intervention. In India, the HIV prevention program tends to focus extensively on HIV testing as an important tool for HIV control. Our study points to the need for propagating STI testing not only for syphilis but also for other bacterial STIs.

The present paper is limited by its cross-sectional presentation reporting the prevalence of baseline STIs. We do not know how long participants may have harbored these infections, so estimates of incidence need to await the follow-up assessments, which will present a broader picture of STIs over time across the two sites. Additionally, despite using ACASI the concerns of sexual history can still be a challenge with socially desirable responses.[12,13]

Despite these limitations, the results clearly show a high burden of STIs in this MSM study population. Interestingly, results varied across two urban areas – Mumbai and Chennai – where Mumbai had significantly higher numbers of bacterial STIs but lower levels of self-reported condomless sex acts than Chennai. Future investigation and replication would be needed to determine if there is increased disease burden in Mumbai or if there are differences by city with respect to the validity of self-report of sexual behavior. Nonetheless, the high prevalence of untreated STIs in both cities suggests that more prevention intervention efforts for MSM in urban India are needed.

Authors' contribution

Steven A Safren, Matthew Mimiaga, Beena Thomas, Kenneth Mayer, Sunil Menon, and Souymya Swaminathan developed the overall design of the parent grant, which included the data elements utilized here. Safren developed the idea for the specific data analysis project and wrote the first draft of the document, with the input and assistance of Bella Devaleenal, particularly on the introduction and discussion sections, and from Kristen Regenauer. Safren and Mimiaga led the development of the data tool for assessing sexual risk behavior, with input from the other collaborators. Kenneth Mayer, with the input of Bella Devaleenal, Rakesh Thorat, Luke Hanna, Ramesh Karunaianantham developed and led the implementation of the protocols and procedures for STI data collection. Katie Biello oversaw and led the data analyses, with input from Mimiaga, Conall O'Cleirigh, and the team. C Andres Bedoya, Conall O'Cleirigh, Alpana Dange, Shruta Rawat, Vinoth Balu, and Dicky Baruah assisted with the procedures and implementation of all data collection procedures. All authors reviewed and contributed to the manuscript.

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Data availability

The data are not currently in a repository. However, request for de-identified data can be made by contacting the first author (ORCID 0000-0002-0121-0806; ssafren@miami.edu). We anticipate that these data will be made available approximately two years after publication of the primary outcome paper for the trial; however, conditions of use/reuse will be in place with respect to prioritizing research ideas of the study investigator team for secondary data analysis projects, projects already planned with the data for secondary analysis, and relevant institutional data use agreements will need to be in place.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

The study was approved by the Partners (Massachusetts General Hospital), Boston Massachusetts, USA institutional review board (FWA00003136), the Ethics Committee of the Humsafar Trust (FWA00005331), Mumbai India, and the Ethics Committee of the National Institute for Research in Tuberculosis (FWA00025949) Chennai, India.

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ANNEXURE-A9

215

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Sexually transmitted infections and HIV in self reporting men who have sex with men: A two-year study from India

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Summary Homosexuality is not legally and socially accepted in India. Thus, this area of research has largely been ignored by Indian authors, resulting in dearth of knowledge, particularly with respect to sexually transmitted infections (STIs) in this high-risk group.

Over a period of two years (2013–2014), 738 males sought care at skin and venereal diseases clinics, 52 (7.05%, 95% CI = 5.4–9.14%) of who identified themselves as MSM and were enrolled in the study. Diagnosis was made on the basis of clinical presentation and laboratory testing, wherever indicated. Thirty six percent of MSM had only homosexual preferences, while 64% were bisexual. The most common sexually transmitted infection was genital warts (23.08%, 95% CI = 13.58–36.28%). Fourteen patients (26.92%, 95% CI = 16.67–40.35%) were VDRL and TPHA positive (two, five and four with primary syphilis, secondary syphilis and latent syphilis, respectively). These were followed by genital herpes (11.54%, 95% CI = 5.03–23.34%), genital molluscum contagiosum (9.62% 95% CI = 3.75–21.04%), and gonorrhea (5.77%, 95% CI = 1.38–16.25%). Of those tested, 23.08% (95% CI = 13.58–36.28%) of patients were reactive for HIV serology. Thus, MSM is a high-risk group with high prevalence of HIV and other STIs in this group, mandating greater focus, education and counseling.
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Introduction

In India, homosexuality is a topic that everyone is aware of but seldom discusses. Intercourse and marriage between individuals of same sex are not legal in India as per section 377 in the Indian Penal Code. Despite several attempts by LGBT rights activists to decriminalize these relationships, a one and a half century old law has not been reversed; those found guilty are punishable with imprisonment.

Various studies conducted among general male populations and sexually transmitted infection (STI) clinic attendees in different parts of India report a prevalence of same-sex behavior ranging from 6% to 15% [1]. Despite a high incidence of STIs in men who have sex with men (MSM), these individuals hesitate in providing information to the health clinic due to fear of family, society and the law. Even when MSM seek medical advice, many do not wish to disclose their homosexuality status.

Indian studies regarding STIs among MSM are far and few. International studies are numerous; unfortunately, their data are of little relevance in India and other similar countries owing to differences in sexual, cultural and legal practices. Thus, the purpose of this study was to analyze the prevalence of various sexually transmitted infections among Indian MSM and to compare these findings with data from other reports.

Materials and methods

Study setting

The study was carried out at a medical college and tertiary care hospital located in the capital city of India, New Delhi over a period of two years (2013–2014). The consenting male patients who sought care at the Skin and Venereal Diseases outpatient department and reported being involved in sexual relationships with other males were retrospectively enrolled in the study. Sociodemographic data with regards to their sexual orientation, age, marital status, educational status, present occupation, etc. were collected. The identity of the patients was kept confidential. Clinical history and examination details regarding the reason for the visit to the outpatient department were also collected. Patients were managed on the basis of algorithms of the syndromic approach recommended by National AIDS control organization (NACO), India, after carrying out risk assessment [2].

Laboratory tests

The Sexually Transmitted Infections Laboratory at our medical college is the Regional STI Reference, Research and Training Laboratory of Delhi region. Microbiological testing was performed according to the clinical symptoms of the patient as needed. Five milliliters of sera was collected and transported to STI laboratory for serological testing for syphilis. The venereal diseases research laboratory (VDRL) test was carried out using antigen from serologist to the government of India, Kolkata. Specimens reactive by qualitative tests were subsequently subjected to quantitative VDRL test with successive two-fold dilutions of the serum in 0.9% saline. All of the sera reactive in qualitative VDRL test were confirmed for specific anti-treponemal antibodies by the treponema pallidum hemagglutination (TPHA) test. VDRL and TPHA tests were performed according to standard procedures following manufacturer's instructions.

Urethral swabs/discharge were collected from patients complaining of urethral discharge and subjected to gram staining of the prepared smear to look for presence of polymorphonuclear cells and gram negative diplococci. Samples were also inoculated immediately onto modified Thayer Martin medium (MTM) and incubated in 3–7% CO_2 (candle jar) at $36 \pm 1\,^{\circ}C$ for 48 h. The colonies suspected to be *Neisseria gonorrhoeae* were presumptively identified by gram stain, oxidase test and superoxol test.

For the diagnosis of candida balanoposthitis, KOH wet mount was prepared with the secretions present in the glans penis region; visualization of budding yeast cells was considered to be diagnostic. Tzank smear was prepared wherever indicated.

All the patients were also referred to the Integrated Counseling and Testing Center (ICTC) at our medical college for voluntary counseling and testing of the patients' sera for HIV, where the samples were tested strictly in accordance with strategy III of the NACO guidelines [3].

Statistical analysis

The present work was designed as a descriptive and analytical study. The data are presented as percentages and proportions. 95% confidence intervals were calculated wherever required. Comparisons between MSM and heterosexual male groups, as well as between strictly homosexual and bi-sexual males were done using Fisher's exact test, and where indicated, a p value of ≤ 0.05 was considered as a statistically significant difference in proportions.

Table 1 Socio-demographic profile of MSM patients.

	Number (n = 52)	Percentage (95% confidence interval)
Age groups (in years)		
10–19	8	15.38 (7.74–27.79)
20–29	30	57.69 (44.18–70.14)
30–39	11	21.15 (12.08–34.20)
40–49	2	3.85 (0.32–13.72)
≥50	1	1.92 (0–16.15)
Education status		
Uneducated	8	15.38 (7.74–27.79)
Till primary school	6	11.54 (5.03–23.34)
Till higher secondary	27	51.92 (38.69–64.9)
Graduate	9	17.31 (9.15–29.96)
Post-graduate	2	3.85 (0.32–13.72)
Occupation		
Salaried	11	21.15 (12.08–34.20)
Self-employed	14	26.92 (16.67–40.35)
Laborer/daily wage worker	12	23.08 (13.58–36.28)
Student	10	19.23 (10.6–32.09)
Unemployed	2	3.85 (0.32–13.72)
Others	3	5.77 (1.38–16.25)
Marital status		
Married	18	34.62 (23.11–48.24)
Unmarried	34	65.38 (51.76–76.89)
Sexual orientation		
Only homosexual	19	36.54 (24.77–50.16)
Bi-sexual	33	63.46 (49.84–75.23)

Results

Over a period of two years, 738 male patients sought care at the skin and venereal diseases outpatient department; 52 (7.05%, 95% CI = 5.4–9.14%) patients disclosed their homosexuality status and were enrolled in the study. The sociodemographic profile of the patients is shown in Table 1. The age of patients ranged from 16 to 57 years (median = 26 years); more than half of the patients were between 20 and 29 years. Most of the individuals had completed at least a primary school level of education. Only one-third of patients were married to a female partner. Sixty four percent reported having sexual relationships with both males and females, while approximately 36% had never had a physical relationship with females.

The most common STI, as determined by clinical and/or laboratory evaluation, was genital warts, seen in 12 of the 52 patients (Table 2). VDRL test was performed on the sera collected from all 52 patients, of which 14 (26.92%) were reactive. The titers ranged from reactive at 0 dilutions (weakly reactive) to reactive at 32 dilutions. Six sera were strongly reactive by VDRL test (titers ≥ 1:8). The TPHA test was done on all reactive sera, and all were found to be reactive; hence, there were no biological false positive reactions. On the basis of VDRL and TPHA tests and clinical presentation, two patients were diagnosed with primary syphilis, five with secondary syphilis and four with latent syphilis. Three VDRL/TPHA positive patients did not complain of symptoms pertaining to any stage of syphilis; two of them had co-existing genital warts and one had genital herpes.

Six cases were found to have genital herpes and five cases were found to have genital molluscum contagiosum. Based on gram staining and urethral discharge cultures, three cases were identified as gonorrhea. Cases of genital scabies, genital molluscum contagiosum and Candida balanoposthitis were relatively less common (Table 2). There was no statistically significant difference between strictly homosexual and bisexual men, though genital warts (26.3% vs. 21.2%) and molluscum contagiosum (15.8% vs. 6.1%) were slightly more common in homosexual males.

Some of the patients did not have any apparent STI and were diagnosed as having psycho-sexual disorders. Two patients sought care soon after a recent sexual encounter, fearing that they might have become infected with an STI, but were

Table 2 Sexually transmitted infections in MSM based on clinical and laboratory findings.

	Number of STI cases [number of HIV positive patients]	Percentage (95% confidence interval)
Genital warts	12 [3]	23.08 (13.58–36.28)
Herpes genitalis	6 [2]	11.54 (5.03–23.34)
Primary syphilis	2 [0]	3.85 (0.32–13.72)
Secondary syphilis	5 [1]	9.62 (3.75–21.04)
Latent syphilis	4 [2]	7.69 (2.53–18.68)
Genital molluscum contagiosum	5 [1]	9.62 (3.75–21.04)
Gonorrhea	3 [1]	5.77 (1.38–16.25)
Candida *balanoposthitis*	4 [0]	7.69 (2.53–18.68)
Genital scabies	1 [0]	1.92 (0.01–11.07)
Asymptomatic with history of recent sexual contact	2 [0]	3.85 (0.32–13.72)
Psychosexual disorder	3 [0]	5.77 (1.38–16.25)
No final diagnosis	5 [2]	9.62 (3.75–21.04)
Total	52 [12]	100

asymptomatic and tested negative for VDRL and HIV. These individuals were asked to follow up with the department. In five patients, no final diagnosis could be reached. These patients included those who were reported as VDRL reactive from external laboratory, but were non-reactive on repeat testing (VDRL and TPHA) in our laboratory, patients with ''Dhat syndrome'' and patients with non-specific skin rashes.

Sera from 12 of 52 (23.08%, 95% CI = 13.58–36.28) patients were reactive for HIV serology. Among these, three patients also had genital warts, three had syphilis, two had herpes genitalis, one each had genital molluscum contagiosum and gonorrhea. Two patients did not have any STI (Table 2). HIV reactivity was more common in strict MSM (31.58%) compared to bisexual men (18.18%). However, the difference was not statistically significant.

Discussion

In India, three groups of populations are highly stigmatized and prefer to remain invisible to the world: intravenous drug users (IDU); female and male sex workers; and men who have sex with men (MSM). Their health-care seeking behavior is known to be extremely poor. As estimated by an expert group in 2006, there are approximately 830,000–1,250,000 female sex workers, 2,350,000 MSM, 235,000 male sex workers, 96,000–189,000 male IDU, and 10,000–33,000 female IDU in India, making the MSM the largest group among them [4].

In India, MSM largely have been classified as *kothis*, who are the receptive male partners in oral and anal sexual intercourse and present typically feminine characteristics; *panthis*, who present as typically masculine and play the role of insertive male partner in oral and anal sex; and *double deckers*, who may be both receptive and insertive partners [5]. In the present article, the term 'MSM' was used to denote the males who reported being in sexual relationships of any of the above forms with other males on one or more occasion. It also included bisexual men, who have had sexual relationships with both men and women.

Most MSM individuals belonged to a sexually active age group, were well educated and employed. None of them reported being a male sex worker. Two-thirds of the patients reported being in bisexual relationships, serving as an important bridge population between men and women. One-third were married to a female counterpart; this is common in India as homosexuality is considered a social taboo and to have intercourse with a female counterpart or get married is a part of one's ''social duty'' [6].

The prevalence of STIs among MSM is rising globally [7]. The factors responsible may include high frequency of anal sex, infrequent use of condoms while performing anal intercourse, multiple partners and unwillingness to go for routine health checkups. Loss of fear regarding HIV transmission as a result of increased manageability of the infection, availability of internet as an efficient way to find sex partners, increasing use of erectile dysfunction agents, and use of disinhibiting substances that increase risk-taking behavior have been reported in international studies; however, these may have limited applicability in India [8,9].

Thorough literature searches using the various indexing websites (Pubmed Central, NCBI database, Google scholar, etc.) as well as independent journal websites led us to conclude that despite the widespread and exhaustive availability of data on the subject of STI prevalence from abroad, Indian authors have missed this vital area. As a result, only three Indian studies were found to be similar to ours and match our criteria [10–12]. Moreover, what studies are available differ greatly in their methodology, definitions and results, partly due to different study protocols, methodologies, available diagnostic facilities and variability in population characteristics. This has resulted in data that are difficult to comprehend and generalize. Thus, an attempt was made to briefly review these in order to come to a conclusion.

The data presented in various Indian studies pertaining to STIs in MSM are compiled in Table 3. One may be tempted to conclude that HSV is the most common STI among MSM in India. However, evaluation in most studies was based only on IgG serology, which may not indicate an active or recent infection [10,11]. This was followed by syphilis, which was diagnosed both serologically as well as clinically. Urethral gonorrhea, urethral chlamydia, trachomatis infection, and genital warts were other common infections seen in this segment of the population.

In our study, diagnosis was clinical and supported by laboratory investigations wherever required. Genital warts (23.08%) was the most common disease, followed by syphilis (21.15%). An almost equal prevalence of condyloma acuminata (genital warts) and syphilis has been reported by Garg et al. from Delhi. This is unlike studies from other parts of India, where these diseases were reported in fewer MSM [10–12]. Herpes genitalis was the next most common STI, being diagnosed on the basis of clinical evaluation and supported by Tzank smear if required. HSV 1/2 serology was not conducted unlike many other studies [10,11]. Genital Molluscum, gonorrhea, candida balanoposthitis and genital scabies were less common, as has also been noted by Garg et al. [12]. A few patients voluntarily sought advice following homosexual intercourse fearing that they might have contracted an STI; however, these individuals were found to be uninfected. Some patients were diagnosed with "Dhat syndrome"; characterized by vague somatic symptoms of fatigue, weakness, anxiety, loss of appetite and guilt associated with the notion of seminal loss through nocturnal emissions, urine and masturbation though there is no evidence of loss of semen. "Dhat syndrome" is characteristically seen in Indian subcontinent, though similar

Table 3 Indian studies on sexually transmitted infections in MSM.

Author	Study period	Place of study	Herpes genitalis	Syphilis	Genital warts	HIV	Chlamydia trachomatis/NG urethritis	Gonorrhea	Genital molluscum contagiosum	Genital scabies	Candida balanoposthitis	Chancroid
		Andhra Pradesh	61.5[b]	13.0[c]	–	20.9	1.6	0.6	–	–	–	–
Brahmam et al. [10]	2006–2007	Maharashtra	43.8[b]	8.4[c]	–	11.3	4.0	0.3	–		–	–
		Tamil Nadu	32.2[b]	7.5[c]	–	7.5	0.6	0.1	–		–	–
		Karnataka	36.7[b]	17.3[c]	–	17.3	1.6	0.6	–		–	–
Setia et al. [11]	2006[a]	Mumbai	40[b]	17[c]	2.5	17		5.8	1.7	1.7		
Garg et al. [12]	2004–2010	Delhi	19	27	26	4	6.7	12	–	4	4	2.7

[a] Year of publication of study.
[b] HSV-2 serology.
[c] Syphilis serology (treponemal/non-treponemal tests).

presentations are common in other parts of the world [13].

International studies have reported slightly different profiles of STIs in MSM. A study from Vietnam reported the prevalence of HIV, syphilis, gonorrhea, chlamydia, and gonorrhea/chlamydia to be 6.3%, 1.3%, 1.8%, 3.2%, and 4.7%, respectively [14]. Meanwhile, in a community based study in Honk Kong, Wong et al. found that the prevalence of HIV, gonorrhea and chlamydia was found to be 3.6%, 0.2% and 4.7%, respectively [15]. The STD Surveillance Network (SSuN) in the USA monitors the trends in prevalence of STDs among MSM visiting STD clinics; it has reported the median gonorrhea and chlamydia prevalence during 2013 to be 16.9% and 15.2%, respectively [16]. These differences in prevalence of STI and HIV infection can be explained due to differences in study methods as well as in cultural and sexual practices.

The importance of addressing STIs and HIV in MSM has recently been realized in India, which has led the National AIDS Control Organization (NACO) India to include MSM as a high-risk group in the National Behavioral Surveillance Survey [17]. Studies from India suggest great variation in HIV prevalence in the Indian population based upon geographical region and study methodology [10,18]. An Indian study conducted in four states reported that the prevalence of HIV among self-identified MSM was 20.9% in Andhra Pradesh, 17.3% in Karnataka, 11.3% in Maharashtra and 7.5% in Tamil Nadu [10]. Annual HIV surveillance in India from 2008 to 2009 has reported HIV prevalence to be 6.9% among MSM; approximately 35% of the districts and 28 sites in 10 of the 21 states had an HIV prevalence among MSM of over 5% [19]. Another study concluded that overall HIV prevalence among MSM has decreased at the national level, from 8.5% in 2003 to 4.43% in 2010–2011 [1].

Prevalence of HIV infection has been reported to be much higher in MSM than in heterosexual males. Vivian et al., from South India reported an odds ratio of 8.57 when comparing HIV prevalence in MSM versus heterosexual males [18]. NACP, NACO has also found HIV prevalence among MSM to be 20 times greater than in the general population [4]. In our study, prevalence of HIV in the self-identified MSM was 23.07%, while in non-MSM male patients presenting to STI clinic, it was only 6.39% ($p = 0.0002$), thus putting MSM at higher risk. This may be due to obvious behavioral differences such as the practice of high-risk anal sex, presence of genital ulcers and several other host factors. As has been shown previously, the presence of STI is positively associated with HIV infection in MSM due to variety of reasons [11]. In our study, we found higher HIV prevalence in men who did not have any female partners; this is similar to a Brazilian study [20], but is in contrast to another Indian study by Saha et al. [21].

Our study had a few limitations. This study was not community based, it represents the self-reporting MSM population who had symptoms or concerns pertaining to STIs. Thus, the findings may not be representative of the entire MSM population, though it does give a fair amount of information regarding this group. In addition, despite probing, MSM often do not wish to disclose their homosexuality status. Therefore, it is possible that few men who claimed to be heterosexual and did not reveal their statuses may have been missed.

Conclusion

MSM is a high-risk group, which has remained neglected for a long time in India, resulting in unawareness regarding the health related risks involved. High incidence of STIs and HIV in this group mandates greater focus, education and counseling to urge individuals to avoid high risk activities and seek health advice when needed.

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Competing interest

None declared.

Ethical approval

Not required.

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222

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Research Article

Prevalence and Assessment of Clinical Management of Sexually Transmitted Infections among Female Sex Workers in Two Cities of India

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Objective. Control of sexually transmitted infections (STIs) among female sex workers (FSWs) is an important strategy to reduce HIV transmission. A study was conducted to determine the prevalence and assess the current clinical management of STIs in India. *Methods.* FSWs attending three clinics for regular checkups or symptoms were screened for study eligibility. A behavioral questionnaire was administered, clinical examination performed, and laboratory samples collected. *Results.* 417 study participants reported a mean number of 4.9 (SD 3.5) commercial clients in the last week. 14.6% reported anal sex in the last three months. Consistent condom use with commercial and regular partners was 70.1% and 17.5%, respectively. The prevalence of gonorrhea was 14.1%, chlamydia 16.1%, and trichomoniasis 31.1% with a third of all infections being asymptomatic. Syphilis seropositivity was 10.1%. *Conclusions.* At study sites, presumptive treatment for gonorrhea, chlamydia, and syphilis screening should continue. Presumptive treatment for trichomoniasis should be considered. Consistent condom use and partner treatment need to be reemphasized.

1. Introduction

Globally, sexually transmitted infection (STI) rates are the highest among population subgroups such as sex workers with high rates of partner change and unprotected sex [1–4]. The presence of an STI increases the risk of acquisition and transmission of HIV [5, 6]. Integrated services for sex workers such as peer education, empowerment, condom promotion, and effective treatment for STIs along with structural interventions have demonstrated reductions in STI and HIV prevalence [7–9]. Asymptomatic STIs, more common in females, are usually managed through regular screening and presumptive treatment [10]. Various clinical strategies including one-time and periodic presumptive treatment used in different countries have been evaluated [11] which concluded that presumptive treatment should be included within a package of comprehensive STI services for sex workers. Cost-effectiveness studies among female sex workers (FSWs) in Madagascar [12] and Bangladesh [13] have reiterated the importance and utility of syphilis screening and the presumptive treatment for genital tract infections.

Several STI prevalence studies using multiple diagnostic methods in community and clinic-based settings among FSWs in India from 2000 to 2009 have shown widely varying rates across different parts of the country. The prevalence of gonorrhea and chlamydia ranged from 0 to 19.1% [14, 15] and from 0.9 to 22.6% [16], respectively, while prevalence

of syphilis and trichomoniasis was in the range of 1.2–51% [16, 17] and 2–54.1% [14, 18], respectively. HIV prevalence also ranged from 2.2 to 54% [16, 19] at different locations.

Avahan, the India AIDS initiative of the Bill & Melinda Gates Foundation has been providing HIV prevention services since 2004 to over 200,000 FSWs in 83 districts (of a total of 130 districts) in six high-HIV-prevalence states of India [20]. Avahan works either alongside government or donor-supported nongovernmental organizations (NGOs) or as the sole service provider in a district. The main components of the intervention are peer-led outreach education, condom promotion and distribution, STI clinical services, community empowerment, and structural interventions. The *Clinic Operational Guidelines and Standards* (COGS) [21] developed for Avahan clinics describe the essential STI service package for treating the beneficiaries. The package comprises of syndromic management of symptomatic infections as per Indian national guidelines, presumptive treatment for gonorrhea and chlamydia at the first clinic visit which is repeated if the individual has not attended the clinic for an STI checkup for six months, quarterly clinical STI checkups, and biannual syphilis screening. Figure 1 shows the Avahan algorithm for clinical management of STIs among FSWs. The STI services were designed at the outset in 2005 based on limited STI prevalence studies among FSWs in India and relevant experience from other countries and modified slightly based on survey data in 2006 [16]. The National STI program adopted the Avahan guidelines for STI control among FSWs in 2007 [22].

The integrated behavioral and biological assessments (IBBAs) are periodic cross-sectional surveys to measure the outcome and impact of Avahan interventions on district-wise community-based samples. Two rounds of IBBAs have been conducted, the first from 2005 through 2007 (two years after the start of Avahan) and the second round concluded recently. The first round in 2005–2007 (IBBA-1) [16], conducted in 29 districts among 25,162 respondents, showed a low prevalence of gonorrhea and chlamydia in most districts. However, some FSWs sites in the cities of Hyderabad and Mumbai had a higher prevalence of cervical infections. A study was conducted at FSW clinics in these cities to determine the prevalence of STIs and assess the current clinical strategies for STI management among clinic attendees.

2. Materials and Methods

From October 2008 to May 2009, 417 consecutive, eligible, and consenting clinic attendees were recruited from three dedicated FSW clinics in two cities of India (Hyderabad and Mumbai). The support for the outreach and clinic services varied across sites.

The criteria for site selection were the following:

(a) known high prevalence of gonorrhea and chlamydia based on results from IBBA-1,

(b) providing clinical services to large numbers of stable (not highly mobile) FSWs as determined from the clinic records,

(c) operational feasibility for conducting the study defined as proximity to a local laboratory with facilities for conducting required tests and storage of specimens with facilities for transporting specimens to the tertiary laboratory at the National AIDS Research Institute (NARI), Pune, India.

The eligibility criteria for participants were based on rates of partner change (commercial sex at least twice in the last week and/or eight times in the last month) and age between 18 and 40 years. Additionally, those pregnant or under the influence of drugs or alcohol were excluded from the study.

2.1. Study Procedures. At workshops conducted at each site before the initiation of data collection, outreach workers and peer educators of the NGO were oriented about the study. During field visits, they created awareness about the study and encouraged eligible individuals to participate. All FSWs attending the clinic for any reason (STI symptoms, STI checkups, or other reasons) were screened for eligibility criteria. Written or witnessed verbal informed consent was obtained from the individuals found eligible. Trained female investigators from a research agency administered a behavioral questionnaire pertaining to demographics, sexual behavior, condom use, treatment seeking, and past exposure to HIV prevention interventions.

A detailed clinical history was elicited and clinical examination of the anogenital area including speculum and bimanual examination was carried out by the clinic physician who had been trained on the study protocols. The physicians were trained to elicit signs of cervical infection (cervical discharge, friability, or ectopy) and pelvic inflammatory disease (cervical motion or adnexal tenderness). Findings were recorded in a clinical assessment form. Vaginal swabs for laboratory investigation were collected from all participants during the clinical examination. If endocervical discharge or genital ulcers were detected, endocervical and ulcer swabs were obtained.

2.2. Laboratory Investigations. Saline and potassium hydroxide (KOH) mounts of the vaginal swabs were microscopically examined at the site for *Trichomonas vaginalis* (TV) and *Candida spp.*, respectively. Gram-stained slides of vaginal swabs were scored by Nugent's criteria for bacterial vaginosis (BV), while Gram-stained slides of endocervical swabs were examined for Gram-negative intracellular diplococci and pus cells at the local laboratory. At the tertiary laboratory, infections with *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) were detected in the vaginal swab samples using transcription-mediated amplification (Gen-Probe APTIMA Combo-2 Assay, Gen-Probe Inc, San Diego, Calif, USA). Vaginal swabs were tested by the nucleic acid amplification technique using polymerase chain reaction method published by Van Der Pol et al. for TV [23].

Sera from all participants were screened for syphilis by rapid plasma reagin (RPR, Span Diagnostics Ltd, India), and confirmation of all RPR-reactive sera was done by *Treponema pallidum* hemagglutination assay (TPHA) using Syphagen TPHA (Biokit, Barcelona, Spain). *Herpes simplex virus* type

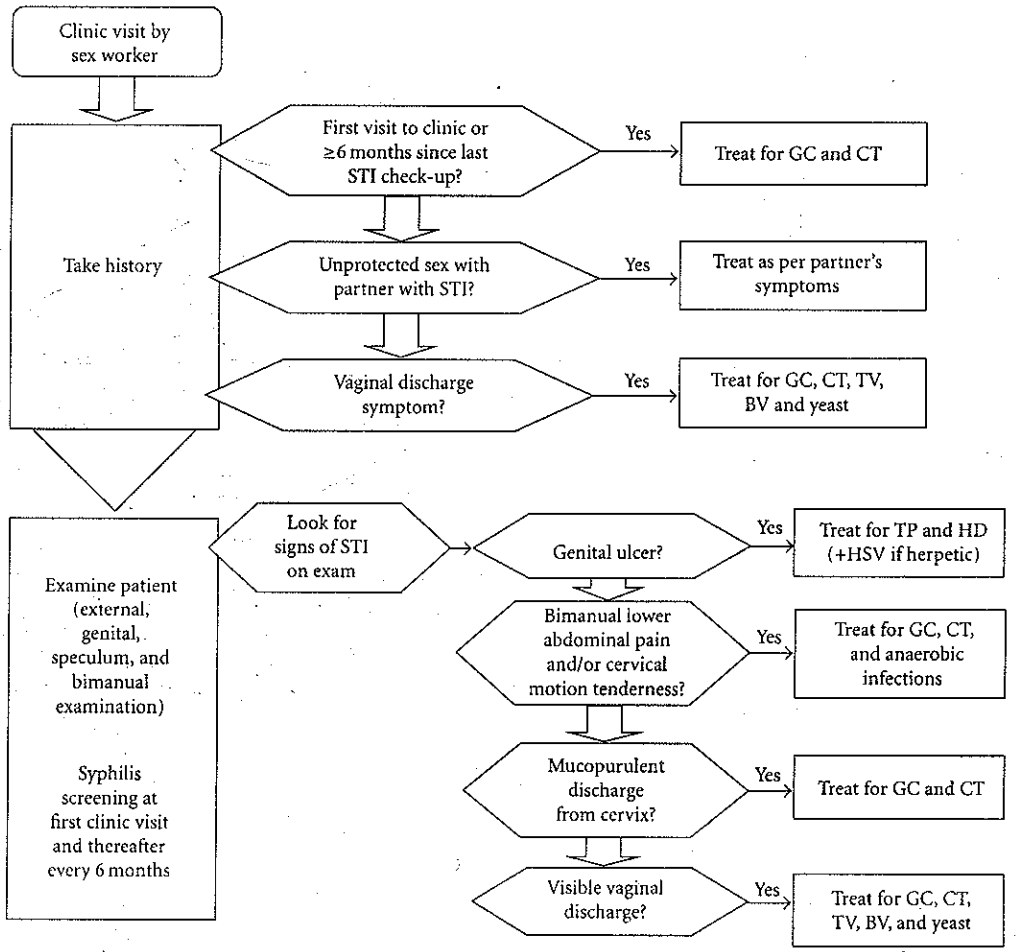

FIGURE 1: Flowchart for female sex worker visit.

2 (HSV-2) IgG ELISA was also performed on all serum samples using EIA-Herpeselect-2 IgG kit (Focus Diagnostics Inc, Cypress, Calif, USA).

Genital ulcer swabs were tested for *Treponema pallidum* (TP), *Haemophilus ducreyi* (HD), and HSV by multiplex PCR using the method described by Orle et al. [24].

2.3. Ethical Approval. The study was approved by the ethics committee of NARI, Pune, India and the Protection of Human Subjects Committee of FHI, NC, USA.

2.4. Statistical Analysis. The questionnaire and clinical data of participants were entered into CSPro 3.3 (US Bureau of Census, USA), and univariate and bivariate analyses were performed using SPSS version 17.0 (SPSS Inc, Chicago, Ill, USA). Chi-square tests were used for determining the behavioral and biological correlates of laboratory-confirmed STIs. The performance of the STI flowcharts was done by calculating the sensitivity, specificity, positive, and negative predictive value of the syndromic diagnosis compared to the etiological diagnosis obtained from gold standard laboratory tests for the respective pathogen.

3. Results

A total of 517 individuals were approached at the clinics for study participation, of them 468 were found to be eligible. 455 individuals gave informed consent, and 417 individuals completed all study procedures.

3.1. Sociodemographic Profile. The median age of the participants was 30 years, and 80% were unable to read or write. Most of them (96%) had been or were currently married with 70% currently having regular partner/s. Most of the FSWs

Table 1: STI prevalence.

Sample	Test	Pathogen	No. Tested	No. of positives with symptoms (%)	No. of positives without symptoms (%)	No. of positives (total)	Prevalence % (95% CI)
Vaginal swab	Gen-Probe APTIMA Combo II	*Neisseria gonorrhoeae* (GC)	417	39 (66.1)	20 (33.9)	59	14.1 (10.8–17.5)
		Chlamydia trachomatis (CT)	417	46 (78.7)	21 (31.3)	67	16.1 (12.5–19.6)
		GC and/or CT	417	74 (67.9)	35 (32.1)	109	26.1 (21.9–30.4)
Vaginal swab	Gram stain Nugent's criteria	Bacterial vaginosis	396	182 (64.8)	99 (35.2)	281	71.0 (66.5–75.5)
	PCR	*Trichomonas vaginalis*	399	80 (64.5)	44 (35.5)	124	31.1 (26.5–35.6)
	KOH mount	*Candida spp.*	402	62 (72.9)	23 (27.1)	85	21.1 (17.3–25.5)
Ulcer swab	mPCR	*Treponema pallidum*	12			6	
		Haemophilus ducreyi	12			0	
		Herpes Simplex Virus (HSV)	12			1	
Serum	RPR + TPHA	Syphilis serology	416			42	10.1 (7.4–13.4)
		High-titer syphilis (≥1 : 8)	416			24	5.8 (3.7–8.5)
	IgG serology	HSV-2	400			307	76.8 (72.3–80.8)

were street-based (70%) or home-based (21%). The median duration of sex work was three years, and 60% said that they had an additional source of income.

3.2. Risk Behavior. The mean numbers of commercial clients on the last working day and last week were 1.7 and 4.9 (Standard Deviations: 0.9 and 3.5), respectively. While 82.7% said that they had used condoms at their last commercial sexual encounter, 70.1% claimed to be consistently using condoms with commercial partners. Most participants (70.4%) said that they had one or more (mean 1.3, SD 0.7) regular, noncommercial partner/s. Reported condom use with regular partner/s was low, with 29% reporting using a condom at last sex and only 17.5% reporting consistent condom use. A small (14.6%) but not insignificant number of participants reported anal sex in the last three months, and condom use at the last anal sex was 75.4%.

The majority (77.7%) of participants reported an STI or reproductive tract infection (RTI) symptom in the last six months, of whom about two-thirds sought treatment from a trained provider. When asked about the reason for the current clinic visit, 54.5% said that they had been requested by the outreach staff; 28% cited STI/RTI-related complaints, 13% had come for an STI checkup while 4% stated non-STI/RTI symptoms.

3.3. Clinical Findings. The majority (74.6%) of participants had clinical symptoms and/or signs of STIs, with 311 of a total of 417 participants being syndromically diagnosed with an STI. The most common syndromes were vaginal discharge (78.5%) and lower abdominal pain (18.7%).Only 12 participants had genital ulcer disease syndrome.

3.4. Laboratory Test Results. Table 1 shows the prevalence of STIs among the study participants. A total of 109 participants (26.1%) had gonorrhea and/or chlamydia; of these 68% presented with symptoms of vaginal discharge and/or lower abdominal pain, while the rest were asymptomatic. Of those with laboratory-confirmed GC/CT, about half (45%) had classical signs such as cervical discharge or friability or ectopy, cervical motion, or adnexal tenderness. The significant clinical correlates associated with GC/CT infection were the presence of abnormal vaginal discharge on speculum examination ($P = .009$) and cervical friability ($P = .013$). More than half of the GC/CT infections were among those relatively new to sex work (<2 years) while chlamydial infection was significantly associated with attending the clinic for the first time ($P = .023$). There was no significant difference in prevalence of STIs (GC, CT, TV, syphilis, and HSV-2 serology) between street-based and home-based sex workers. Of the individuals with laboratory-confirmed trichomoniasis and bacterial vaginosis, 36% and 35%, respectively, did not complain of vaginal discharge.

The performance of the flowcharts for vaginal discharge syndrome against gold standard laboratory tests is shown in Table 2. Sensitivity values for GC and CT were reasonably high while the positive predictive value (PPV) increased

Table 2: Performance of FSWs' vaginal discharge flowchart against gold standard laboratory tests.

Pathogen	No. of infected based on laboratory tests	No. of correctly diagnosed by flowchart	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Neisseria gonorrhoeae	59	40	67.8	43.0	16.4	89.0
Chlamydia trachomatis	67	46	68.7	43.4	18.9	87.9
Cervical infections (GC/CT)	109	76	69.7	45.5	31.2	80.9
Bacterial vaginosis	281	168	59.8	35.7	69.4	26.6
Trichomonas vaginalis	124	78	62.9	43.6	33.5	72.3
Candida spp.	85	62	72.9	42.6	25.4	85.4
Vaginal infections (BV/TV/Can)	308	188	61.0	41.9	81.4	20.5

when the flowchart was used for detection of cervical infections due to GC and/or CT.

Table 3 shows the incremental effect of diagnosis of cervical infections by history alone, by history and clinical examination including speculum findings, and by history, clinical examination, and simple onsite laboratory tests. The addition of speculum examination findings significantly improved the sensitivity.

Of the 12 participants who had genital ulcers, multiplex PCR of ulcer swabs showed TP in six, and one had HSV. Of the six individuals with TP, only one had a positive syphilis serology (RPR titer 1 : 2, TPHA-positive).

4. Discussion

The clinic-based study made attempts to recruit participants from the general population of sex workers by awareness-building through the outreach staff. The three clinics selected provide services for regular checkups and general health complaints in addition to STI symptoms. However, a majority of the study participants had STI/RTI-related symptoms and signs. One in every four sex workers attending STI clinic services had laboratory-confirmed cervical infections; additionally, there was a high prevalence of vaginal infections including BV and trichomoniasis. There was no variability in STI prevalence between street-based and home-based sex workers. Presumptive treatment for GC and CT is justified at the study sites given the high prevalence (26.1%) of cervical infections of which a third were asymptomatic. Presumptive treatment with metronidazole for TV, as recommended in other studies [25] should also be considered in this group given the high prevalence (31.1%) with a third of infections being asymptomatic.

One in every four participants who presented complaining of vaginal discharge had laboratory-confirmed cervical infections. Our study reconfirms that FSWs (all of whom will have a positive risk assessment) with vaginal discharge syndrome should be treated for both cervical and vaginal infections. Additionally, speculum examination detected signs of cervical infection such as abnormal vaginal discharge and cervical friability even in the absence of complaints of vaginal discharge. The clinical diagnosis shows markedly increased sensitivity for predicting cervical infections when speculum examination is added to history-taking. All clinics providing STI services to FSWs should have facilities for speculum examination to improve the diagnosis of gonorrhea and chlamydia.

The prevalence of latent syphilis (RPR of any titer confirmed with TPHA) was 10.1% while high-titer syphilis (RPR titer $\geq 1:8$) was 5.8%. The high prevalence of latent syphilis indicates the necessity of providing periodic syphilis screening and appropriate treatment when indicated. Over three-fourths of FSWs were found having anti-HSV-2 IgG antibody. However, only 12 participants were clinically diagnosed with genital ulcer disease (GUD). The ulcer swab showed that the etiology of GUD was due to syphilis in most cases, unlike an earlier study from India which showed HSV and chancroid as the leading causes [26].

In addition to the clinical interventions, health education and counseling sessions at the clinics need to reemphasize risk reduction measures including consistent condom use. Since reported condom use with regular partners was very low, renewed efforts should be made to treat the regular partners of FSWs with STIs. Partner treatment strategies should be customized for the local situation. Health care providers need to ask about anal sex and provide appropriate management.

Reported condom use and STI prevalence in our clinic-based study were compared with the data from IBBA-1 [16] conducted among district-wise community-based samples (using time-location or respondent-driven sampling) of FSWs in 23 districts of the four southern states in 2005–2007. The IBBA showed that self-reported consistent condom use with occasional clients ranged from 36% (Chittoor, Andhra Pradesh, India) to 93% (Kolhapur, Maharashtra, India) and with regular nonpaying partners from 1% (Chittoor) to 58% (brothel-based FSWs, Thane, Maharashtra, India). Consistent condom use with occasional clients and regular nonpaying partners in Hyderabad was 56% and 4%, in Mumbai 73% and 12%, respectively, as reported in the IBBA. In our study, consistent condom use appears to be slightly higher at 70% and 17.5% with commercial and regular partners, respectively.

Table 3: Diagnosis of cervical infections.

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
History of vaginal discharge	67.9	36.9	27.2	76.8
History + speculum-abnormal vaginal discharge, cervical discharge/friability/ectopy, and cervical motion/adnexal tenderness	83.5	21.4	27.3	78.6
History + speculum + simple laboratory tests: Presence of Gram −ve intracellular diplococci, >10 pus cells per HPF in endocervical discharge	85.3	18.8	27.1	78.4

The IBBA-1 reported overall low gonorrhea prevalence (<5%) from 20 districts while chlamydia prevalence was less than 5% in 15 districts of a total of 23 districts. The prevalence of gonorrhea ranged from 0.2% (Prakasam, Andhra Pradesh, India) to 9.3% (brothel-based FSWs, Mumbai, Maharashtra, India) while chlamydia prevalence ranged from 0.9% (Madurai, Tamil Nadu, India) to 14.2% (street-based FSWs, Thane, Maharashtra, India). In Hyderabad, prevalence of gonorrhea and chlamydia was 6.4% and 6.5%, respectively, while among brothel-based Mumbai FSWs prevalence was 9.3% and 8.5%, respectively as reported in the IBBA-1. The IBBA Round 2 (2009-2010) results have shown a declining trend of gonorrhea and chlamydia in most districts [27]. As mentioned earlier, the sites for our study were selected based on the high prevalence of gonorrhea and chlamydia shown in the IBBA-1. However, our study showed a higher prevalence of gonorrhea and chlamydia probably owing to being a clinic-based sample as compared to the community-based sample in the IBBA. The data illustrate the heterogeneity of India, both in terms of STI prevalence and response, and the challenges of making generalized recommendations for STI control in such a heterogeneous, large country based on findings from two cities.

Syphilis prevalence in the IBBA-1 ranged from 4.7% (street-based FSWs, Thane, Maharashtra, India) to 51% (Yavatmal, Maharashtra, India), and syphilis prevalence among Hyderabad and brothel-based Mumbai FSWs was 17.4% and 13%, respectively. Syphilis prevalence in our study was lower and may be the result of the intensified efforts by Avahan-implementing agencies for universal syphilis screening (including introduction of rapid, point-of-care syphilis tests) and appropriate treatment. The declining syphilis trends have been confirmed in IBBA-2 [27].

Studies from certain sites in medium HIV prevalence states in India have also shown a high prevalence of STIs among FSWs. A study in the year 2000 from a red-light area in Surat, Gujarat [28], India showed prevalence of syphilis 22.7%, trichomoniasis 14.4%, gonorrhea 16.9%, and chlamydia 8.5%. The study also found poor performance of the STI syndrome algorithms against laboratory diagnosis of STIs and recommended exploring additional strategies including presumptive treatment for STI control among FSWs. 'A more recent study from Goa, India by Shahmanesh et al. [29] reported prevalence of trichomoniasis 9.4%, gonorrhea 8.9%, chlamydia 7.3%, and positive-HSV-2 serology 57.2%.

Our study results reveal a fair proportion of asymptomatic cervical infections and minimal correlation with known behavioral or biological factors. Several studies [30–33] have been conducted among sex workers to generate and test algorithms for diagnosing cervical infections through associations with sociodemographic, behavioral, clinical, and biological factors. These studies have also found limited correlations with factors such as duration of sex work, number of commercial clients, classical signs of cervical infections, training and experience of clinicians and onsite laboratory tests (e.g., Gram stain). The general recommendations were to initiate or continue periodic presumptive treatment and the need for rapid, reliable diagnostics for onsite use.

A technical consultation on presumptive treatment for STIs in 2005 [11] conducted by the World Health Organization, London School of Hygiene and Tropical Medicine, and the Population Council recommended that presumptive treatment should be seen as a way of quickly reducing STI prevalence while other preventive and curative services are being established. In the Avahan program, a package of STI clinical services to address both symptomatic and asymptomatic infections was offered, and overall efforts are ongoing to increase accessibility to STI services by promotion through outreach and provision of services at suitable locations and timings. Routine monitoring data shows that of the FSWs ever contacted through outreach services by December 2008, 86% had visited the project STI clinics at least once while about 25% were availing clinical services each month [34].

This study was a clinic-based study conducted at known high STI prevalence sites in urban areas; hence, the STI prevalence cannot be generalized to other sex work sites in India. The study is not representative of all Avahan or other FSW sites run by the government program. We used clinic-based sampling supported by awareness-building about the study by outreach workers. While we used a "take-all" strategy for all sex worker clinic attendees who met the eligibility criteria, most of the study participants (74.6%) were clinically diagnosed with at least one STI. However, the high prevalence of curable bacterial STIs and RTIs in the study population is a cause for concern. In addition to STIs, earlier studies from India [35] and elsewhere [36] have shown that the presence of an RTI such as BV is also significantly associated with acquisition of HIV infection. The study results indicate the need for national-level periodic STI surveillance to identify the changing patterns and etiologies and intensified efforts for STI control at high prevalence sites for effective HIV prevention.

5. Conclusions

At the study sites, presumptive treatment for gonorrhea, chlamydia, and syphilis screening is justified. Presumptive treatment for trichomoniasis should be considered. FSWs with vaginal discharge syndrome should be treated for both cervical and vaginal infections. All clinics providing STI services for sex workers should have facilities for speculum examination to improve the diagnosis of cervical infections. Consistent condom use and partner treatment need to be re-emphasized. The epidemiological diversity in India indicates the need for periodic surveillance to identify changing patterns and etiologies and intensified efforts for STI control at high prevalence sites.

Acknowledgment

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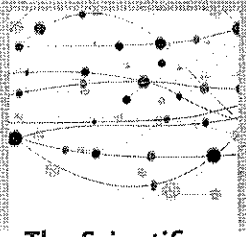
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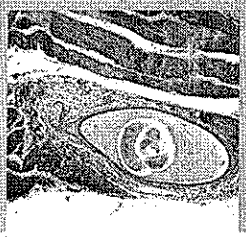
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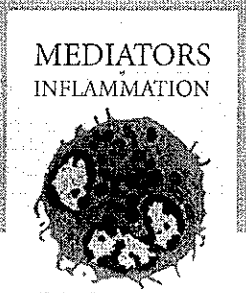

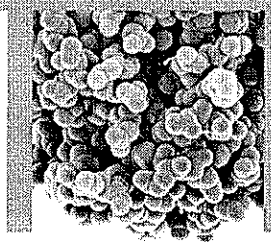
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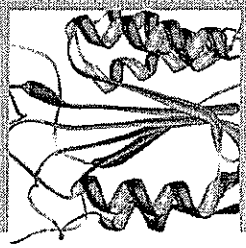
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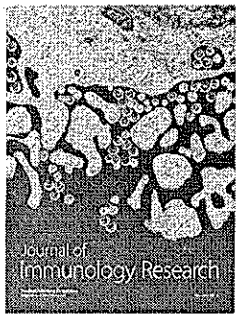
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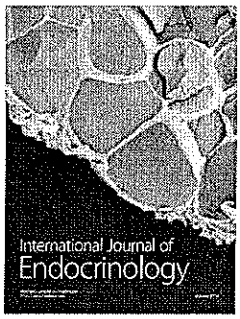
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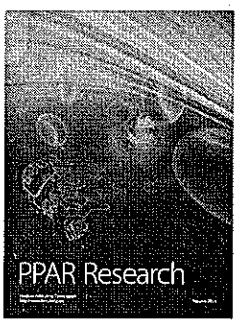
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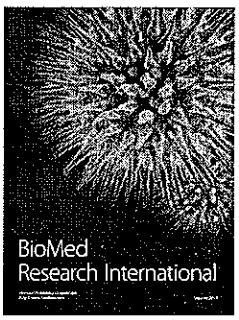
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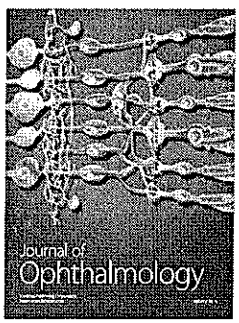
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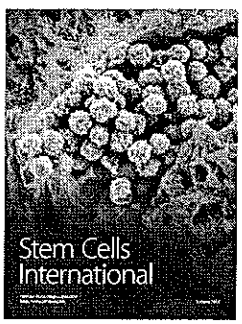
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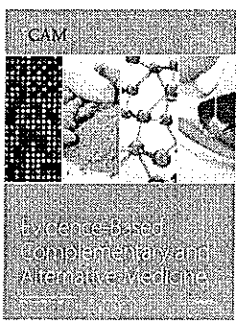

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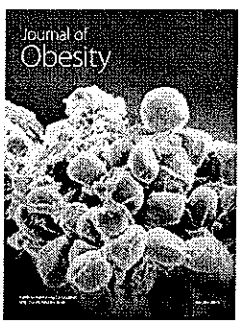
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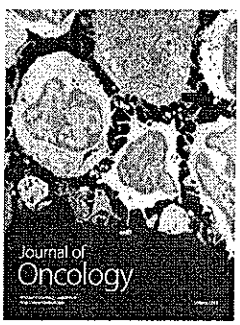
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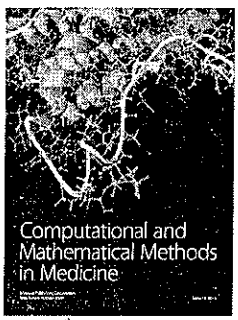
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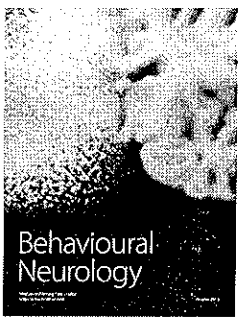
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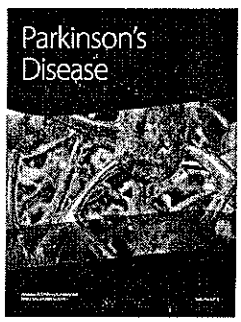
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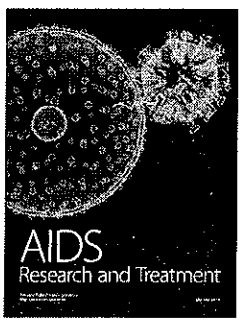
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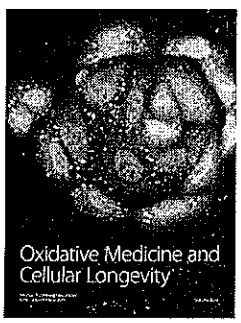
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ANNEXURE-AII

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Original Article

HIV/AIDS-Related Risk Behaviors, HIV Prevalence, and Determinants for HIV Prevalence among Hijra/Transgender People in India: Findings from the 2014–2015 Integrated Biological and Behavioural Surveillance

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Abstract

Background: Hijra or transgender (H/TG) people are significantly affected by HIV in India. HIV prevalence among H/TG is the second highest after people who inject drugs. Effective interventions require understanding about various risk behaviors and associated factors for high prevalence. **Objectives:** This study analyzes the known risk behaviors and vulnerabilities of HIV-positive and HIV-negative H/TG people to identify the determinants of HIV seropositivity in this high-risk group. **Methods:** Using secondary data from India's 2014 to 2015 Integrated Biological and Behavioural Surveillance survey, this analysis was conducted among 3325 H/TG people across seven states. Probability-based sampling methods were used to recruit H/TG people. Informed consent was obtained for the collection of behavioral information and blood samples for HIV testing. Multivariable binary logistic regression analysis was undertaken to identify the determinants of HIV seropositivity. **Results:** HIV prevalence for this group of respondents was 9.5%. Multivariable analysis of survey data revealed higher odds of HIV infection if H/TG had regular male partners (adjusted odds ratio [AOR]: 1.81, confidence interval [CI]: 1.07–3.06), were living in the states of Maharashtra (AOR: 6.08. CI: 3.02–12.22) and Odisha (AOR: 2.91, CI: 1.05–8.06), and were members of self-help groups (AOR: 2.08, CI: 1.04–4.14). None of the demographic or behavioral correlates of risk were found to be associated with HIV infection. **Conclusion:** The findings suggest that community and structural factors, which are inadequately covered in surveys such as IBBS, play a more important role than individual behavioral factors.

Key words: Determinants, Hijras/transgender people, HIV, sexual behavior, surveillance

Introduction

Transgender (TG) people bear a disproportionately higher risk for HIV and sexually transmitted infections (STIs).[1,2] The term "TG" refers to individuals whose gender identity or expression differs from the sex assigned at birth.[3] TG people, who were born male, but self-identify as female, are at much higher risk for HIV infection as shown by evidence collected around the world.[2,4,5] Through a systematic review of data from 15 countries, Baral *et al.* estimated HIV prevalence in TG at 19.1% with a 49-fold increase in odds of infection in this group compared to the general adult population.[3] Research suggests that HIV infections among TG are driven by multiple factors.[6] At the individual level, sex work, unprotected anal sex, multiple sex partners, coinfections with perianal STIs, limited HIV knowledge, gender-affirming hormone use, and interplay of psychosocial health problems, such as depression and substance use/abuse, play an important role in increasing HIV vulnerability and risk.[1,2] At the community level, social determinants such as stigma, discrimination, violence, and

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victimization due to TG identity, together with high levels of HIV within the group, are major factors of HIV risk.[2,7,8]

In India, HIV prevalence in TG or Hijras (H), as they are commonly called in the national context in addition to many other names, is also much higher (3.14%) than in the general population (0.26%).[9,10] For a long time, Hijra or transgender (H/TG) people have been the second most affected population group in the country.[11-13] HIV Sentinel Surveillance (HSS 2017) confirmed that H/TG people have a higher HIV prevalence (3.14%) than men who have sex with men (MSM) (2.69%) and female sex workers (1.56%).[10] Only people who inject drugs have a higher HIV prevalence rate (6.26%) than H/TG people.[10] In 2012–2013, a mapping study in 17 states estimated around 62,137 H/TG people, with the majority (61%) living in Andhra Pradesh, Maharashtra, Odisha, Uttar Pradesh, and West Bengal.[14]

H/TG people in India continue to be organized into *Gharanas* which are systems of social organization like a fraternity or clan.[14,15] Their traditional occupation is "badhai" (i.e., blessing of newborn babies and newly married couples), singing, and dancing. Nowadays, however, due to lack of education, job opportunities, and economic constraints, H/TG people may resort to sex work or begging for a livelihood.[15,16] Engagement in these stigmatized occupations contribute to further marginalization and discrimination of H/TG.[6,16,17]

India's National AIDS Control Programme (NACP) has recognized H/TG as a high-risk group. Originally, H/TG people were seen as a subpopulation of men who have sex with men (MSM), but then it became apparent that H/TG people are at higher risk for HIV.[6] In NACP-IV (2012–2017), prevention interventions specifically tailored for H/TG people were already introduced.[15] As some of the specifically targeted interventions started only around 5 years ago, and HIV prevalence in H/TG people remains higher than in other key populations, a better understanding is needed of HIV risk and vulnerability in this group.[6,15,16] This study presents the results of an analysis of known risk and vulnerability factors in HIV-positive and HIV-negative H/TG persons.[6] The determinants of HIV infection are also examined to identify individual predictors of risk in H/TG using data from national biobehavioral surveillance.

Materials and Methods

Study design, setting, and data source

Data used in this study were drawn from India's 2014–2015 Integrated Biological and Behavioural Surveillance (IBBS) survey conducted among H/TG people across 14 domains in 11 states. For this analysis, data from only seven states were used, including Andhra Pradesh and Telangana, Karnataka, Maharashtra, Delhi, Odisha, Tamil Nadu, and West Bengal. These states were selected due to an H/TG prevalence above the average of 3.14% (HSS 2017).[10] The present analysis using the secondary data of IBBS 2014–2015 was undertaken during January–March 2019.

Study subjects, sampling, tools/techniques

By definition, the survey covered H/TG "aged 15 years or more, whose self-identity does not conform unambiguously to conventional notions of male or female gender roles, but combines or moves between them."[13] H/TG people were recruited into the survey across eleven domains, each comprising a single district or a conglomerate of neighboring districts with similar sociocultural characteristics. In each domain, 400 H/TG people were to be recruited using a conventional cluster sampling method for fixed sites (i.e., homes) and time-location cluster sampling approach to recruit mobile H/TG. Where the number of H/TG people was deemed too limited to easily reach the desired sample size, a "take all" approach was used to recruit respondents. Altogether, 3325 H/TG people from seven high-prevalence states are included in the current analysis.

Behavioral information was collected through a questionnaire using computer-assisted personal interview tools. Blood specimens for HIV testing were collected through a finger prick test using dried blood spot filter paper cards.[13] All tools used in the survey were standardized and translated into different vernacular languages. Field teams who implemented the survey were rigorously trained with the help of technical guidelines and manuals to ensure consistency in data collection across multiple sites. Details of the survey methodology are available elsewhere.[13]

Ethical considerations

Ethical approval was obtained from the National AIDS Control Organisation (NACO) Ethics Committee vide letter number T-11020/20/2008-NACO (R&D) dated September 26, 2013. Informed consent was obtained from all participants following administration of the participation information sheet. For respondents aged 15–17 years, assent was obtained from local guardian. Confidentiality of respondents was given utmost priority; data specimens in IBBS had unique respondent numbers and cannot be linked to any respondent. Referral to the nearest HIV counseling and testing center for free HIV counseling and testing was offered to each participant.

Variables: Definitions/descriptions

The primary outcome measure for the current analysis was HIV status (dichotomized as HIV positive and HIV negative), determined based on laboratory testing using two-test protocols. Specimen testing was done using enzyme-linked immunosorbent assay kits, and samples reactive in both tests were labeled HIV-positive.[13]

The independent measures considered in this analysis to assess the HIV risk and vulnerability among HIV-positive and HIV-negative H/TG people and to identify the determinants of HIV infection include individual profile characteristics, alcohol and drug use, sexual risk behaviors, stigma/discrimination, experience of violence, HIV/AIDS knowledge, program exposure, and community collectivization.

Profile characteristics included age (grouped into 15–18, 20–24, 25–34, and 35 + years); education (no schooling,

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secondary, and high school and above); marital status (never married, currently married, and widowed/separated/divorced); self-identification (Akwa or operated, Nirvan or nonoperated, and others); occupation (sex work, traditional [such as dancing, singing, begging, and "badhai"] and others); and state of residence.

Variables for sexual behavior included age at first sexual encounter with a male (≤14, 15–17, 18–24, and 25+ years); forced sex at first sexual intercourse (yes/no); partner types (regular [lover/boyfriend or live-in partners], paying [respondent receives cash or kind from a partner for selling sex], paid [respondent pays cash or kind to a partner when buying sex], and casual [those other male partners besides the regular partner who does not pay the respondent for sex]); consistent condom use (defined as use of condom at each sex act, every time, in the past 12 months) with each of these different partners (yes/no); had sex with male/Hijra partner during travel outside their current place of residence (yes/no); and having reported to have had an STI (yes/no).

Other key independent variables included substance use (alcohol and drugs [yes/no]); experience of physical and sexual violence (yes/no); stigma and discrimination (yes/no); self-risk perception (high, moderate, low, and no risk); HIV/AIDS knowledge and program exposure including HIV testing and collection of test results (yes/no); comprehensive knowledge of HIV (dichotomized [yes/no] and defined as (i) knowing two major ways of preventing the sexual transmission of HIV [using condoms and limiting sex to one faithful, uninfected partner], (ii) rejecting two most common local misconceptions about HIV transmission, and (iii) being aware that a healthy-looking person can be infected with HIV); awareness about medication for prevention of mother-to-child transmission of HIV (yes/no); exposure to any prevention interventions (yes/no); and comprehensive exposure to interventions (dichotomized and includes those who received all of the four services, i.e., information on STI/HIV/AIDS from peer educators or outreach workers, condoms from peer educators or outreach workers, checkup and counseling for STIs, and referral to other services [i.e., STI clinics, HIV testing, and detox centers]).

Factors on community collectivization included membership in a self-help group, membership in any MSM/TG collective (yes/no), perception of H/TG on participation of other H/TG for problem resolution (all H/TG will work together, most, some or none will work together and don't know), and negotiated with/stood up against: (i) police (yes/no), (ii) goons/local leaders (yes/no), (iii) fellow H/TG or MSM (yes/no) to support/help other H/TG members in the community.

Statistical analysis

Data gathered from the seven selected states were combined, and national weights were calculated and used for the whole data analysis. Multivariable binary logistic regression analysis was undertaken using SVY commands in STATA 13 (Stata Statistical Software: Release 13. College Station, TX: StataCorp LP) to identify factors independently predictive of HIV infection. Adjusted odds ratios (AORs) and 95% confidence intervals (95% CIs) were generated. Factors significantly associated with HIV infection ($P < 0.05$) in the bivariate analysis were included in the final model along with known confounders, including age, education, occupation, marital status, self-identity, and state of residence irrespective of their significance levels. Due to the skewed distribution, except for the state variable, all others were dichotomized for the multivariable analysis. Missing cases, no response options, or do not know responses were removed.

Results

HIV prevalence in the samples (3325) drawn from seven states was 9.5% (CI: 7.8–11.5). The prevalence was highest in Maharashtra (17.3%, CI: 13.4–22.1), followed by Odisha (9.1%, CI: 5.9–13.9), Tamil Nadu (8.1%, CI: 2.2–25.5), Karnataka (6.1%, CI: 4–9.0), NCT of Delhi (5.3%, CI: 3.2–8.6), Andhra Pradesh (5.2%, CI: 3.4–7.8), and West Bengal (4.7%, CI: 2.8–7.9). Comparison of HIV status at the bivariate level revealed that a higher proportion of HIV-positive H/TG people were 35 years or older (25.9% vs. 15.0%, $P = 0.010$) and engaged in sex work (46.4% vs. 43.6%, $P = 0.016$) and traditional occupations (19.6% vs. 11.8%, $P = 0.016$) than HIV-negative H/TG people who were younger or mainly involved in other occupations. Similarly, a higher share of HIV-positive than HIV-negative H/TG people reported having a regular partner (59.8% vs. 48.8%, $P = 0.022$) [Table 1]. This was also the case of H/TG people who were aware of ART (76.2% vs. 67.2%, $P = 0.025$), had a comprehensive knowledge of HIV (63.7% vs. 54.8%, $P = 0.041$), and were aware of medications for the prevention of mother-to-child transmission of HIV (73.6% vs. 63.9%, $P = 0.043$). Further, a higher proportion of HIV-positive than HIV-negative H/TG people were members of self-help groups (49.1% vs. 32.8%, $P = 0.001$); believed that if there was a problem in the H/TG community, all will work toward its resolution (67.6% vs. 52.9%, $P = 0.003$); and in the past 12 months negotiated with/stood up against the police (51.4% vs. 36.3%, $P = 0.002$), goons/local leaders (36.7% vs. 28.3%, $P = 0.049$), and fellow MSM or H/TG (71.0% vs. 61.9%, $P = 0.025$) to help/support other H/TG community members [Table 2].

Multivariable analysis found that higher odds of HIV positivity if H/TG people had a regular male partner (AOR: 1.81, CI: 1.07–3.06), were living in the state of Maharashtra (AOR: 6.08, CI: 3.02–12.22) or Odisha (AOR: 2.91, CI: 1.05–8.06), and were members of self-help groups (AOR: 2.08, CI: 1.04–4.14). In contrast, odds of positivity were lower if H/TG people had travelled outside their current place of residence and had sex with male/Hijra partner at the place they visited last (AOR: 0.59, CI: 0.35–0.99) [Table 3].

However, demographic or behavioral correlates of risk, such as education, marital status, condom use, alcohol/drug use, stigma and discrimination, violence, self-perceptions of HIV risk and

234

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Table 1: Distribution of profile characteristics and sexual behavior among Hijra/transgender persons according to HIV status, Integrated Biological and Behavioural Surveillance, 2014-2015*

Variables	HIV positive H/TG (n=322), n (%)	HIV negative H/TG (n=3003), n (%)	χ^2/P
Profile			
Age (years)			
15-19	10 (3.41)	214 (7.3)	29.23/0.010
20-24	77 (23.4)	836 (27.0)	
25-34	153 (47.2)	1460 (50.5)	
35+	82 (25.9)	493 (15.0)	
Education			
No schooling	53 (11.7)	295 (9.7)	1.35/0.695
Secondary school	100 (29.6)	958 (31.3)	
High school and above	169 (58.6)	1748 (58.9)	
Marital status			
Never married	238 (75.0)	2339 (79.6)	9.18/0.207
Currently married	59 (19.9)	413 (13.8)	
Widowed, divorced, separated	22 (5.02)	230 (6.5)	
Occupation			
Traditional	77 (19.6)	434 (11.8)	21.70/0.016
Sex work	144 (46.4)	1283 (43.6)	
Others†	101 (33.8)	1281 (44.4)	
Self-identification			
Nirvan (operated)	128 (38.9)	1170 (32.8)	5.41/0.227
Akwa (nonoperated)	190 (60.1)	1761 (65.6)	
Others	4 (0.86)	70 (1.5)	
State			
Andhra Pradesh + Telangana	50 (7.3)	599 (13.9)	99.15/0.001
Karnataka	30 (3.6)	361 (5.7)	
Maharashtra	137 (50.0)	622 (25.0)	
NCT of Delhi	28 (8.8)	368 (16.5)	
Odisha	36 (16.3)	359 (16.9)	
Tamil Nadu	22 (7.7)	340 (9.1)	
West Bengal	19 (6.07)	354 (12.7)	
Substance use			
Alcohol consumption before or during sex act	115 (50.6)	1145 (57.1)	4.47/0.209
Injected drugs for nonmedical reasons	19 (4.1)	161 (3.9)	0.04/0.852
Sexual behavior			
Age at first sexual encounter with a male (years)			
≤14	97 (29.9)	865 (27.0)	18.10/0.059
15-17	96 (29.6)	926 (29.9)	
18-24	76 (27.0)	593 (20.7)	
25+	3 (0.28)	53 (1.9)	
Don't remember	50 (13.1)	566 (20.2)	
Forced sex at first sexual intercourse	108 (36.0)	866 (29.7)	5.42/0.173
Had sex with male/Hijra partner during travel outside current place of residence	82 (39.4)	914 (54.4)	27.81/0.019
Partner types			
Regular	165 (59.8)	1530 (48.8)	13.71/0.022
Paying	196 (56.4)	1887 (62.4)	4.30/0.230
Paid	78 (21.8)	753 (26.8)	3.68/0.233
Casual	102 (36.9)	961 (31.7)	3.45/0.353
Consistent condom use with			
Regular	90 (53.8)	779 (57.3)	1.66/0.664
Paying	129 (74.7)	1097 (66.5)	7.83/0.085
Paid	51 (77.5)	448 (64.1)	19.49/0.078

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Table 1: Contd...

Variables	HIV positive H/TG (n=322), n (%)	HIV negative H/TG (n=3003), n (%)	χ^2/P
Casual	62 (58.7)	497 (61.4)	1.03/0.814
Having any STI‡	78 (23.4)	810 (24.9)	0.34/0.688

*All proportions presented are weighted, and totals may not add up to 100% due to missing values, others, or no response categories, †Others include unemployed, self-employed, students, laborers, domestic servants, skilled/semiskilled workers, service, transport workers, and hotel staff, ‡Among those who reported suffering from at least one STI symptom in the last 12 months (genital ulcer/sore, anal ulcer/sore, discharge from rectum, urethral discharge, swelling in groin/scrotal area, genital warts, and anal warts). STI: Sexually transmitted infection, H/TG: Hijra or transgender

Table 2: Distribution of contextual risk and vulnerability factors among Hijra/transgender persons according to HIV status, Integrated Biological and Behavioural Surveillance, 2014-2015*

Variables	HIV positive H/TG (n=322), n (%)	HIV negative H/TG (n=3003), n (%)	χ^2/P
Violence and stigma/discrimination			
Beaten by someone in last 12 months	237 (20.3)	799 (23.3)	1.37/0.407
Experienced sexual violence†	70 (19.5)	720 (22.2)	1.26/0.401
Treated disrespectfully by family/friends/neighbors	156 (54.1)	1582 (56.0)	0.41/0.696
Experienced discrimination at health facility‡	133 (43.1)	1166 (40.7)	0.69/0.631
Awareness, exposure to HIV/AIDS services and perceptions			
Self-risk perception for exposure to HIV			
High risk	72 (22.1)	478 (15.0)	16.85/0.104
Moderate risk	5419.5)	497 (17.9)	
Low risk	87 (19.5)	863 (27.8)	
No risk	101 (38.8)	1113 (39.1)	
Tested for HIV and collected test results	263 (80.8)	2415 (77.5)	1.86/0.405
Comprehensive HIV knowledge	187 (63.7)	1625 (54.8)	9.35/0.041
Aware of ART	234 (76.2)	2057 (67.2)	10.95/0.025
Aware of medications for the prevention of mother-to-child transmission of HIV	215 (73.6)	1877 (63.9)	11.97/0.043
Received information on STI/HIV/AIDS from peer educators or outreach workers	262 (76.1)	2418 (77.9)	1.71/0.693
Received condoms from peer educators or outreach workers	267 (82.3)	2368 (74.9)	8.96/0.141
Received checkup and counseling for STIs	215 (69.1)	1817 (60.4)	11.11/0.063
Referred to other services (STI clinics, HIV testing, and detox centers)	177 (58.8)	1626 (53.4)	4.48/0.388
Received comprehensive package of services	152 (45.2)	1244 (41.7)	1.37/0.490
Member of a self-help group	136 (49.1)	1057 (32.8)	33.34/0.001
Membership in a collective for MSM/TG	243 (78.3)	2242 (76.5)	0.53/0.713
Perception of H/TG people on problem resolution			
All H/TG people will work together to deal with problem	213 (67.6)	1708 (52.9)	30.11/0.003
Most will work together	58 (18.1)	679 (26.0)	
Some will work together	34 (8.6)	432 (13.6)	
None will work together	9 (3.3)	59 (2.3)	
Don't know	8 (2.1)	123 (5.1)	
Negotiated with/stood up against the below to help fellow H/TG			
Police	153 (51.4)	1164 (36.3)	27.9/0.002
Goons/Local leaders	117 (36.7)	924 (28.3)	9.72/0.049
Fellow H/TG or MSM	201 (71.0)	1878 (61.9)	10.11/0.025
H/TG people negotiated with/stood up against, police, goons, and H/TG or MSM to help fellow H/TG (collectivization)	83 (28.2)	595 (19.3)	16.04/0.013

*All proportions presented are weighted, and totals may not add up to 100% due to missing values, others, or no response categories, †Sexual violence: Forced by someone in the last 12 months to have sexual intercourse, ‡Discrimination: if H/TG people felt that they were being treated differently (such as received less care and attention) than others in health facilities because of being a H/TG. ART: Antiretroviral therapy, STIs: Sexually transmitted infections, H/TG: Hijra or transgender, MSM: Men who have sex with men

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Table 3: Association of HIV seropositivity with profile characteristics and other contextual risk and vulnerability factors among Hijra/transgender persons, Integrated Biological and Behavioural Surveillance, 2014-2015*

Variables	*n* (% HIV positive H/TG)	Crude OR (95% CI)	AOR (95% CI)	*P*
Profile				
Age (years)				
15-24	87 (26.8)	Referent	Referent	
25+	235 (73.1)	1.42 (0.99-2.03)	1.16 (0.70-1.92)	0.559
Education				
Up to secondary school	153 (41.3)	Referent	Referent	
High school and above	169 (58.6)	0.98 (0.68-1.41)	0.82 (0.51-1.32)	0.426
Marital status				
Never married	238 (75.0)	Referent	Referent	
Ever married	81 (24.9)	1.30 (0.77-2.19)	1.45 (0.82-2.58)	0.197
Occupation				
Other jobs	178 (53.5)	Referent	Referent	
Sex work	144 (46.4)	1.12 (0.76-1.64)	0.83 (0.50-1.38)	0.480
Self-identification				
Nirvan (operated)	128 (39.3)	Referent	Referent	
Akwa (nonoperated)	190 (60.6)	0.77 (0.50-1.17)	0.80 (0.48-1.34)	0.408
State				
Andhra Pradesh + Telangana	50 (7.37)	Referent	Referent	
Karnataka	30 (3.61)	1.18 (0.65-2.15)	0.79 (0.39-2.01)	0.634
Maharashtra	137 (50.0)	3.78 (2.23-6.40)	6.08 (3.02-12.22)	0.001
NCT of Delhi	28 (8.8)	1.00 (0.51-1.99)	0.87 (0.36-2.11)	0.763
Odisha	36 (16.3)	1.81 (0.96-3.43)	2.91 (1.05-8.06)	0.040
Tamil Nadu	22 (7.71)	1.59 (0.38-6.59)	2.49 (0.54-11.30)	0.236
West Bengal	19 (6.07)	0.90 (0.44-1.81)	1.24 (0.41-3.76)	0.693
Other contextual factors				
Had sex with male/Hijra partner during travel outside current place of residence	82 (39.4)	0.54 (0.32-0.91)	0.59 (0.35-0.99)	0.048
Had a regular partner	165 (59.8)	1.55 (1.06-2.28)	1.81 (1.07-3.06)	0.025
Aware of ART	234 (76.2)	1.57 (1.05-2.34)	1.41 (0.74-2.69)	0.291
Comprehensive HIV knowledge	187 (63.7)	1.45 (1.01-2.07)	1.00 (0.57-1.76)	0.978
Aware of medications for the prevention of mother-to-child transmission of HIV	215 (73.6)	1.57 (1.01-2.46)	0.96 (0.50-1.85)	0.916
Member of a self-help group	136 (49.1)	1.97 (1.31-2.94)	2.08 (1.04-4.14)	0.037
Perceived that all H/TG people will work together to deal with problems of H/TG community	213 (69.2)	1.78 (1.19-2.65)	1.76 (0.91-3.42)	0.091
Collectivization: Negotiated with/stood up against, police, goons, H/TG, or MSM to help fellow H/TG	83 (28.8)	1.69 (1.11-2.57)	1.09 (0.61-1.94)	0.765

*Adjusted for all variables significantly associated with HIV status and profile characteristics including age, education, marital status, occupation, self-identity, and state of residence. OR: Odds ratio, AOR: Adjusted OR, H/TG: Hijra or transgender, MSM: Men who have sex with men, CI: Confidence interval, ART: Antiretroviral therapy

HIV testing, and collection of results, were not found to be significantly associated with HIV infection. Neither was an association found with variables related to prevention program exposure including having received one or more HIV/AIDS services or a comprehensive package of services.

Discussion

HIV prevalence in H/TG people at 9.5% in seven high prevalence states confirms that this group continues to be highly affected by the epidemic in India. Earlier surveys recorded even higher HIV prevalence levels among H/TG people across India ranging from 9.8% to 45.2%.[6] Maharashtra was already known to have very high HIV prevalence in this group, but higher odds of infection in H/TG people in Odisha compared to those in other states are unexpected.[3-5] This finding calls for a stronger targeting of prevention interventions, especially at these locations where the epidemic is concentrated in H/TG people to avert new infections and provide adequate care and treatment.

Having a regular partner and membership in a self-help group were the only factors resulting in a higher likelihood of HIV infection. An ethnographic research conducted by Khan *et al.* in Bangladesh helps explain why H/TG people who have a regular partner may be more likely to get infected with HIV.[18] For H/TG people who face a lot of stigma and discrimination in their community and society more at large due to their gender variant identity, having a regular male partner is of

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great importance as this is a source of moral and emotional support. The desire to have a sustained relationship with a man, similar to the one he would have with a woman, may lead a H/TG person to make concessions and neglect consistent condom use to please and maintain a regular partner.[8,19] The practice by which H/TG people tend to engage in multiple concurrent partnerships, because if one partner leaves, he/she will have another partner whom he/she can rely upon, has also been documented.[18] These aspects should be taken into consideration in the design of prevention intervention for H/TG people and their partners, both regular and casual.

In this study, H/TG people who reported being a member of a self-help group were twice as likely to be HIV-infected than nonmembers. This result could be due to sampling or because H/TG people who are at higher risk may be more likely to take part in self-help groups which could be the result of efforts made through targeted prevention programs. This finding needs to be further investigated including thorough analysis from programs and qualitative data to better understand realities on the ground. Self-help groups and community collectives have been created by the national program as a platform for key populations to discuss their needs and become involved in the development, implementation, monitoring, and evaluation of programs.[15,20] That HIV-positive H/TG may be overrepresented in these groups and may have greater access to services and information than HIV-negative H/TG, would not be surprising. This could explain why the former were found to be better aware of HIV and of availability of AIDS treatment as shown by this analysis.

Besides membership in a self-help group, measures relating to problem resolution in the community and negotiation (i.e., with police and others who posed a threat to the community) were found to be associated with HIV infection in the bivariate analysis. This association, however, was not found to be significant in the multivariate analysis. Regardless, these factors, operating at the community level, seem to be important and should be examined more in depth in the future. Research should be conducted to better understand the role of community-level factors in influencing risk-taking tendencies among H/TG people (e.g., peer norms on safe sex, condom use, HIV testing, and STI treatment). Information on these aspects was not collected in the IBBS and therefore their impact on HIV infection unknown. Future bio-behavioral surveys should take community-level factors into consideration to enhance the understanding of HIV vulnerability and risk among H/TG.

Against expectations, like in earlier studies from southern India,[21,22] this multivariable analysis shows a lack of association of HIV infection with engagement in sex work, consistent condom use, HIV testing, substance use/abuse, stigma and discrimination, and violence. However, key factors of HIV risk and vulnerability should not be underestimated. The analysis found that nearly half of the samples from the seven selected states reported sex work as their main occupation. Around one in three of HIV-positive H/TG people indicated using condoms consistently with paying/paid partners. Keeping consistent condom at a high level is a major priority, especially among H/TG people and people who inject drugs who are at highest risk for HIV. Similarly, there is a need to scale-up initiatives aimed at reducing their vulnerability due to alcohol use, as IBBS results show that such consumption is high before or during sex act.[13] Sexual and other violence, stigma and discrimination have to continue to be addressed, although not found to be directly associated with HIV infection in the logistic regression analysis. Such measures are in any case important to reduce H/TG people's vulnerability and ensure their adequate access to vital services including HIV testing and care and treatment.[23]

This study has some limitations which are mainly related to the design and implementation of the 2014–2015 IBBS. The selection of domains in the IBBS was not done randomly; hence, the sample may be somewhat biased as is suggested by the analysis of results. Four hundred H/TG people were to be recruited in each domain, but in some, this sample size could not be achieved. This has impacted statistical significance of results, as smaller sample sizes are sufficient for behavioral estimates, but do not provide robust enough estimates of HIV prevalence. As the IBBS was conducted only in select geographical areas, its results cannot so easily be generalized to the whole country. Further, analysis of behaviors is largely based on self-reported data, which may suffer from social desirability bias. Long recall periods used in some questions may also have affected the quality of responses. Investigators put in place measures to address these biases from the outset of the survey, including through rigorous training of field enumerators and other measures aimed at ensuring best possible survey results.

Conclusion

The findings of this study have significant implications for the H/TG interventions in the next phase of India's NACP. The prevalence of HIV in this group remains the second highest nationally and is alarmingly high in some states such as Maharashtra. Thus, H/TG need to continue to be a major target of prevention efforts in India. Given the complex interaction of multilevel risks in and across these groups, and absence of an association between known proximate determinants and HIV infection, additional factors predictive of HIV status at community and structural level will need to be studied to inform prevention policies and programs.

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Conflicts of interest
There are no conflicts of interest.

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ANNEXURE-A12

240

Worldwide burden of HIV in transgender women: a systematic review and meta-analysis

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For more on CDC data on HIV in transgender people see http://www.cdc.gov/hiv/transgender/

Summary

Background Previous systematic reviews have identified a high prevalence of HIV infection in transgender women in the USA and in those who sell sex (compared with both female and male sex workers). However, little is known about the burden of HIV infection in transgender women worldwide. We aimed to better assess the relative HIV burden in all transgender women worldwide.

Methods We did a systematic review and meta-analysis of studies that assessed HIV infection burdens in transgender women that were published between Jan 1, 2000, and Nov 30, 2011. Meta-analysis was completed with the Mantel-Haenszel method, and random-effects modelling was used to compare HIV burdens in transgender women with that in adults in the countries for which data were available.

Findings Data were only available for countries with male-predominant HIV epidemics, which included the USA, six Asia-Pacific countries, five in Latin America, and three in Europe. The pooled HIV prevalence was 19·1% (95% CI 17·4–20·7) in 11 066 transgender women worldwide. In 7197 transgender women sampled in ten low-income and middle-income countries, HIV prevalence was 17·7% (95% CI 15·6–19·8). In 3869 transgender women sampled in five high-income countries, HIV prevalence was 21·6% (95% CI 18·8–24·3). The odds ratio for being infected with HIV in transgender women compared with all adults of reproductive age across the 15 countries was 48·8 (95% CI 21·2–76·3) and did not differ for those in low-income and middle-income countries compared with those in high-income countries.

Interpretation Our findings suggest that transgender women are a very high burden population for HIV and are in urgent need of prevention, treatment, and care services. The meta-analysis showed remarkable consistency and severity of the HIV disease burden among transgender women.

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Introduction

The term transgender is used most often to refer to people whose gender identity or expression differs from their birth sex.[1] Gender presentations and social categories vary greatly across cultures, and many different terms are used to describe individuals who live between or outside a male-female binary.[2–4] For the purposes of this report, the terms male and female will be used to refer to biological sex, and the term man and woman will be used to refer to gender identity or expression. Transgender women, defined here as people who were assigned male at birth but who identify as women, have long been known to be at high risk for HIV acquisition and transmission. As of 2012, there remains a poor understanding of the burden of HIV among transgender women because of the limited inclusion of these populations in national HIV surveillance systems. In the few countries where epidemiological data for transgender women have been obtained, results have shown a disproportionate risk for HIV infection.

A 2008 meta-analysis by Herbst and colleagues[5] at the US Centers for Disease Control and Prevention (CDC) identified 22 studies that reported HIV infection rates for transgender women. The average prevalence was 27·7% (range 16–68%) from the four studies that reported laboratory-confirmed HIV infections. African American transgender women had twice the prevalence of HIV infection (56·3%) than did those who were white (16·7%) or Hispanic (16.1%). When the results were averaged across the 18 studies where respondents self-reported their HIV serostatus, the average dropped to 11·8% (range 3–60%). Although selection bias might account for the difference in HIV prevalence between studies with self-reported HIV status and those with biologically confirmed HIV, CDC has reported that as many as 73% of the transgender women who tested HIV-positive were unaware of their status. Therefore, the difference in HIV prevalence between studies that used laboratory markers and those with only self-report provide support for the hypothesis that many transgender women might not be aware of their HIV status.[5]

One international systematic review and meta-analysis of HIV risk in a subset of transgender women was done by Operario and colleagues in 2008.[6] This study compared HIV prevalence in transgender women sex workers versus transgender women who do not engage in sex work, male sex workers, and female sex workers. The investigators identified 25 studies including 6405 participants

(3159 transgender women—2139 categorised as sex workers and 1020 categorised as non-sex workers—1633 male sex workers, and 1613 female sex workers) recruited from 14 countries on five continents. Although most studies were done in the USA, study populations also included transgender women in Spain, Singapore, Israel, Netherlands, Brazil, Belgium, Indonesia, Australia, Thailand, Uruguay, India, and Italy. Most sites were large metropolitan cities and all used convenience samples. Participants were recruited at venues that included HIV testing clinics, medical and community-based organisations serving transgender populations, street locations, and social and workplace venues. Six of the 25 studies established HIV status on the basis of self-report.

Overall crude HIV prevalence was 27·3% in transgender women engaging in sex work, 14·7% in those not engaging in sex work, 15·1% in male sex workers, and 4·5% in female sex workers. There was a significant difference in HIV prevalence in transgender women sex workers compared with all other pooled groups (odds ratio [OR] 1·46, 95% CI 1·02–2·09) and a significant difference between transgender sex workers and female sex workers (4·02, 1·60–10·11). Transgender sex workers were therefore more than four times more likely to be living with HIV than were female sex workers. Studies done outside of the USA showed higher HIV prevalence in transgender sex workers than in all other groups (OR 1·90, 95% CI 1·52–2·37), although studies within the USA did not show this difference (OR 1·24, 95% CI 0·72–2·12). These data highlight the disproportionate burden of HIV infections in transgender women sex workers compared with female sex workers.

We did a global systematic review to better assess the relative HIV burden among all transgender women worldwide. We then completed a meta-analysis comparing the burdens of HIV infection in these populations to those of adults of reproductive age in their countries to characterise the size of the burden of HIV borne by these women.

Methods

Search strategy and selection criteria

We searched PubMed, Embase, Global Health, Scopus, PsycINFO, Sociological Abstracts, Cumulative Index to Nursing and Allied Health Literature, Web of Science, POPLine, and LexisNexis. The WHO publications database was searched, as well as the National Library of Medicine's Meeting Abstracts database. Searches were done in February, 2011, and repeated in November, 2011. Conference abstracts were searched from the online archives of the International AIDS Conference, the Conference on HIV Pathogenesis, Treatment, and Prevention, and the Conference on Retroviruses and Opportunistic Infections. Other data sources searched included national surveillance system data reports, including AIDS indicator surveys, demographic health surveys, and integrated biobehavioural surveillance studies done by large international non-governmental organisations. However, non-peer reviewed literature were not used on their own as sources of data. Rather, these documents guided secondary searches for further literature to ensure sensitive searches. Articles and citations were downloaded, organised, and reviewed with the QUOSA information management software package (version 8.05) and EndNote (version X4).

The search included medical subject headings (MeSH) terms for HIV or AIDS, and terms associated with transgender (transgender* OR "travesty" OR "koti" OR "hijra" OR "MTF" or "male to female transgender" OR transsexual* OR transvest* OR "mahuvahine" OR "mahu" OR "waria" OR katoey OR "cross dresser" OR "bantut" OR "nadleehi" OR "berdache" OR "xanith"). Gender identities are complex and fluid; a full explication of gender identities is beyond the scope of this text. Many terms have been used in the scientific literature to refer to transgender women. The aforementioned search terms represent those used in the international biomedical literature and are not inclusive of all local terms describing transgender women worldwide.

Studies of any design were included that measured the prevalence or incidence of HIV in transgender women. Studies were accepted if descriptions of HIV testing methods were included such as laboratory derived HIV status using biological samples from blood, urine, or oral specimens. To be included, detailed descriptions of the sampling, HIV testing, and analytical methods were needed, with sources including peer-reviewed journals and non-peer reviewed publications meeting other criteria and available online in the public domain. Studies published in English, French, and Spanish were included. Studies were excluded if the sample size of transgender women was less than 50. Studies were excluded if self-reported HIV status rather than biological testing was used to assess the burden of HIV. Finally, studies were excluded if the prevalence of HIV was presented in another study already included in the analysis.

This analysis focuses on people who were born male but identify as a different gender, in view of the evidence for a disproportionate burden of HIV in this population, irrespective of whether they had sexual reassignment surgery or altered their bodies with hormones, silicone injections, or surgical procedures. Most studies meeting the inclusion criteria did not describe the surgical status of the transgender women participants.

Screening and data extraction

The search described above was completed on Feb 22, 2011. After the removal of duplicates, titles were screened by two independent reviewers to exclude those that clearly did not include HIV prevalence data. If either reviewer thought a title relevant, the abstract was reviewed. Two independent reviewers (TP and MS) assessed the abstracts of the remaining articles and retained those that either clearly met the inclusion

criteria or for whom the full text of the article had to be reviewed before a final decision about inclusion could be made. If either reviewer thought an article relevant, a full-text copy was obtained. A second search with the same search terms was done for the period Feb 22–Nov 30, 2011. Additional citations were identified and the titles were reviewed by two independent reviewers (TP and MS). The resulting abstracts were reviewed and articles were pulled for full text review. Full text review was completed by two independent reviewers (TP, MS, or SS). Data were extracted by two trained coders with standardised data extraction forms that included details about study design, methods of recruitment, location, sample size, reported HIV prevalence or incidence in transgender women, HIV prevalence in comparison groups (if provided), and CIs. Coders (TP, MS) showed high (90%) agreement, with discrepancies resolved through referral to a third senior study team member (SDB). Methodological quality of each study was assessed via evaluation of sampling and recruitment methods, response rates, data reporting, and information on unmeasured biases and confounders.

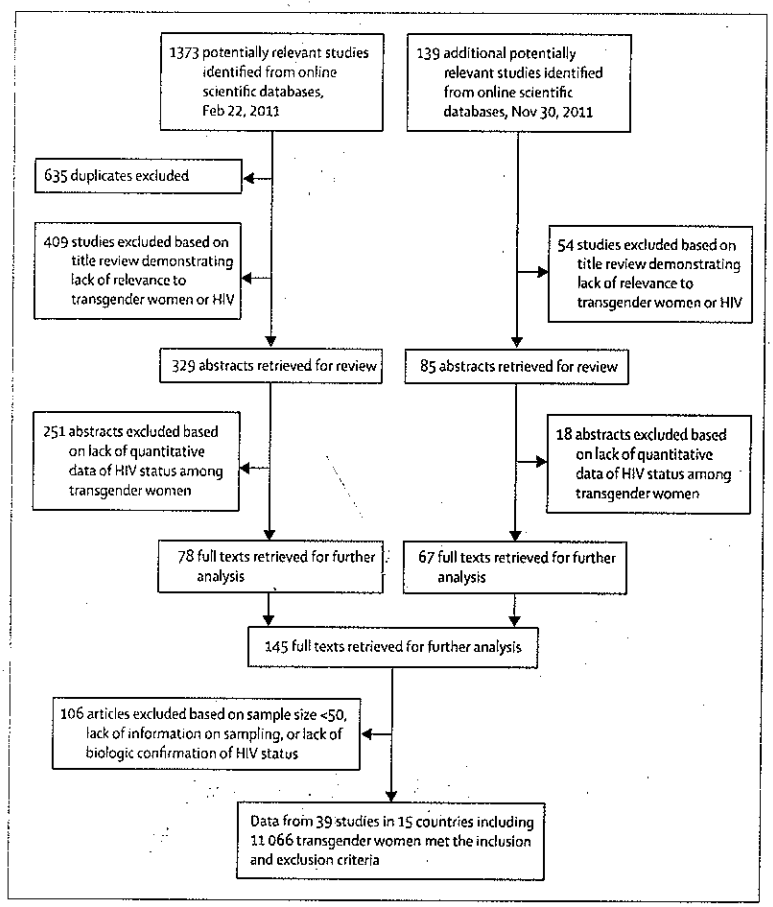

Figure 1: Study selection

Meta-analysis

These methods have been described previously.[7] Briefly, HIV prevalence data from different studies in transgender women were pooled and weighted by sample size for each country. The prevalence for the general population was calculated with the most recent UNAIDS estimates to assess the number of people living with HIV, aged 15 years or older, in each country as the numerator. US Census Bureau International Division was used to separately assess the total number of men and women who are aged 15 years and older and also the total number of men and women of reproductive age, or those between the ages of 15 and 49 years.[8] The primary meta-analysis represents the increased odds of being HIV seropositive for transgender women compared with other people of reproductive age. However, separate analyses were also completed that compared HIV rates in transgender women with that of only men and with that of only women of reproductive age. Most infections are in people aged 15–49 years; thus, we decided to make the comparisons against people in this age range.

The meta-analysis was completed with the Mantel-Haenszel method with a random-effects model with the assumption that the HIV prevalence in one population or country was independent of the HIV prevalence in other countries. A standard correction of 0·5 is added to all zero cells by the statistical package used (STATA, version 11). Heterogeneity testing was completed with the DerSimonian and Laird Q test.[9] Data are presented in forest plots including the OR, its 95% CI, and the relative weight of any particular study in estimating the summary OR for all countries.

Sensitivity analyses

Prevalent infections in transgender women comprise a portion of the prevalent infections in men and women used to characterise the denominator. Midpoint estimates of the prevalence of men who have sex with men (MSM) in the population and the prevalence of transgender women who were included in MSM estimates were obtained from Caceres and colleagues.[10] Census data were then used to scale up these estimates to calculate the approximate number of MSM and transgender women by country.[8] This estimate was then multiplied by the prevalence of HIV in transgender women in each country to approximate the number of HIV infections in each country. The Caceres method was focused on estimating the number of MSM and potentially underestimated the number of transgender women by excluding those who are not part of the MSM community (passing or post-transition transgender women who have sex with heterosexual male partners). However, these methods provided a range for the numbers of infections potentially attributable to transgender women in each of the countries studied. Meta-analyses were completed with and without these infections included as part of the background estimates,

	n	HIV prevalence in transgender women (95% CI)	Odds ratio (95% CI)	HIV prevalence in reproductive-age adults	HIV prevalence in reproductive-age males	Proportion of total HIV infections in men	Income level
Argentina[15–14]	931	33·5% (28·3–38·8)	92·4 (80·6–105·8)	0·54%	0·73%	67·3%	M
Brazil[15–17]	638	33·1% (26·7–39·4)	85·3 (72·3–100·6)	0·58%	0·68%	59·2%	M
El Salvador[18]	67	19·4% (0·0–40·9)	23·2 (12·7–42·5)	1·03%	1·42%	65·6%	M
Peru[19]	450	28·9% (21·1–36·7)	84·7 (69·1–103·9)	0·48%	0·73%	75·3%	M
Uruguay[20,21]	260	18·8% (7·9–29·8)	38·3 (28·1–52·3)	0·60%	0·82%	67·7%	M
Australia[22]	133	4·5% (0·0–21·1)	24·9 (11·0–56·5)	0·19%	0·26%	69·0%	H
India[23,24]	135	43·7% (31·0–56·4)	208·0 (148·0–292·3)	0·37%	0·44%	61·7%	M
Indonesia[25–27]	1384	26·1% (21·6–30·6)	180·3 (159·9–203·3)	0·20%	0·32%	70·7%	M
Pakistan[28–30]	2643	2·2% (0·0–6·0)	21·9 (16·9–28·4)	0·10%	0·14%	70·5%	M
Thailand[31,32]	614	12·5% (5·1–19·9)	9·9 (7·8–12·6)	1·43%	1·71%	59·6%	M
Vietnam[34]	75	6·7% (0·0–28·5)	15·6 (6·3–38·8)	0·45%	0·73%	70·0%	M
Italy[35,36]	826	24·5% (18·5–30·4)	65·8 (56·1–77·1)	0·49%	0·65%	65·7%	H
Netherlands[37]	69	18·8% (0·0–40·1)	81·8 (44·7–149·5)	0·28%	0·39%	68·6%	H
Spain[38,39]	136	18·4% (3·2–33·6)	40·9 (26·5–63·1)	0·55%	0·81%	75·4%	H
USA[45–48]	2705	21·7% (18·4–25·1)	34·2 (31·2–37·5)	0·81%	1·18%	74·2%	H
Pooled estimate*	11066	19·1% (17·4–20·7)	48·8 (31·2–76·3)	0·44%	0·58%	..	..

*Degrees of freedom=14, heterogeneity χ^2=914·7, I^2=98·5%, test of odds ratio=1, z=16·21, p=0·0001. Income level: M=middle-income; H=high-income.

Table 1: Meta-analyses of aggregate country data for HIV prevalence in transgender women versus all reproductive age adults, 2000–11

and there was no statistical difference in view of the small proportion of males who are transgender women (data not shown).

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 1 shows our study design. Across 15 countries with data that were included in this review, the pooled HIV prevalence was 19·1% (95% CI 17·4–20·7) for transgender women (table 1).[11–48] In transgender women sampled in low-income and middle-income countries, HIV prevalence was 17·7% (95% CI 15·6–19·8); in high-income countries, HIV prevalence was 21·6% (18·8–24·3; table 2). The OR for infection with HIV as compared with all adults of reproductive age across all 15 countries was 48·8 (95% CI 21·2–76·3); the OR in low-income and middle income countries was 50·0 (95% CI 26·5–94·3) and 46·3 (95% CI 30·3–70·7) in high-income countries (table 2) and was not statistically different across these strata.

All countries with studies meeting inclusion and exclusion criteria have male-predominant infections, defined as at least 50% of prevalent infections in 2009 being in men. Male predominance of HIV ranged from 59% in Brazil and Thailand to 75% in Peru. Concurrently, the HIV prevalence was higher in men of reproductive age in each of these countries than in women of reproductive age. Meta-analyses were completed to assess the measure of association between HIV in transgender women and that compared with men of reproductive age and also to women of reproductive age. Across all 15 countries, the relative odds for transgender women to have HIV compared with males was 35·5 (95% CI 23·0–54·6), whereas the odds compared with females was 78·0 (95% CI 48·7–124·8). In the five high-income countries included, the odds of transgender

	Number of countries	Sample size of transgender women	Pooled transgender HIV prevalence (95% CI)	Background HIV prevalence	Background male HIV prevalence	Background female HIV prevalence	Pooled ORs (95% CI)
Low and middle income	10	7197	17·7% (15·6–19·8)	0·39%	0·49%	0·29%	50·0 (95% CI 26·5–94·3)
High income	5	3869	21·6% (18·8–24·3)	0·69%	1·00%	0·37%	46·3 (95% CI 30·3–70·7)
Total	15	11066	19·1% (17·4–20·7)	..	..	..	48·8 (95% CI 31·2–76·3)

OR=odds ratio.

Table 2: Subgroup meta-analysis of pooled OR for HIV infection among transgender women by region and prevalence level

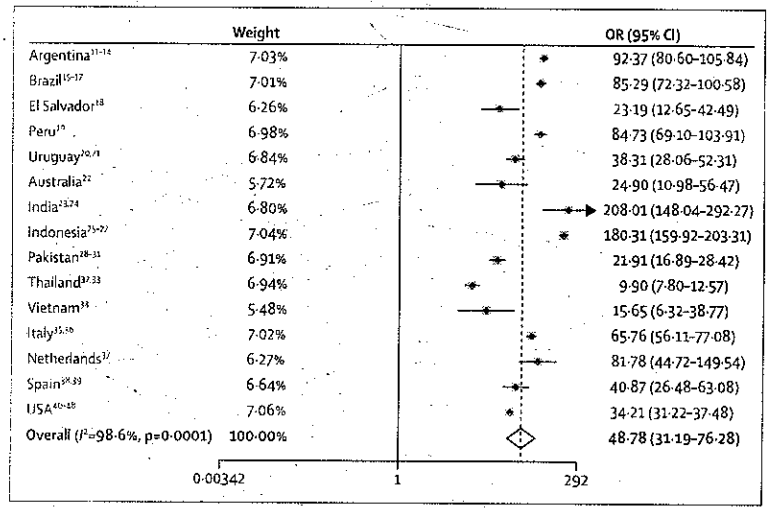

Figure 2: Meta-analysis of risk of HIV infection in transgender women versus all adults 15–49 by country, 2000–11

women having HIV compared with other males was 33·0 (95% CI 20·4–53·3) and with females was 79·7 (95% CI 60·0–106·0). In the ten low-income and middle-income countries included, the odds of transgender women having HIV compared with other males was 37·0 (95% CI 20·4–65·8) and compared with other females was 77·5 (37·5–160·3).

Discussion

Our findings suggest that transgender women are a very high burden population for HIV and are in urgent need of prevention, treatment, and care services. The findings of the meta-analysis of HIV infection rates are remarkable for the severity and consistency of disease burdens across these populations. This was true in all regions including Europe, Central and South America, Asia-Pacific, and the USA, and when stratified by income level of the country. Pooled ORs for HIV ranged from a low of 9·9 in Thailand to a high of 208 in India, but were consistently in the 20–90-times elevated range in most of the world (figure 2). This consistency is particularly notable in view of the wide cultural and social variability of transgender identities and communities, and of the political and legal contexts in which these communities live. How can this consistency be explained and what might these findings mean for transgender women, providers, and HIV programmes?

A primary driver of HIV infection in transgender women, similar to MSM, is the very high transmission probability of unprotected receptive anal intercourse.[49,50] Since transgender women have been consistently identified as engaging in receptive anal sex with men, this biological vulnerability to HIV acquisition is undoubtedly an important factor in the high acquisition risk identified. Yet individual-level risks and sexual practices have been shown to be insufficient to explain disease burdens in other populations at high risk for HIV infection, most notably black MSM in the USA.[51] Network level risks, particularly the HIV prevalence in subgroups, have emerged as crucial drivers of sustained HIV incidence in these populations.[49,51]

This article identified data for HIV in transgender women in just 15 countries (figure 3). All these countries have predominant HIV epidemics in men, and all (except Pakistan, Vietnam, and Indonesia, which have high rates of injecting drug use, although again almost all users are men) have their highest rates of HIV infection in gay, bisexual, and other MSM. This finding too is probably important in understanding the very high rates of HIV infection in transgender women. Epidemics in transgender women happen in the wider context of high burden epidemics in men who have sex with males (irrespective of their sexual identity or partnerships with females), some of whom might also partner with transgender women.[52] Additionally, transgender women are often included as a subpopulation of MSM in epidemiological studies because many share risk behaviours with MSM, such as receptive anal intercourse, which is a much more efficient mode of HIV transmission than penile-vaginal intercourse.[50] However, there remains a dearth of research on HIV acquisition risks from neovaginal intercourse after vaginoplasty, as well as from sex between transgender women and female partners. Transgender women in low-income countries have limited access to any types of sex-reassignment surgery. For example, even in Thailand where sex-reassignment is more accessible, only 11% of transgender women from three cities sampled had undergone surgery.[53] Moreover, recruitment criteria for studies focused on MSM could advertently or inadvertently exclude transgender women because of gender identity or sexual practices. Together, these issues have complicated our understanding of epidemic transmission dynamics and prevalence estimates in these groups. A growing body of research seeks to address this by recruiting specifically transgender women.[53–55]

Our analysis focused on transgender women, but there is also limited data for HIV risks in female-to-male transgender men, some of whom identify as gay and have exclusively or predominantly receptive anal sex with other men.[56] Although transgender men have not traditionally been considered at risk for HIV, recent studies challenge this assumption. Between the years 2006 and 2010 in New York City, 11 (6%) of the 183 newly diagnosed HIV cases among transgender people were in transgender men.[57] In a retrospective analysis of HIV status in attendees of sexually transmitted disease clinics from 2006 to 2009 in San Francisco, HIV infection rates were similar for transgender men (10%) and transgender women (11%).[40]

The systematic review by Herbst and colleagues[5] showed that high-risk sexual practices for HIV are common, and included unprotected receptive anal

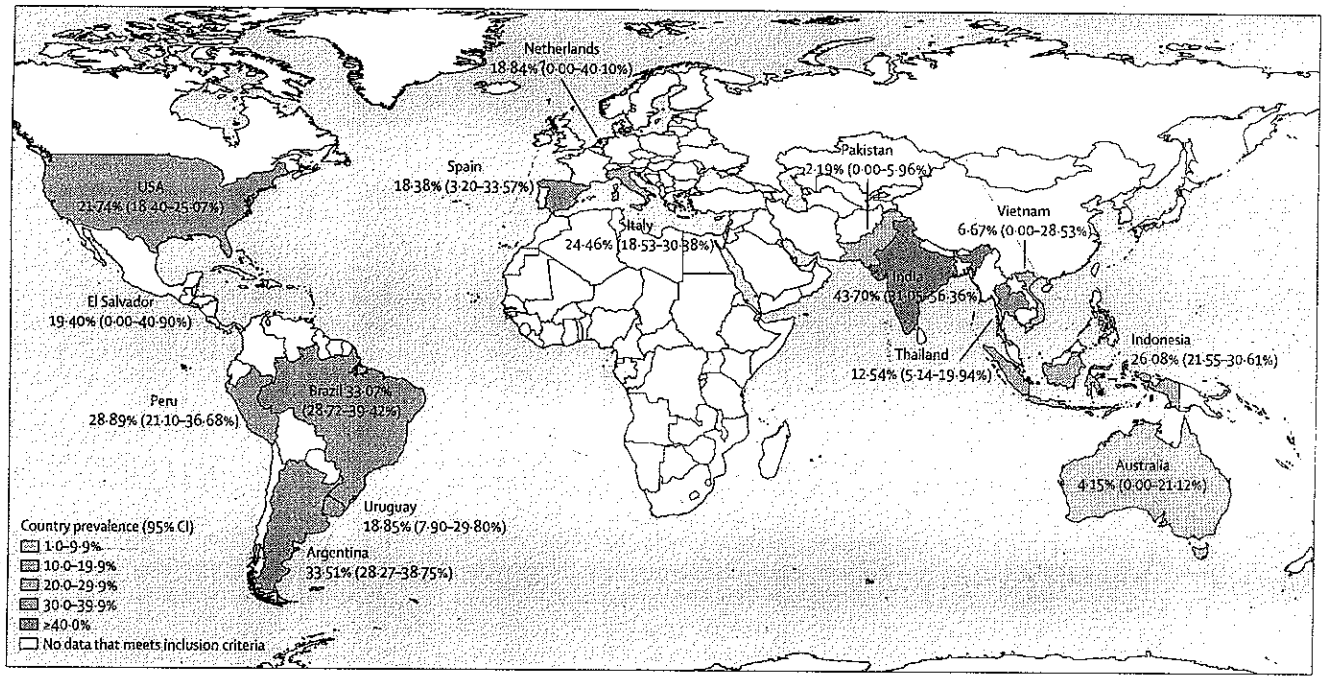

Figure 3: Prevalence of HIV in transgender women, 2000–11

intercourse and multiple sexual partners. Other individual-level risks for HIV include high rates of depression as well as risk of parenteral acquisition through illicit hormone and silicone injections.[58,59] In addition to biological and network-level factors, the structural risks for HIV infection, such as social exclusion, economic marginalisation, and unmet health-care needs, transcend the level of the individual and might also help explain why HIV rates are so high in transgender women compared with other adults.[60] In many of the countries for which data were available, transgender women face stigma, social discrimination, and discrimination in health-care settings, which can lead to exclusion from HIV prevention and treatment services.[61–65] Few health-care workers, from HIV counsellors to nurses and physicians, have received any training on addressing the specific health needs of transgender women. Consequently, consistent access to competent clinical prevention, treatment, or care services is rare, even in many high-income settings and even more so in low-income and middle-income settings.[58,66] Physical and social violence targeted towards transgender women is commonly reported and might be an intermediate variable in the causal pathway towards HIV infection. Many transgender women engage in sex work and transactional sex because of employment discrimination and lack of other income opportunities.[58] Sex work has been consistently associated with high HIV acquisition risks.[6] And finally, transgender women have been noted to have high rates of substance use in some of the countries where data was available, including Thailand, USA, Brazil, Argentina, and Italy.[41,65,67–72]

There are several limitations with the approach used for this meta-analysis. There is probably limited generalisability of pooled estimates to represent the rates of all transgender women in a country, especially in the countries where only small studies have been done. Traditional sampling methods such as time-location sampling, a method through which the study population is sampled randomly from within a sampling frame of times and venues such as brothels or clinics for sexually transmitted infections, might result in oversampling of transgender women who are sex workers or report any transactional sex or transgender women who are seeking medical care related to a sexually transmitted infection or HIV.[73,74] Sampling biases could result in overestimation of the actual HIV prevalence in all transgender women in a country. To address this improved sampling frames are needed, such as is being done with the 2011 census in Nepal that allowed formal registration of third gender people.[75] Studies have previously analysed HIV prevalence between transgender women who are sex workers and those who were not.[6] For this article, we noted that unless the studies exclusively targeted transgender sex workers, the proportion of transgender participants with a history of sex work was often not described, rendering subgroup analysis by sex work impossible. Transgender women who have undergone medical and social transition might assimilate into the general population and not identify themselves as transgender. These women could be less

246

likely to be accrued into epidemiological or prevention studies on transgender populations. Inclusion criteria requiring biological testing for HIV excluded a substantial number of studies where self-reported HIV prevalence was provided. However, in view of the low coverage of HIV testing and potential social desirability bias, objective evidence of HIV infection was deemed necessary. Thus, only data from publications and reports where methods of sampling and testing were described in detail were included in the analysis. Moreover, pooling hides the substantial intracountry spatial variation of the burden of HIV in large countries such as Brazil. Random-effects models were used to partly address the substantial heterogeneity of the HIV prevalence results included in the meta-analysis since these are studies from different populations of transgender women completed across different settings and contexts. Although a random-effects model for meta-analysis was deemed more appropriate, this approach does tend to equalise the weight of studies of different size and precision to the pooled estimate.[76]

In view of the limited worldwide data for transgender women and extraordinary disease burdens we have identified, the present HIV surveillance and prevention interventions for transgender women are clearly inadequate. Studies were available only in countries with male predominant epidemics probably attributable to same-sex practices among men, with no data available in generalised epidemics, including an absence of any quantitative data at all from Africa and the Pacific islands. The high burden of HIV is probably a function of both low coverage rates for effective interventions, and an insufficient range of interventions to reduce HIV infection risks for this population. Transgender-specific interventions are scarce, and no randomised trials of prevention technologies have included sufficient transgender participants to assess efficacy for these people. Consistent condom use with appropriate lubricants is an essential prevention method for anyone engaging in anal sex.[77,78] Coverage of this basic intervention can be low in the lowest income settings. Acceptance and use of condoms remain challenging even where cost and access might not be barriers. The female condom could be an important alternative for transgender women, and this is an important area for acceptability research. Oral pre-exposure prophylaxis has shown efficacy in MSM for HIV prevention, and the iPrEx (Prexposure Prophylaxis Initiative) trial did include some transgender participants (in Thailand, Peru, and Brazil); therefore, this intervention could be promising.[79] New interventions, most crucially a rectal microbicide that could reduce acquisition risk in anal sex, might be essential for transgender women. Inclusion of transgender women in rectal microbicide trials is arguably a research imperative for this population. Further, social and behavioural research that clarifies HIV risk contexts in this population will probably provide the link between efficacy in biomedical studies and real-world effectiveness of prevention, treatment, and care strategies.

Structural change will also be essential. Transgender women and communities are emerging and advocating for their rights as citizens, and their full inclusion in the HIV response. The sexual orientation and gender identity strategy of the Global Fund is a welcome example of expanding efforts at such inclusion.[80] Removing gender dysphoria/gender identity disorder from chapter 5 (mental and behavioural disorders) of the 11th International Classification of Diseases (ICD-11) could provide support for increased visibility of transgender people with less fear of being automatically labelled mentally ill. Greater visibility should be coupled with transgender people and communities having a stronger voice and be counted in national surveillance programmes and in HIV-focused research studies by disaggregating them from MSM. The findings of this meta-analysis make clear that urgency is needed to address this severe and widespread component of worldwide HIV.

Contributors

SDB, TEG, and CB devised the study design and wrote sections of the manuscript. SDB and TP developed the search protocol, which was implemented by TP, SS, and ALW. All authors contributed to the writing of the manuscript. TP, SS, and ALW abstracted data with SB acting as a tiebreaker at all stages. ALW also developed the global prevalence map.

Conflicts of interest

We declare that we have no conflicts of interest.

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ANNEXURE A13

249

PLOS ONE

RESEARCH ARTICLE

The worldwide burden of HIV in transgender individuals: An updated systematic review and meta-analysis

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Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

Abstract

Introduction

Transgender individuals are at risk for HIV. HIV risks are dynamic and there have been substantial changes in HIV prevention (e.g., pre-exposure prophylaxis [PrEP]). It is thus time to revisit HIV prevalence and burden among transgender individuals. The objective of this systematic review and meta-analysis was thus to examine worldwide prevalence and burden of HIV over the course of the epidemic among trans feminine and trans masculine individuals.

Methods

We conducted an updated systematic review by searching PsycINFO, PubMed, Web of Science, and Google Scholar, for studies of any research design published in in a peer-reviewed journal in any language that reported HIV prevalence among transgender individuals published between January 2000 and January 2019. Two independent reviewers extracted the data and assessed methodological quality. We then conducted a meta-analysis, using random-effects modelling, to ascertain standardized prevalence and the relative burden of HIV carried by transgender individuals by country and year of data collection, and then by geographic region. We additionally explored the impact of sampling methods and pre-exposure prophylaxis (PrEP).

Results

Based on 98 studies, overall standardized HIV prevalence over the course of the epidemic, based on weights from each country by year, was 19.9% (95% CI 14.7% - 25.1%) for trans feminine individuals (n = 48,604) and 2.56% (95% CI 0.0% - 5.9%) for trans masculine individuals (n = 6460). Overall OR for HIV infection, compared with individuals over age 15, was 66.0 (95% CI 51.4–84.8) for trans feminine individuals and 6.8 (95% CI 3.6–13.1) for trans masculine individuals. Prevalence varied by geographic region (13.5% - 29.9%) and sampling method (5.4% - 37.8%). Lastly, PrEP effects on prevalence could not be established.

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Competing interests: The authors have declared that no competing interests exist.

Conclusion

Trans feminine and trans masculine individuals are disproportionately burdened by HIV. Their unique prevention and care needs should be comprehensively addressed. Future research should further investigate the impact of sampling methods on HIV prevalence, and monitor the potential impact of PrEP.

Introduction

Transgender individuals, defined as individuals who experience a misalignment between the sex they were assigned at birth and their gender identity or whose gender identity is incongruent with gender norms, [1, 2] are at significant risk for an HIV infection [3]. Individual level risk factors include condomless sex, particularly receptive anal sex, coinfection with other sexually transmitted infections, transactional sex, and the shared use of needles for hormone and/or silicon injections [4–8]. Individual level risk factors do not stand alone; they result from, and intersect with, other factors such as mental health difficulties, substance use, and many forms of marginalization and stigmatization that limit, among other things, educational and work opportunities, as well as legal recognition of one's chosen gender [6, 9–14]. Given that HIV risk among transgender individuals is a dynamic phenomenon, it is important to regularly monitor and update our knowledge of HIV prevalence and burden, such that we can identify trends that can inform policy-making and interventions. Here, we present a comprehensive updated systematic review of HIV prevalence over the course of the epidemic and a meta-analyses of HIV burden among transgender individuals covering literature from 2000 until 2019.

Previous systematic reviews and meta-analyses

Since 2008, a series of systematic reviews and meta-analyses have been published [1, 4, 5, 11, 15–17]. The first, by Herbst and colleagues, [15] investigated HIV prevalence among trans individuals in the United States, covering literature from 1988 until early 2007, and included laboratory-confirmed and self-reported prevalence. Pooled HIV prevalence based upon studies reporting laboratory-confirmed HIV status was, for trans women, 27.7%. HIV prevalence among trans women based upon self-reported HIV status was 11.8%. Among trans men, only one study reported laboratory confirmed prevalence (2%) and self-reported prevalence rates ranged from 0% to 3%. The second systematic review and meta-analysis by Operario et al. [16] set out to assess whether transgender female sex workers (FSW) experienced higher HIV infection rates than cis-gender sex workers and transgender women who do not engage in sex work, using both laboratory-confirmed and self-reported HIV prevalence rates published between 1998 and 2006. HIV prevalence was 27.3% in transgender FSW and 14.7% in trans women who did not engage in sex work. Operario et al.'s meta-analysis further showed that transgender FSW are at significantly higher risk for HIV than cis-gender sex workers and trans women who do not engage in sex work [16]. In 2013, Baral and colleagues [4] published a systematic review and meta-analysis of HIV prevalence among transgender women, covering literature from 2000 to November 2011 and using only laboratory-confirmed HIV prevalence rates. Pooled prevalence was 19.1% and the meta-analytical findings showed that, compared to all adults of reproductive age, the odds ratio for HIV infection in trans women was 49 across the 15 countries included, thus demonstrating that transgender women carry a high burden of HIV [4]. Poteat and colleagues [5] followed up on Baral et al.'s work with a systematic review, but not a meta-analysis, of HIV

prevalence literature published between 2012 and 2015, looking now at both trans feminine and trans masculine populations. Prevalence rates varied substantially based on locale but Poteat et al. [5] concluded, in line with the previous reviews, that HIV prevalence was high in trans feminine populations. They also concluded that data on HIV among trans masculine individuals is still very limited. Almost simultaneously, Reisner and Murchison [1] published a global research synthesis of HIV and STI risks in adult trans men, but not trans women, using 25 studies. They found HIV prevalence rates for trans men ranging from 0% to 4.3% for laboratory-confirmed HIV status and 0% to 10% for self-reported HIV, suggesting that trans masculine individuals may also be more vulnerable to HIV than cis-gender adults. Additionally, in 2017, MacCarthy and colleagues [11] published a global systematic review of HIV and sexually transmitted infections among transgender individuals. They reported HIV prevalence rates ranging from 0% to 17.6% for self-reported HIV status and 0.6% to 34.1% for laboratory-confirmed HIV status. However, given their focus on HIV and STI co-infection, the HIV prevalence rates reported in that review were derived only from studies that also reported STI prevalence rates. The reported prevalence rates were thus based on a mere 6 studies for self-reported HIV status and 13 studies for laboratory-confirmed HIV status. Recently, Becasen et al. [17] published a systematic review and meta-analysis of HIV prevalence among transgender individuals in the United States only using literature published in the United States between 2006 and May 2017. They established that laboratory-confirmed HIV prevalence was 14.1% for trans women and 3.2% for trans men; self-reported prevalence was 16.1% and 1.2% for trans women and trans men, respectively.

Current concerns

Overall, the various systematic reviews and meta-analyses demonstrate that transgender individuals, particularly trans feminine individuals, are disproportionately burdened with HIV but none of the more recent systematic reviews have comprehensively updated Baral et al.'s worldwide systematic review and meta-analysis with both transfeminine and transmasculine individuals. Furthermore, from a methodological perspective, more fine-grained analyses (e.g. by country and year of data collection) are being called for, rather than only pooled analyses by country or region, as has been the methodological approach in previous meta-analyses. Additionally, critique about reported prevalence rates has been levied, with the claim that many studies have relied on convenience samples of, often, transgender women who engage in sex work, which may inflate prevalence rates [18, 19]. Also, previous meta-analyses have not differentiated between various sampling strategies and this may impact meta-analytical findings. Further, there have been substantial and fundamental changes in HIV prevention in recent years. One is the emergence of pre-exposure prophylaxis (PrEP) as a powerful tool for HIV prevention for at risk groups like transgender individuals [5, 8, 20–23]. With these considerations in mind, we feel it is time to revisit worldwide HIV prevalence and burden among transgender individuals. We therefore systematically reviewed literature published between 2000 and 2019 on HIV prevalence among transgender individuals and then conducted a meta-analysis 1) to establish prevalence rates for both trans feminine and trans masculine individuals; and 2) to compare the burden of HIV infection among transgender individuals to individuals over 15 years of age in the countries and regions from which samples were derived, taking year of data collection into account. We then explored the possible impact of sampling methods and of PrEP on prevalence rates and the burden of HIV infection.

Methods

Search strategies and eligibility

We searched, in November 2017 and again in January 2019, PsycINFO, PubMed, Web of Science, and Google Scholar®, for studies in all languages published between January 1st, 2000

and January 28th, 2019. We selected this timeframe in order to gain a complete, comprehensive, and nuanced understanding of worldwide prevalence over and burden of HIV among transgender individuals. We also reviewed the studies included in Baral et al. [4] and in Poteat et al. [5] to ensure that they were covered in our analysis as well. We explicitly overlapped the timeframe in our meta-analysis with those of previous meta-analyses in order to generate comprehensive and robust meta-analytical findings. It also allowed us to explore the impact of applying more refined methodology (standardized vs. pooled prevalence rates) in the meta-analysis, and compare findings delivered by the different meta-analytical approaches. Articles and citations were downloaded and managed in the reference software Mendeley®.

We searched for articles on (the treatment of) HIV and transgender individuals using the following search terms: HIV OR AIDS OR "PrEP" OR "Pre-Exposure Prophylaxis" OR "TasP" OR "treatment as prevention" AND *transgender* OR "MTF" or "male to female transgender" OR "FTM" OR "female to male transgender" OR *transsexual* OR "travesty" OR "cross dresser" OR "koti" OR "hijra" OR "mahuvahine" OR "mahu" OR "waria" OR "katoey" OR "bantut" OR "nadleehi" OR "berdache" OR "xanith". These terms are in line with the terms previously used by Baral et al. [4].

Studies of any research design published in peer-reviewed journals that reported laboratory- confirmed prevalence of HIV among transgender individuals were included. When prevalence rates were pooled across trans feminine and trans masculine individuals or when prevalence was pooled across trans feminine individuals and men who have sex with men (MSM), we contacted the authors and requested separate prevalence rates for the populations included.

Study selection and data extraction

Titles and abstracts were screened by two independent reviewers and articles that clearly did not include HIV prevalence data were excluded, as were duplicates. All articles that met the inclusion criteria and articles that needed further review to ascertain whether they met the criteria were subsequently downloaded. When one reviewer deemed the title and/or abstract potentially relevant and the other did not, the full-text for that article was nonetheless downloaded. Subsequently, the full texts were reviewed. When studies reported duplicate data, the study with the smallest sample size was excluded. If sample sizes were identical, the later publication was excluded. Any conflicts over study inclusion were resolved by project leads (KJ and SS) in conjunction with the researchers running the meta-analysis (MvD and HW). The PRISMA reporting checklist was used to guide the reporting of this study. No protocol was registered for this review.

Data were extracted by two trained coders using a standardized extraction form that included details about sample size, sampling method, sample description, recruitment location, time period of study, age range, transgender type (trans masculine/trans feminine/both), HIV measure (self-reported/laboratory testing), and HIV prevalence or incidence.

Methodological quality assessment

Given the lack of consensus on fitting quality assessment tools for epidemiological studies, [24] we developed criteria specifically for this systematic review and meta-analysis. In doing so, we used and adapted appropriate criteria from the JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data [25]. Studies were deemed of sufficient quality if: 1) biological testing (rather than self-reported HIV status) was used to establish HIV diagnoses, as was done in Baral et al. [4]; 2) study participants were described in sufficient detail, meaning that prevalence was reported, or subsequently obtained directly from the authors, specifically for

trans feminine and/or trans masculine individuals (rather than transgender individuals as a whole group); 3) if the study setting/location was sufficiently detailed; 4) if the data collection timeframe was reported; 5) if prevalence or frequency of HIV diagnosis within the total sample were reported; and 6) if sample size was at least 40 for trans feminine individuals. We did not apply a minimum sample size for studies reporting prevalence among trans masculine individuals as the majority of studies had small sample sizes, and a minimum sample size would have led to the exclusion of most studies reporting HIV prevalence among trans masculine individuals. Additionally, we did not exclude studies based on sampling method as investigating the impact of sampling methods was one of the objectives of this meta-analysis.

Data analyses

First, we used analogous methodology to prior meta-analyses [4, 26, 27]. We grouped studies by country, weighted by sample size. We calculated pooled HIV prevalence and 95% confidence intervals (CIs) per country. We did this separately for trans feminine and trans masculine samples. In line with previous meta-analyses, we then calculated odds ratios per country by dividing the HIV prevalence among transgender individuals (numerator) by the HIV prevalence rate among individuals over 15 years of age in the general population in the country from which the sample was derived (denominator), as reported by the 2017 UNAIDS reports (where prevalence estimates for adults are from 15 years of age onward) [28] and estimations of adult population size from the US Census Bureau International Division [29]. These results are reported in S1 Appendix.

Then, to achieve a more refined methodological analysis, we standardized rather than pooled prevalence rates, and ran the meta-analysis again, this time matching country-level prevalence rates to year(s) of data collection for the included studies. When data were collected over multiple years in the original studies, the median year of the year-span was chosen for the country by year analysis. If HIV prevalence in the sample was 0, we calculated confidence intervals using the Wilson interval [30]. Then, we grouped countries by geographic region (Africa, Latin America, Asia, and Global North) and calculated, per geographic region, the standardized HIV prevalence among trans feminine individuals as well as odds ratios based on weights from each country-year.

Subsequently, given recent discussions about the impact of sampling methods on findings pertaining to HIV prevalence among trans feminine individuals, [18] we grouped studies by sampling method, and calculated standardized HIV prevalence by sampling method. We delineated ten sampling methods, namely cluster sampling, convenience sampling, purposive sampling, respondent driven sampling, snowball sampling, sampling from database health plan, as well as sampling via STI clinic, via hospital, via NGO, and via surveillance. Overlap in categories may exist as some studies used multiple sampling methods. In such cases, we categorized the study under its primary sampling method.

Lastly, we explored possible effects of the introduction of PrEP on HIV prevalence among trans feminine individuals. We focused on US studies only as PrEP has been available in the US since 2012, which is longer than in any other country. We conducted subgroup analyses, with data being collected either prior to the introduction of PrEP (1997–2011), or after the introduction of PrEP (2012–2017).

The meta-analysis was conducted with the statistical software R [31] using the metafor package [32]. We used a random-effects model and the DerSimonian-Laird method to estimate the model. The DerSimonian-Laird Q test and I^2 values were used to assess heterogeneity, with low, moderate, and high heterogeneity corresponding to I^2 values of 25%, 50%, and 75%. [33] We investigated publication bias by inspecting funnel plots [34].

Results

The study selection process is presented in Fig 1. We included 98 studies from a total of 34 countries, of which 78 studies described HIV prevalence in trans feminine individuals, 4 described prevalence in trans masculine individuals, and 16 described both. In total, we included 48,604 trans feminine individuals from 34 countries and 6460 trans masculine individuals from 5 countries. The included studies and relevant characteristics of those studies are reflected in Table 1.

The overall standardized HIV prevalence over the course of the epidemic, based on weights from each country by year, was 19.9% (95% CI 14.7% - 25.1% Table 2) for trans feminine individuals and 2.56% (95% CI 0.0% - 5.9%; Table 3) for trans masculine individuals. The overall OR for HIV infection, compared with individuals over 15 years of age, was 66.0 (95% CI 51.4–84.8; Table 2 and Fig 2) for trans feminine individuals and 6.8 (95% CI 3.6–13.1, Table 3 and Fig 3) for trans masculine individuals. Tables 2 and 3 also show the overall standardized prevalence rates and overall odds ratios per country by year for trans feminine individuals and trans masculine individuals, respectively.

Standardized prevalence rates and overall odd ratios (based on weights from each country by year) according to geographic region are presented in Table 4. In sub-Saharan Africa (n = 1192), standardized HIV prevalence among trans feminine individuals was 29.9% (95% CI 22.5% - 37.3%) and the overall OR for HIV infection, compared to individuals over 15

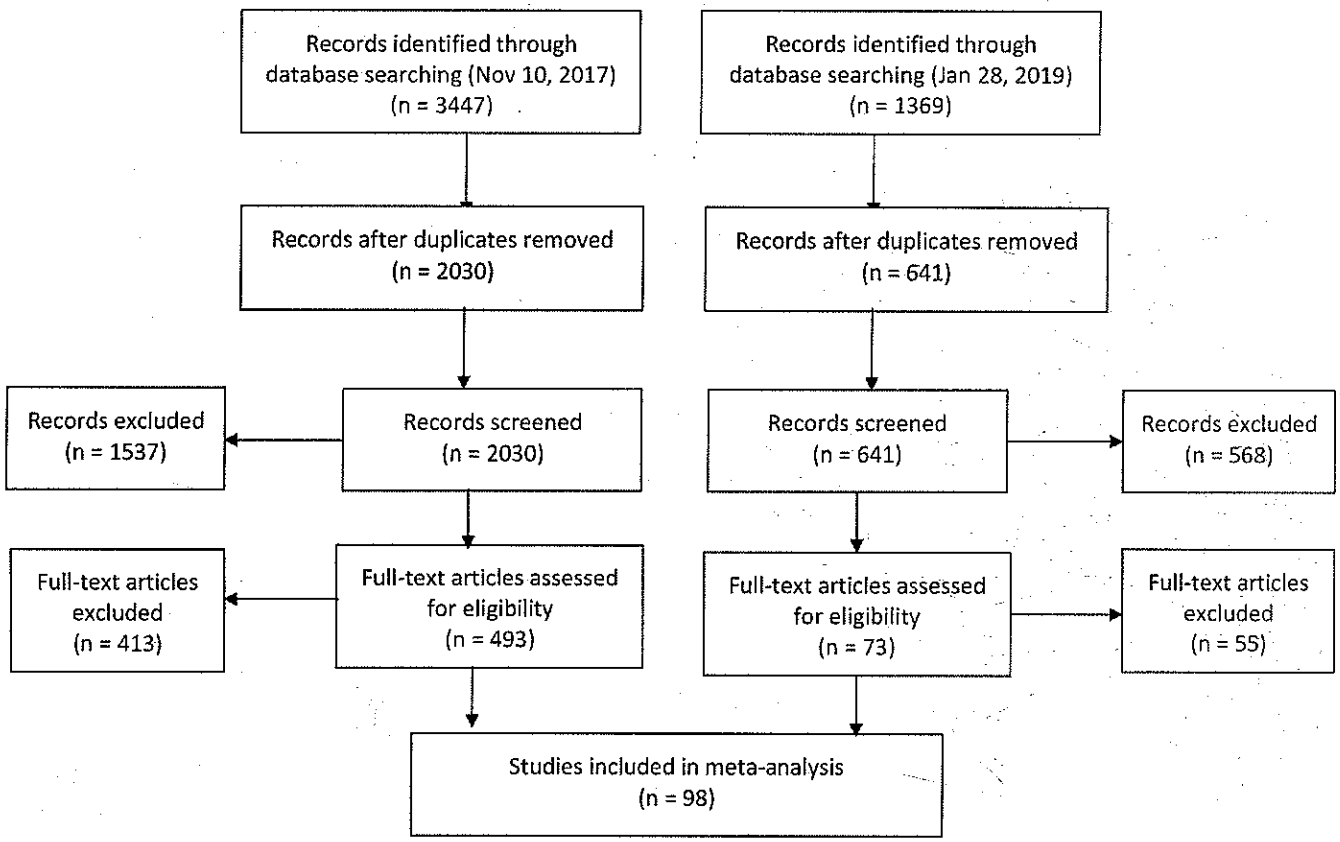

Fig 1. PRISMA flow chart describing the study selection process.

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Table 1. Studies included in review and meta-analysis.

Authors	Year of publication	Year of data collection	Transgender sample	HIV prevalence (%)	HIV frequency (n)	Sample size	Country	Geographic region	Sampling method
Aguayo, Munoz, & Aguilar [35]	2013	2011	TF	27.00%	64	237	Paraguay	Latin America	Cluster sampling
Akhtar, Badshah, Akhtar, et al. [36]	2012	2009–2010	TF (hijras)	21.60%	66	306	Pakistan	Asia	Respondent driven sampling
Altaf [37]	2009	2006–2007	TF (hijras)	4.70%	38	810	Pakistan	Asia	Surveillance
Altaf, Zahidie, & Agha [38]	2012	2008	TF (hijras)	6.40%	75	1181	Pakistan	Asia	Surveillance
Baqi, Shah, Baig et al. [39]	2006	1998	TF (hijras)	0.00%	0	208	Pakistan	Asia	Respondent driven sampling
Barrington, Weijnert, & Guardado et al. [40]	2012	2008	TF	19.00%	13	67	El Salvador	Latin America	Respondent driven sampling
Bastos, Bastos, Coutinho et al. [41]	2018	2016–2017	TF	29.62%	843	2846	Brazil	Latin America	Respondent driven sampling
Bellhouse, Walker, Fairley et al. [42]	2016	2011–2014	TM	3.57%	1	28	Australia	Global North	STI clinic visit
			TF	10.39%	8	77			
Brahmam, Kodavallaa, Rajkumar et al. [43]	2008	2006–2007	TF (hijras)	18.10%	104	575	India	Asia	Cluster sampling
Carballo-Dieguez, Balan, Dolezal et al. [44]	2012	2005–2006	TF	13.00%	12	84	Brazil	Latin America	Respondent driven sampling
Castel, Magnus, Peterson et al. [45]	2012	2006	TF & TM	10.59%	9	85	US	Global North	STI clinic visit
Castillo, Konda, Leon et al. [46]	2015	2008–2009	TF	16.82%	35	208	Peru	Latin America	Snowball
Chariyalersak, Kosachunhanan, Saokhieo et al. [47]	2011	2008–2009	TF	9.30%	13	140	Thailand	Asia	STI clinic visit
Chen, McFarland, Tompson et al. [48]	2011	2009	TM	0.00%	0	59	US	Global North	STI clinic visit
Chhim, Ngin, Chhoun et al. [49]	2017	2015–2016	TF	5.90%	81	1375	Cambodia	Asia	Respondent driven sampling
Clements-Noelle, Wilkenson, Kitano et al. [50]	2001	1997	TM	2.00%	2	123	US	Global North	Respondent driven sampling
			TF	35.00%	137	392			
Colby, Nguyen, Le et al. [51]	2016	2015	TF	18.00%	37	205	Vietnam	Asia	Snowball
Costa, Fontanari, Jacinto et al. [52]	2015	1998–2014	TM	25.00%	0	51	Brazil	Latin America	Hospital
			TF	25.00%	71	284			
Dasarathan & Kalaivani [53]	2017	2011–2014	TF	13.40%	11	82	India	Asia	STI clinic visit
Diez, Bleda, Varela et al. [54]	2014	2000–2009	TF	24.50%	129	529	Spain	Global North	STI clinic visit
Dos Ramos Farias, Garcia, Reynaga et al. [55]	2011	2006–2009	TF	34.10%	93	273	Argentina	Latin America	Respondent driven sampling
Fernandes, Zanini, Rezende et al. [56]	2015	2011–2013	TF	24.34%	37	152	Brazil	Latin America	Cluster sampling
Fernandez-Balbuena, Belza, Urdaneta et al. [57]	2015	2008–2012	TF & TM	45.54%	46	101	Spain	Global North	NGO
Fernandez-Lopez, Reyes-Uruena, Agusti et al. [58]	2018	2014–2016	TF	8.83%	40	453	Spain	Global North	STI clinic visit

(*Continued*)

Table 1. (Continued)

Authors	Year of publication	Year of data collection	Transgender sample	HIV prevalence (%)	HIV frequency (n)	Sample size	Country	Geographic region	Sampling method
Grandi, Goihman, Ueda et al. [59]	2000	1992–1998	TF	40.00%	174	434	Brazil	Latin America	Respondent driven sampling
Green, Hoenigl, Morris et al. [60]	2015	2008–2014	TM	3.00%	1	30	US	Global North	STI clinic visit
			TF	2.00%	3	151			
Grinsztejn, Jalil, Monteiro et al. [61]	2017	2015–2016	TF	31.20%/ 24.20%	141	345	Brazil	Latin America	Respondent driven sampling
Guadamuz, Wimonsate, Varangrat et al. [62]	2011	2005	TF	14.00%	64	474	Thailand	Asia	Convenience sampling
Gutierrez, Tajada, Alvarez et al. [63]	2004	1998–2003	TF	23.00%	14	60	Spain	Global North	Convenience sampling
Guy, Mustikawati, Wijaksono et al. [64]	2011	2006–2008	TF & TM	31.60%	151	477	Indonesia	Asia	STI clinic visit
Habarta, Wang, Mulatu et al. [65]	2015	2009–2011	TM	0.51%	12	2364	US	Global North	STI clinic visit
			TF	2.70%	355	13154			
Hadikusumo, Utsumi, Amin et al. [66]	2016	2012	TF	16.00%	16	100	Indonesia	Asia	STI clinic visit
Hakim, Coy, Patnaik et al. [67]	2018	2014–2015	TF	22.42%	37	165	Mali	Africa	Respondent driven sampling
Hawkes, Collumbien, Platt et al. [68]	2009	2007	TF (khusra)	2.00%	6	269	Pakistan	Asia	Respondent driven sampling
Hiransuthikul, Pattanachaiwit, Teeratakulpisarn et al. [69]	2018	2012–2013	TF	4.26%	2	47	Thailand	Asia	STI clinic visit
Januraga, Wulandari, Muliawan et al. [70]	2013	2009–2010	TF (waria)	36.87%	80	217	Indonesia	Asia	Respondent driven sampling
Jin, Restar, Biello et al. [71]	2019	2012–2015	TF	24.71%	65	263	US	Global North	Convenience sampling
Kaplan, McGowan, & Wagner [72]	2016	2012	TF	10.00%	4	40	Lebanon	Asia	Respondent driven sampling
Kellogg, Clements-Nolle, Dilley et al. [73]	2001	1997–2000	TF	15.00%	37	238	US	Global North	STI clinic visit
Keshinro, Crowell, Nowak et al. [74]	2016	2013–2016	TF	71.43%	75	105	Nigeria	Africa	Respondent driven sampling
Khan, Rehan, Qayyum et al. [75]	2008	2004	TF (hijras)	1.00%	5	409	Pakistan	Asia	Cluster sampling
Kojima, Park, Konda et al. [76]	2017	2013–2014	TF	30.10% / 27.60%	30	89	Peru	Latin America	STI clinic visit
Leinung, Urizar, Patel et al. [77]	2013	prior 2003	TM	0.00%	0	50	US	Global North	Hospital
			TF	8.33%	16	192			
Lipsitz, Segura, Castro et al. [78]	2014	2007–2009	TF	30.00%	64	214	Peru	Latin America	STI clinic visit
Lobato, Koff, Schestatsky et al. [79]	2008	1998–2005	TM	0.00%	0	16	Brazil	Latin America	Hospital
			TF	19.67%	24	122			

(*Continued*)

Table 1. (Continued)

Authors	Year of publication	Year of data collection	Transgender sample	HIV prevalence (%)	HIV frequency (n)	Sample size	Country	Geographic region	Sampling method
Logie, Lacombe-Duncan, Wang et al. [80]	2016	2015	TF	25.20%	26	103	Jamaica	Latin America	Respondent driven sampling
Long, Montano, Cabello et al. [81]	2017	2013–2015	TF	19.68%	61	310	Peru	Latin America	STI clinic visit
Luzzati, Zatta, Pavan et al. [82]	2016	2000–2014	TM	0.00%	0	20	Italy	Global North	Hospital
			TF	12.10%	21	173			
Manieri, Castellano, Crespi et al. [83]	2014	2005–2011	TM	0.00%	0	27	Italy	Global North	Hospital
			TF	5.36%	3	56			
McFarland, Wilson, Raymond et al. [84]	2017	2014	TM	0.00%	0	122	US	Global North	Convenience sampling
Mimiaga, Hughto, Biello et al. [85]	2019	2012–2015	TF	20.60%	48	233	US	Global North	Convenience sampling
Murrill, Liu, Guilin et al. [86]	2008	2004	TF & TM	13.00%	9	92	US	Global North	Convenience sampling
Nemoto, Bödeker, Iwamoto et al. [87]	2014	2000–2001	TF	29.93%	161	538	US	Global North	Purposive sampling
Nguyen, Nguyen, Le et al. [88]	2008	2004	TF ("male transvestites" "bong lo")	7.00%	5	75	Vietnam	Asia	Convenience sampling
Nuttbrock, Bockting, Rosenblum et al. [89]	2013	2004–2007	TF	2.80%	9	230	US	Global North	Convenience sampling
Nuttbrock, Hwahng, Bockting et al. [90]	2009	earlier than 2009	TF	35.98%	186	517	US	Global North	Convenience sampling
Ongwandee, Lertpiriyasuwat, Khawcharoenporn et al. [91]	2018	2015–2016	TF	900.00%	39	435	Thailand	Asia	STI clinic visit
Pando, Gomez-Carrillo, Vignoles et al. [92]	2011	2006–2008	TF	34.00%	38	112	Argentina	Latin America	NGO
Patrascioiu, Lopez, Porta et al. [93]	2013	2006–2010	TM	2.20%	2	92	Spain	Global North	Convenience sampling
			TF	12.60%	18	142			
Peitzmeier, Reisner, Harigopal et al. [94]	2014	2006–2012	TM	0.86%	2	233	US	Global North	Hospital
Pell, Prone, Vlahakis et al. [95]	2011	2004	TM	0.00%	0	17	Australia	Global North	STI clinic visit
			TF	4.26%	6	141			
Pisani, Girault, Gultom et al. [96]	2004	2002	TF (waria)	22.00%	53	241	Indonesia	Asia	Cluster sampling
Pitasi, Oraka, Clark et al. [97]	2019	2010–2013	TM	8.30%	10	120	US	Global North	STI clinic visit
			TF	14.20%	72	506			
Pizzicato, Vagenas, Gonzales et al. [98]	2017	2011	TF	14.59%	104	713	Peru	Latin America	Respondent driven sampling
Poteat, Ackerman, Diouf et al. [99]	2017	2011–2016	TF	2.78%	3	108	Burkina Faso	Africa	Respondent driven sampling
			TF	25.50%	76	298	Côte d'Ivoire		
			TF	59.15%	42	71	Lesotho		
			TF	16.00%	12	75	Malawi		
			TF	37.19%	74	199	Senegal		
			TF	14.17%	17	120	Swaziland		
			TF	17.65%	9	51	Togo		

(*Continued*)

Table 1. (Continued)

Authors	Year of publication	Year of data collection	Transgender sample	HIV prevalence (%)	HIV frequency (n)	Sample size	Country	Geographic region	Sampling method
Poteat, German, & Flynn [100]	2016	2004–2005	TF	43.00%	21	49	US	Global North	Surveillance
Prabawanti, Bollen, Palupy et al. [101]	2011	2007	TF (waria)	24.40%	183	748	Indonesia	Asia	Cluster sampling
Quinn, Nash, Hunkeler et al. [102]	2017	2006–2014	TM	0.31%	9	2892	US	Global North	Database health plan
			TF	5.35%	186	3475			
Rana, Reza, Alam et al. [103]	2016	2012	TF (hijras)	0.80%	7	889	Bangladesh	Asia	STI clinic visit
Raymond, Wilson, Packer et al. [104]	2019	2010	TF	39.17%	123	314	US	Global North	Respondent driven sampling
		2013	TF	36.05%	84	233			
		2016	TF	38.68%	123	318			
Reback, Lombardi, Simon et al. [105]	2005	1998–1999	TF	22.10%	54	244	US	Global North	STI clinic visit
Reisner, White, Mayer et al. [106]	2014	2007	TM	4.35%	1	23	US	Global North	STI clinic visit
Reisner, Vetters, White et al. [107]	2015	2001–2010	TF	7.93%	5	63	US	Global North	STI clinic visit
			TM	2.40%	2	82			
Rich, Scott, Johnston, et al. [108]	2017	2012–2014	TM	0.00%	0	11	Canada	Global North	Respondent driven sampling
Rowe, Santos, McFarland et al. [109]	2015	2012–2013	TF	4.00%	13	292	US	Global North	Snowball
Russi, Serra, Vinoles et al. [110]	2003	1999	TF ("male transvestites")	21.50%	49	200	Uruguay	Latin America	Convenience sampling
Sahastrabuddhe, Gupta, Stuart et al. [111]	2012	1993–2002	TF (hijras)	45.20%	38	84	India	Asia	STI clinic visit
Salas-Espinoza, Menchaca-Diaz, Patterson et al. [112]	2017	2012	TF	22.00%	22	100	Mexico	Latin America	Cluster sampling
Saravanamurthy, Rajendran, Ramakrishnan et al. [113]	2008	2007	TF	17.50%	23	125	India	Asia	Respondent driven sampling
Schulden, Song, Barros et al. [114]	2008	2005–2006	TM	0.00%	0	42	US	Global North	Convenience sampling
			TF	12.00%	67	559			
Seekaew, Pengnonyang, Jantarapakde et al. [115]	2018	2015–2016	TF	8.80%	69	786	Thailand	Asia	Respondent driven sampling
Shan, Yu, Yang et al. [116]	2018	2016	TF	7.60%	38	498	China	Asia	Snowball
Shaw, Lorway, Bhattacharjee et al. [117]	2016	2011	TF (kothi & hijras)	15.30%	27	176	India	Asia	Cluster sampling
Shaw, Emmanuel, Adrien et al. [118]	2011	2005–2006	TF (hijras)	1.00%	10	1162	Pakistan	Asia	Cluster sampling
Sherman, Park, Galai et al. [119]	2019	2016–2017	TF	40.30%	25	62	US	Global North	Convenience sampling
Shinde, Setia, Row-Kavi et al. [120]	2009	earlier than 2009	TF	41.00%	21	51	India	Asia	STI clinic visit
Silva-Santisteban, Raymond, Salazar et al. [121]	2012	2009	TF	30.00%	130	420	Peru	Latin America	Respondent driven sampling
Sotelo & Claudia [122]	2011	2009	TF	34.00%	152	441	Argentina	Latin America	Unknown
Stephens, Bernstein, Philip et al. [123]	2011	2006–2009	TM	2.90%	7	69	US	Global North	STI clinic visit
			TF	11.21%	25	223			

(*Continued*)

Table 1. (Continued)

Authors	Year of publication	Year of data collection	Transgender sample	HIV prevalence (%)	HIV frequency (n)	Sample size	Country	Geographic region	Sampling method
Subramanian, Ramakrishnan, Aridoss et al. [124]	2013	2005–2009	TF	12.00%	48	404	India	Asia	Cluster sampling
Toibaro, Ebensrtejin, Parlante et al. [125]	2009	2002–2006	TF	27.60%	29	105	Argentina	Latin America	STI clinic visit
Van Veen, Götz, van Leeuwen et al. [126]	2010	2002–2005	TF	19.00%	13	69	Netherlands	Global North	Cluster sampling
Waheed, Satti, Arshad et al. [127]	2017	2015–2016	TF	16.40%	22	134	Pakistan	Asia	Convenience sampling
Wasantioopapokakorn, Manopaiboon, Phoorisri et al. [128]	2018	2011–2016	TF	11.85%	82	692	Thailand	Asia	Convenience sampling
Weissman, Ngak, Srean et al. [129]	2016	2012	TF	4.00%	37	891	Cambodia	Asia	Respondent driven sampling
World Health Organization [130]	2016	2015–2016	TF	4.00%	11	299	Philippines	Asia	Surveillance
Wickersham, Gibson, Bazazi et al. [131]	2017	2014	TF	12.00%	24	193	Malaysia	Asia	Respondent driven sampling
Zaccarelli, Spizzichino, Venezia et al. [132]	2004	1993–2003	TF	31.50%	149	473	Italy	Global North	STI clinic visit
Zea, Reisen, del Rio-Gonzalez et al. [133]	2015	2011	TF	13.79%	8	58	Colombia	Latin America	Respondent driven sampling

TF = trans feminine; TM = trans masculine.

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years of age in the countries from which we had prevalence data for trans feminine individuals, matched to year of data collection, was 21.5 (95% CI 6.3–73.7). In Latin America (n = 7917), standardized prevalence was 25.9% (95% CI 20.0% - 31.8%) and the overall OR for HIV infection, compared to individuals over 15 years of age, was 95.6 (95% CI 73.7–122.7). In Asia (n = 14,798), the standardized HIV prevalence was 13.5% (95% CI 2.3% - 17.7%) and the overall OR was 68.0 (95% CI 42.9–107.8). Lastly, in the Global North, thus in Australia, Europe, and North America (n = 24,697), the standardized HIV prevalence was 17.1% (95% CI 13.1% - 21.1%) and the overall OR for HIV infection was 48.4 (95% CI 28.2–83.9).

The standardized HIV prevalence by sampling method is reported in Table 5. The standardized HIV prevalence among transgender individuals when respondent driven sampling was employed (33 studies) was 23.3% (95% CI 18.0% - 28.4%). When prevalence rates were ascertained via STI clinic visits (26 studies), standardized prevalence was 17.4% (95% CI 12.2% - 22.7%). When convenience sampling was employed (14 studies), standardized prevalence was 19.7% (95% CI 14.8% - 24.5%) and when cluster sampling was employed (11 studies), the standardized prevalence was 19.6% (95% CI 14.4% - 24.9%). The remaining sampling methods were relatively infrequently employed (i.e., employed in 5 or fewer studies).

Next, we looked at the potential role of PrEP in reducing HIV prevalence among trans feminine individuals. Prior to the introduction of PrEP (1997–2011), the standardized HIV prevalence in US-based studies was 18.4% (95% CI 14.8% - 22.0%; Table 6) and the overall OR for HIV infection, compared to individuals over 15 years of age in the USA, was 53.5 (95% CI 29.7–96.5). After the introduction of PrEP (2012–2017), the standardized HIV prevalence in

Table 2. Meta-analysis of HIV prevalence in trans feminine individuals compared to all adults (age 15+).

Country	Year of data collection	Number of samples	Sample size	Frequency of HIV among TF in the samples	Prevalence (95% CI)*	Odds Ratio (95%CI)	HIV prevalence in adults (95% CI)
Argentina	2004	1	105	29	27.6 (19.1–36.2)	147.2 (96.0–225.9)	0.258 (0.257–0.260)
Argentina	2007	2	385	131	34 (29.3–38.8)	176 (142.6–217.4)	0.292 (0.290–0.294)
Argentina	2009	1	441	152	34.5 (30–38.9)	168.3 (138.3–204.8)	0.312 (0.310–0.314)
Australia	2004	1	141	6	4.3 (0.9–7.6)	44 (19.4–99.7)	0.101 (0.099–0.102)
Australia	2012	1	77	8	10.4 (3.6–17.2)	92.1 (44.3–191.5)	0.126 (0.124–0.127)
Bangladesh	2012	1	889	7	0.8 (0.2–1.4)	74.7 (35.5–157.3)	0.011 (0.010–0.011)
Brazil	1995	1	434	174	40.1 (35.5–44.7)	304.8 (251.6–369.3)	0.219 (0.218–0.220)
Brazil	2002	1	122	24	19.7 (12.6–26.7)	78 (49.9–121.9)	0.313 (0.312–0.314)
Brazil	2005	1	84	12	14.3 (6.8–21.8)	46.7 (25.3–86.0)	0.356 (0.355–0.357)
Brazil	2006	1	284	71	25.0 (20.0–30.0)	89.3 (68.2–116.8)	0.372 (0.371–0.373)
Brazil	2012	1	152	37	24.3 (17.5–31.2)	69.7 (48.1–100.9)	0.460 (0.459–0.461)
Brazil	2015	1	345	141	40.9 (35.7–46.1)	136.4 (110.1–169.1)	0.504 (0.503–0.505)
Brazil	2016	1	2846	843	29.6 (27.9–31.3)	81.1 (74.9–87.9)	0.516 (0.515–0.517)
Burkina Faso	2013	1	108	3	2.8 (-0.3–5.9)	2.7 (0.9–8.5)	1.043 (1.036–1.049)
Cambodia	2012	1	891	37	4.2 (2.8–5.5)	5.7 (4.1–7.9)	0.756 (0.751–0.762)
Cambodia	2015	1	1375	81	5.9 (4.6–7.1)	9.2 (7.3–11.5)	0.678 (0.673–0.683)
China	2016	1	498	38	7.6 (5.3–10)	187.7 (134.8–261.3)	0.044 (0.044–0.044)
Colombia	2011	1	58	8	13.8 (4.9–22.7)	40.2 (19.1–84.8)	0.397 (0.394–0.399)
Côte d'Ivoire	2015	1	298	76	25.5 (20.6–30.5)	11.7 (9.1–15.2)	2.832 (2.823–2.841)
El Salvador	2008	1	67	13	19.4 (9.9–28.9)	37.9 (20.7–69.4)	0.631 (0.623–0.639)
India	1997	1	84	38	45.2 (34.6–55.9)	183.8 (119.6–282.4)	0.447 (0.447–0.448)
India	2006	1	575	104	18.1 (14.9–21.2)	66.7 (53.9–82.5)	0.330 (0.330–0.330)
India	2007	2	529	71	13.4 (10.5–16.3)	49.8 (38.8–63.9)	0.310 (0.310–0.311)
India	2011	1	176	27	15.3 (10.0–20.7)	65.7 (43.6–99.0)	0.275 (0.275–0.275)
India	2012	1	82	11	13.4 (6.0–20.8)	59.9 (31.7–113.0)	0.258 (0.258–0.258)
India	2009	1	51	21	41.2 (27.7–54.7)	255.3 (146.1–445.8)	0.273 (0.273–0.274)
Indonesia	2002	1	241	53	22 (16.8–27.2)	288.5 (212.7–391.4)	0.098 (0.097–0.098)
Indonesia	2007	2	1225	334	27.3 (24.8–29.8)	160.4 (141.5–181.9)	0.233 (0.232–0.234)
Indonesia	2009	1	217	80	36.9 (30.4–43.3)	214.1 (162.5–282.1)	0.272 (0.271–0.273)
Indonesia	2012	1	100	16	16.0 (8.8–23.2)	61.5 (36.0–105.0)	0.309 (0.308–0.310)
Italy	1998	1	473	149	31.5 (27.3–35.7)	390.4 (321.5–474.1)	0.118 (0.117–0.119)
Italy	2007	1	173	21	12.1 (7.3–17)	65.7 (41.7–103.8)	0.210 (0.208–0.211)
Italy	2009	1	56	3	5.4 (-0.5–11.3)	26.8 (8.4–85.6)	0.211 (0.210–0.212)
Jamaica	2015	1	103	26	25.2 (16.9–33.6)	22.7 (14.5–35.4)	1.468 (1.451–1.484)
Lebanon	2012	1	40	4	10.0 (0.7–19.3)	246.1 (87.5–692.4)	0.045 (0.043–0.047)
Lesotho	2013	1	71	42	59.2 (47.7–70.6)	4.6 (2.9–7.4)	23.950 (23.876–24.023)
Malawi	2013	1	75	12	16.0 (7.7–24.3)	1.8 (1.0–3.3)	9.683 (9.664–9.703)
Malaysia	2014	1	193	24	12.4 (7.8–17.1)	39.9 (26.0–61.1)	0.355 (0.352–0.357)
Mali	2014	1	165	37	22.4 (16.1–28.8)	220.9 (153.1–318.6)	0.131 (0.128–0.133)
Mexico	2012	1	100	22	22 (13.9–30.1)	123.9 (77.2–198.9)	0.227 (0.226–0.228)
Netherlands	2003	1	69	13	18.8 (9.6–28.1)	218.8 (119.7–400.2)	0.106 (0.104–0.108)
Nigeria	2014	1	105	75	71.4 (62.8–80.1)	183 (119.8–279.4)	1.348 (1.346–1.350)
Pakistan	1998	1	208	0	0 (0.0–0.0)	395.9 (24.6–6359.6)	0.001 (0.001–0.001)
Pakistan	2004	1	409	5	1.2 (0.2–2.3)	451.5 (186.8–1091.6)	0.003 (0.003–0.003)
Pakistan	2005	1	1162	10	0.9 (0.3–1.4)	73.0 (39.2–136.1)	0.012 (0.012–0.012)
Pakistan	2006	1	810	38	4.7 (3.2–6.1)	243.0 (175.4–336.6)	0.020 (0.020–0.021)

(*Continued*)

Table 2. (Continued)

Country	Year of data collection	Number of samples	Sample size	Frequency of HIV among TF in the samples	Prevalence (95% CI)*	Odds Ratio (95%CI)	HIV prevalence in adults (95% CI)
Pakistan	2007	1	269	6	2.2 (0.5–4)	78.4 (34.9–176.1)	0.029 (0.029–0.029)
Pakistan	2008	1	1181	75	6.4 (5–7.7)	172.4 (136.4–217.9)	0.039 (0.039–0.040)
Pakistan	2009	1	306	66	21.6 (17–26.2)	560.5 (426.8–736.1)	0.049 (0.049–0.049)
Pakistan	2015	1	134	22	16.4 (10.1–22.7)	214.8 (136.0–339.2)	0.091 (0.091–0.092)
Paraguay	2011	1	237	64	27 (21.4–32.7)	89.5 (67.2–119.3)	0.411 (0.406–0.417)
Peru	2007	1	214	64	29.9 (23.8–36)	158.9 (118.5–212.9)	0.268 (0.266–0.270)
Peru	2008	1	208	35	16.8 (11.7–21.9)	75.3 (52.4–108.3)	0.268 (0.266–0.270)
Peru	2009	1	420	130	31 (26.5–35.4)	166.9 (135.7–205.3)	0.268 (0.266–0.270)
Peru	2011	1	713	104	14.6 (12–17.2)	62.5 (50.7–76.9)	0.273 (0.270–0.275)
Peru	2013	1	89	30	33.7 (23.9–43.5)	176.6 (113.8–274.1)	0.287 (0.285–0.289)
Peru	2014	1	310	61	19.7 (15.3–24.1)	81.1 (61.3–107.4)	0.301 (0.299–0.303)
Philippines	2015	1	299	11	3.7 (1.5–5.8)	50.9 (27.9–92.9)	0.075 (0.074–0.076)
Senegal	2013	1	199	74	37.2 (30.5–43.9)	118.1 (88.6–157.4)	0.499 (0.494–0.504)
Spain	2000	1	60	14	23.3 (12.6–34)	115.6 (63.5–210.2)	0.263 (0.261–0.264)
Spain	2005	1	529	129	24.4 (20.7–28)	109.3 (89.6–133.3)	0.294 (0.293–0.296)
Spain	2008	1	142	18	12.7 (7.2–18.1)	43.6 (26.6–71.5)	0.332 (0.330–0.334)
Spain	2010	1	101	46	45.5 (35.8–55.3)	235.3 (159.1–348.1)	0.354 (0.352–0.356)
Spain	2015	1	453	40	8.8 (6.2–11.4)	28.1 (20.3–38.8)	0.344 (0.342–0.346)
Swaziland	2013	1	120	17	14.2 (7.9–20.4)	74.5 (44.6–124.4)	0.221 (0.218–0.225)
Thailand	2005	1	474	64	13.5 (10.4–16.6)	12.8 (9.9–16.7)	1.202 (1.199–1.205)
Thailand	2008	1	140	13	9.3 (4.5–14.1)	9 (5.1–16)	1.121 (1.119–1.124)
Thailand	2012	1	47	2	4.3 (-1.5–10)	4.4 (1.1–18.1)	1.002 (1.000–1.005)
Thailand	2013	1	692	82	11.8 (9.4–14.3)	13.7 (10.8–17.2)	0.975 (0.973–0.978)
Thailand	2015	2	1221	108	8.8 (7.3–10.4)	10.6 (8.7–12.9)	0.908 (0.906–0.911)
Togo	2013	1	51	9	17.6 (7.2–28.1)	8.9 (4.3–18.2)	2.359 (2.345–2.374)
Uruguay	1999	1	200	49	24.5 (18.5–30.5)	111.3 (80.6–153.8)	0.291 (0.284–0.297)
US	1997	1	392	137	34.9 (30.2–39.7)	190.7 (154.9–234.7)	0.281 (0.280–0.282)
US	1998	2	482	91	18.9 (15.4–22.4)	81.0 (64.5–101.7)	0.287 (0.286–0.287)
US	2000	1	538	161	29.9 (26.1–33.8)	138.9 (115.5–167.1)	0.306 (0.306–0.307)
US	2004	2	141	30	21.3 (14.5–28)	82.3 (55.0–123.2)	0.327 (0.327–0.328)
US	2005	3	852	81	9.5 (7.5–11.5)	31.1 (24.8–39.2)	0.336 (0.335–0.337)
US	2007	1	223	25	11.2 (7.1–15.4)	37.4 (24.7–56.7)	0.337 (0.336–0.337)
US	2009	2	602	195	32.4 (28.7–36.1)	134.8 (113.7–159.9)	0.354 (0.353–0.355)
US	2010	3	16943	664	3.9 (3.6–4.2)	10.8 (10–11.7)	0.375 (0.374–0.376)
US	2011	2	657	75	11.4 (9–13.8)	33.5 (26.3–42.6)	0.383 (0.383–0.384)
US	2012	1	292	13	4.5 (2.1–6.8)	11.8 (6.8–20.7)	0.392 (0.391–0.392)
US	2013	3	729	197	27 (23.8–30.2)	94.1 (79.9–110.8)	0.392 (0.391–0.393)
US	2016	2	380	148	38.9 (34–43.9)	166.6 (135.5–204.7)	0.382 (0.381–0.382)
US	2003	1	192	16	8.3 (4.4–12.2)	18.9 (11.3–31.5)	0.479 (0.478–0.480)
Vietnam	2004	1	75	5	6.7 (1–12.3)	24.7 (10–61.1)	0.289 (0.287–0.290)
Vietnam	2015	1	205	37	18 (12.8–23.3)	68.4 (47.9–97.6)	0.321 (0.320–0.322)
Overall	-	-	-	-	19.9 (14.7–25.1)*	66.0 (51.4–84.8)	-

Note. Heterogeneity: $Q = 6327.25$, $df = 86$, $p < .0001$, $I^2 = 98.63\%$.

*Overall prevalence was calculated by direct standardization based on country-year weights used in meta-analysis.

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Table 3. Meta-analysis of HIV prevalence in trans masculine individuals compared to all adults (age 15+).

Country	Year of data collection	Number of samples	Sample size	Frequency of HIV among TM in the samples	Prevalence (95% CI)*	Odds Ratio (95% CI)	HIV prevalence in adults (95% CI)
Australia	2004	1	17	0	0.0 (0.0–0.2)	28.3 (1.7–470.5)	0.101 (0.099–0.102)
Australia	2012	1	28	1	3.6 (-3.3–10.4)	29.4 (4–216.5)	0.126 (0.124–0.127)
Brazil	2002	1	16	0	0.0 (0.0–0.2)	9.7 (0.6–160.9)	0.313 (0.312–0.314)
Brazil	2006	1	51	0	0.0 (0.0–0.1)	2.6 (0.2–42.1)	0.372 (0.371–0.373)
Canada	2013	1	11	0	0.0 (0.0–0.3)	19.1 (1.1–323.8)	0.227 (0.226–0.229)
Italy	2007	1	20	0	0.0 (0.0–0.2)	11.6 (0.7–191.9)	0.210 (0.208–0.211)
Italy	2009	1	27	0	0.0 (0.0–0.1)	8.6 (0.5–140.9)	0.211 (0.210–0.212)
Spain	2008	1	92	2	2.2 (-0.8–5.2)	6.7 (1.6–27.1)	0.332 (0.330–0.334)
US	1997	1	123	2	1.6 (-0.6–3.9)	5.9 (1.5–23.7)	0.281 (0.280–0.282)
US	2003	1	50	0	0.0 (0.0–0.1)	3.0 (0.2–48.3)	0.331 (0.330–0.332)
US	2005	2	124	2	1.6 (-0.6–3.8)	4.7 (1.2–19.2)	0.345 (0.344–0.345)
US	2007	2	92	8	8.7 (2.9–14.5)	26.2 (12.7–54.2)	0.362 (0.361–0.362)
US	2009	2	292	2	0.7 (-0.3–1.6)	1.8 (0.5–7.3)	0.379 (0.378–0.379)
US	2010	2	5256	21	0.4 (0.2–0.6)	1.0 (0.7–1.6)	0.387 (0.386–0.388)
US	2011	1	120	10	8.3 (3.4–13.3)	22.9 (12–43.8)	0.395 (0.395–0.396)
US	2012	1	30	1	3.3 (-3.1–9.8)	8.7 (1.2–63.7)	0.396 (0.395–0.396)
US	2013	1	122	0	0.0 (0.0–2.8)	1.0 (0.1–16.7)	0.392 (0.391–0.393)
Overall	-	-	-	-	2.56 (0.0–5.9)*	6.8 (3.6–13.1)	-

Note. Heterogeneity: $Q = 13.06$, $df = 16$, $p<0.0001$, $I^2 = 70.62\%$.

*Overall prevalence was calculated by direct standardization based on country-year weights used in meta-analysis.

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US-based studies was 23.7% (95% CI 20.2% - 27.2%) and the OR for HIV infection, compared to individuals over 15 years of age, was 58.0 (95% CI 12.3–275.9). The forest plot of this analysis is presented in Fig 4.

Heterogeneity was high across the studies that included trans feminine individuals ($Q = 6327.25$, $df = 86$, $p < .0001$, $I^2 = 98.63\%$). This may be because the studies were conducted in different countries using different methodologies. Heterogeneity was moderate for the studies that included trans masculine individuals ($Q = 102.06$, $df = 15$, $p<0.0001$, $I^2 = 72.17\%$). The funnel plots showed an asymmetrical distribution of studies and may therefore indicate publication bias (S2 Appendix in Fig A2.1 and Fig A2.2).

Discussion

This systematic review and meta-analysis affirms that transgender individuals are disproportionately burdened by HIV, and that this is the case for not only trans feminine individuals, but also for trans masculine individuals. Using a larger pooled sample than ever compiled before, we ascertained that trans masculine individuals almost seven times more likely to have HIV, and trans feminine individuals are 66 times more likely to have HIV, than other individuals over 15 years of age. Additionally, based on data from 34 countries across major geographic regions, we found support for the contention that the disproportionate burden for HIV carried by transgender individuals is a worldwide phenomenon, and that some regions, such as Africa and Latin America, may be impacted more than others. Further, we established that sampling methods are likely to impact prevalence rates and that, to date, PrEP prevention effects on HIV prevalence cannot be established.

To our knowledge, no previous study has estimated the HIV burden carried by trans masculine individuals worldwide. Reisner and Murchinson [1] did conduct a research synthesis of

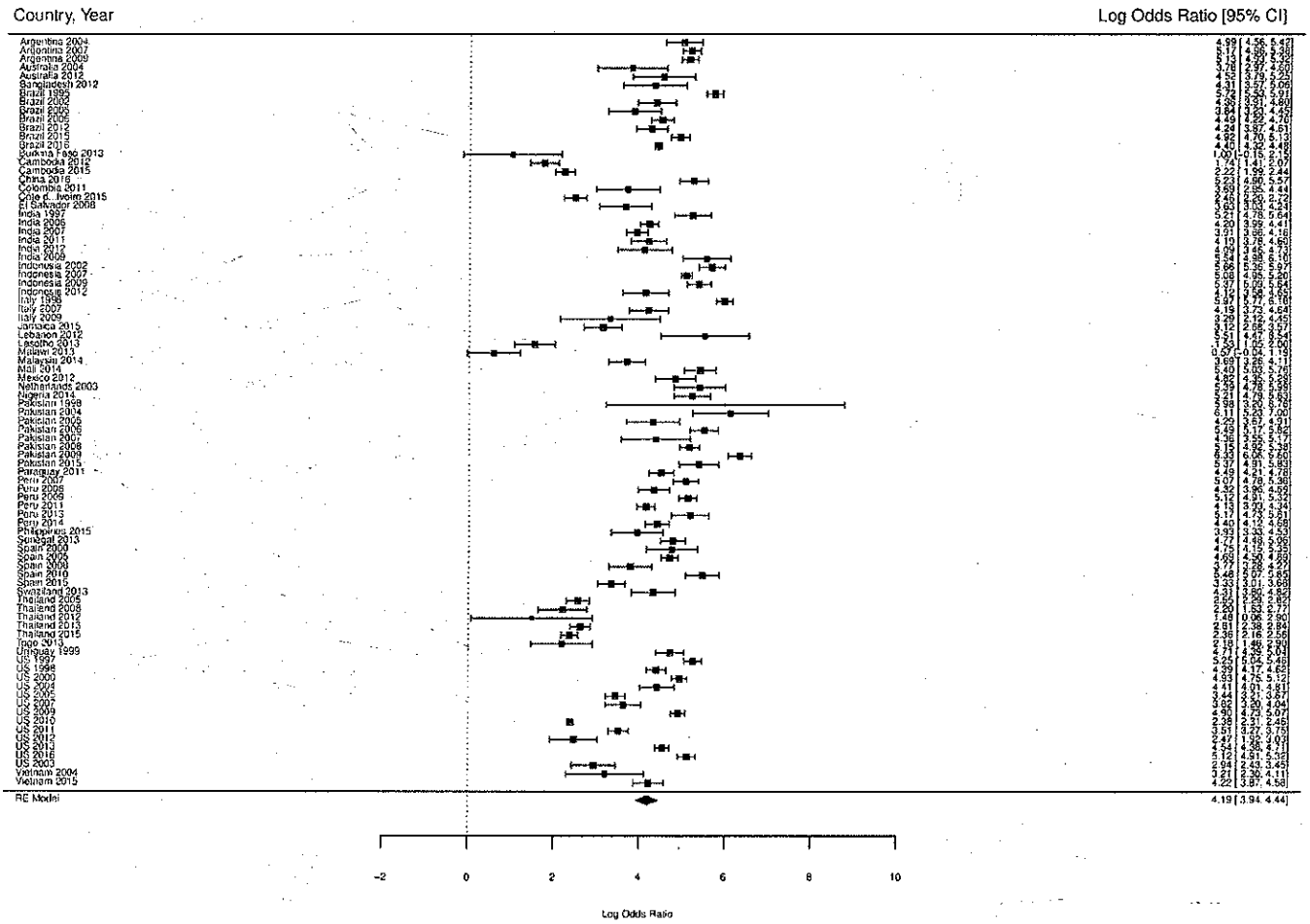

Fig 2. Forest plot of HIV prevalence in trans feminine individuals compared to all adults (age 15+). The scale on the x-axis is log odds ratio. The percentages indicate the weight of each country by year within the meta-analysis. The numbers in the right column are the log odds ratios including their confidence intervals. We converted these log odds ratios into odds ratios, as described in *Table 2*.

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HIV risks in trans masculine individuals where laboratory-confirmed prevalence ranged from 0% to 4.3% and Becasen and colleagues [17] established a laboratory-confirmed estimated prevalence rate of 3.2% but, in both studies, no odds ratios were calculated to ascertain the relative burden of HIV carried by trans masculine individuals. Our finding that trans masculine individuals are almost seven times more likely to have HIV than other individuals over 15 years of age indicates that many trans masculine individuals are indeed at risk for HIV. The presumption that trans masculine individuals almost exclusively have sex with cis-gender women and are therefore not at risk for HIV is thus incorrect [1]. As indicated by Reisner and Murchinson, there is a diverse range of bio-anatomies represented among trans masculine individuals and their partners in sexual encounters, and these should be considered in HIV prevention efforts [1].

Our finding that trans feminine individuals are 66 times more likely to have HIV than other individuals over 15 years of age is a higher estimate that the estimate generated in Baral and colleagues' meta-analysis, [4] where the odds ratio for HIV infection among transgender women was 49.1. We believe that the odds ratio and prevalence rates established in our

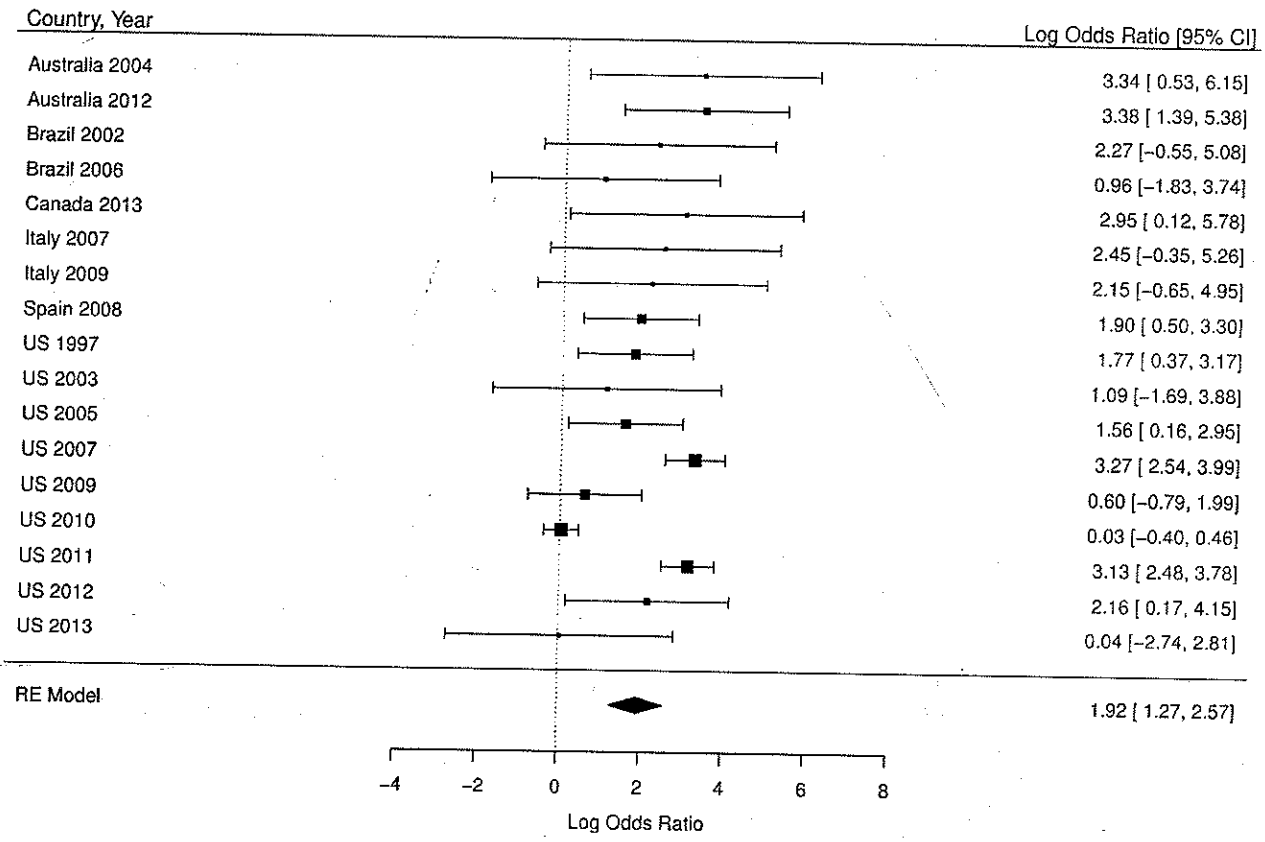

Fig 3. Forest plot of HIV prevalence in trans masculine individuals compared to all adults (age 15+). The scale on the x-axis is log odds ratio. The percentages indicate the weight of each country by year within the meta-analysis. The numbers in the right column are the log odds ratios including their confidence intervals. We converted these log odds ratios into odds ratios, as described in *Table 3*.

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systematic review and meta-analysis are likely more realistic estimations for two reasons. First, our methodological approach used standardized rather than pooled prevalence and took into account not only country but also year of data collection. In a pooled estimate, the total study population and total HIV cases are summed, and then a crude proportion is calculated. This does not take heterogeneity and variation among the included studies into account. Our standardization approach entailed taking the weights from each country-year into account. Without the weighted standardization, a country-year combination that contains large or small

Table 4. HIV prevalence and odds ratios for trans feminine individuals compared to all adults (age 15+), separated by geographic region.

Region	Number of countries	Number of Samples	Sample size	Prevalence (95% CI) *	Odds Ratio (95% CI) *	HIV prevalence in adults (95% CI)*
Africa	9	9	1192	29.9 (22.5–37.3)	21.5 (6.3–73.7)	4.69 (4.67–4.71)
Asia	11	35	14798	13.5 (2.3–17.7)	68.0 (42.9–107.8)	0.344 (0.343–0.345)
Global North	5	35	24697	17.1 (13.1–21.1)	48.4 (28.2–83.9)	0.297 (0.296–0.298)
Latin America	9	23	7917	25.9 (20.0–31.8)	95.6 (73.7–122.7)	0.391 (0.388–0.394)

Note. The HIV prevalence in adults of the population (last column) is the weighted prevalence of the countries included in this meta-analysis, not overall prevalence in the region.

* Results were calculated by direct standardisation of country-year sample size instead of pooling.

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Table 5. HIV prevalence in trans feminine individuals, separated by sampling method.

Sampling method	Number of samples	Sample size	HIV prevalence (95% CI)*
Respondent driven sampling	33	12202	23.3 (18.0–28.4)
STI clinic visit	26	19360	17.4 (12.2–22.7)
Convenience sampling	14	3733	19.7 (14.8–24.5)
Cluster sampling	11	4273	19.6 (14.4–24.9)
Hospital	5	827	15.0 (9.8–20.4)
Snowball	4	1203	11.8 (8.0–15.6)
Surveillance	4	2339	9.1 (6.1–12.0)
NGO	2	213	37.8 (31.5–44.2)
Database health plan	1	3475	5.4 (4.6–6.1)
Purposive sampling	1	538	29.9 (26.1–33.8)

Note. For one study, the sampling method was unknown and is not included in this table.

*: Results were calculated by direct standardisation of country-year sample size instead of pooling.

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study samples is likely to deliver misleading pooled results. The standardized approach thus delivers a more robust estimation than a pooled approach. Second, due to recent increases in the number of studies reporting HIV prevalence among transgender individuals, the total sample of transgender individuals in our meta-analysis was almost four and a half times larger than the pooled sample in Baral et al. [4] Third, the data reviewed in Baral et al. was derived from 15 countries, all of which have male-dominant epidemics, while the data in the meta-analysis reported here was derived from 34 countries, thus lending additional support to the contention that the high burden of HIV among transgender individuals is a worldwide phenomenon.

Our finding that HIV prevalence among transgender individuals appears to be, over the course of the epidemic, higher in African and Latin American regions may point to greater disapproval of gender fluidity and the accompanying marginalization that puts transgender individuals more at risk for HIV in these regions, although we recognize that overall prevalence rates for HIV are higher in Sub-Saharan Africa than in many other regions. Nonetheless, this was the first systematic review and meta-analysis to include samples from Sub-Saharan Africa, and the findings from Sub-Saharan Africa point to a significant burden of HIV among transgender individuals. However, given that, in our analyses, the sample sizes for African regions and Latin America were smaller than the sample sizes for other regions, more research is needed to confirm that transgender individuals in these regions do indeed have higher prevalence rates and carry an even greater burden of HIV. Additionally, future research should also seek to establish HIV prevalence rates and burdens in other understudied regions such as Eastern Europe.

This meta-analysis also demonstrated that sampling methods are likely to impact prevalence rates. This is in line with critiques of sampling methods that were levied in earlier

Table 6. HIV prevalence and odds ratios for trans feminine individuals compared to all adults (age 15+) in US-based studies, according to whether data was collected before or after the introduction of PrEP (2012).

	Number of studies	Sample size	Frequency of HIV among TF in the samples	Prevalence (95%CI)*	Odds Ratio (95%CI)
Before PrEP	18	21022	1475	18.4 (14.8–22.0)	53.5 (29.7–96.5)
After PrEP	6	1401	358	23.7 (20.2–27.2)	58.0 (12.3–275.9)

Note. *Overall prevalence was calculated by direct standardization based on country-year weights used in meta-analysis.

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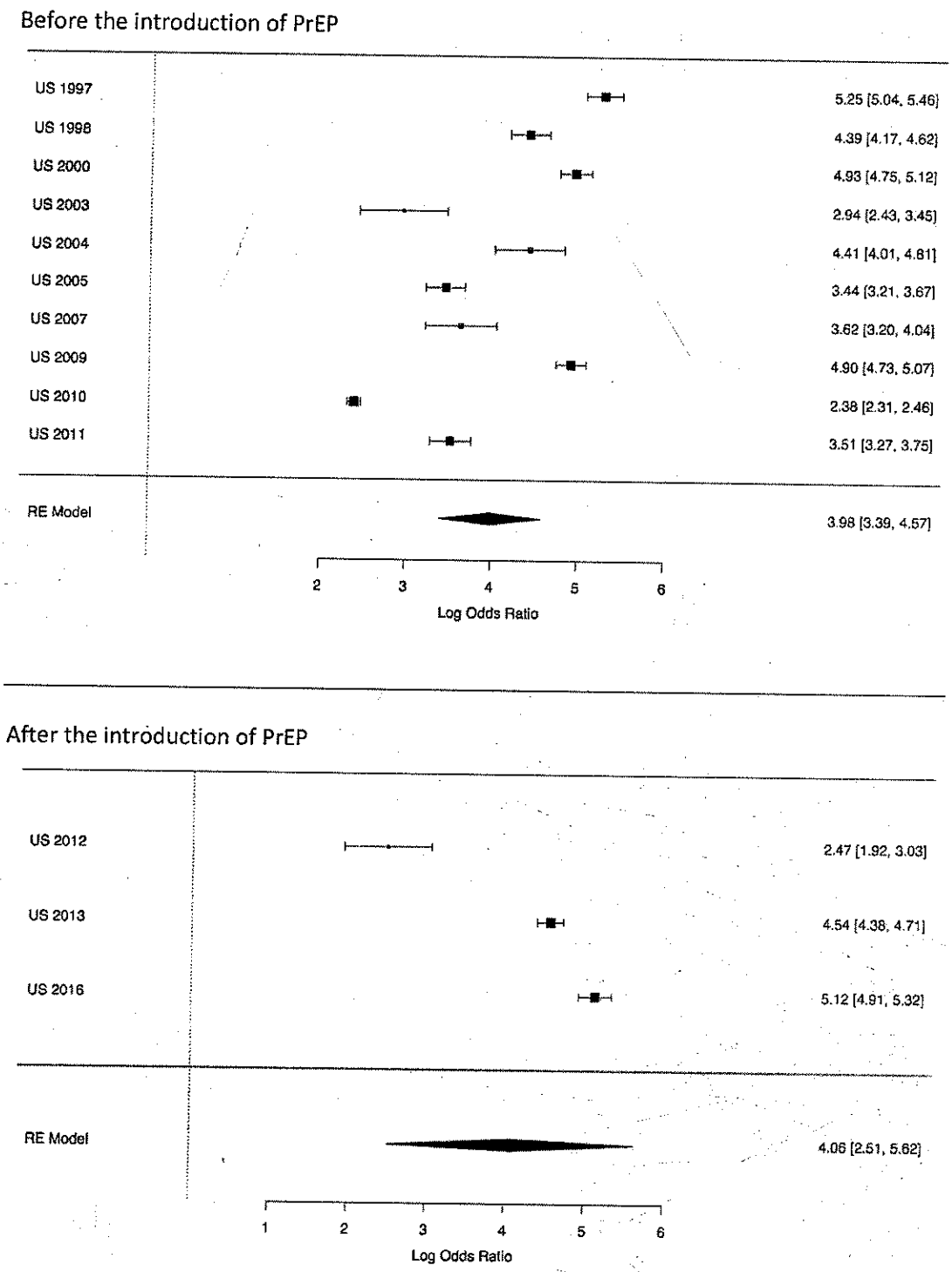

Fig 4. Forest plot of HIV prevalence in trans feminine individuals in the USA compared to all adults (age 15+) in the USA. The 10 country-year including 18 studies above the line are studies where data were collected prior to the introduction of PrEP (2012). The 3 country-year including 6 studies below the line are studies where data were collected after the introduction of PrEP. The scale on the x-axis is log odds ratio. The percentages indicate the weight of each sample within the meta-analysis. The numbers in the right column are the log odds ratios including their confidence intervals.

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commentaries on Baral et al. [4] and in other studies [11, 18, 134]. In our study, the various sampling methods generated very different prevalence rates for HIV in trans feminine individuals ranging from 5.4% to 37.8%. However, the four most frequently used sampling methods, namely respondent-driven sampling, sampling via STI clinics, convenience sampling, and cluster sampling had similar ranges (17.4% to 23.3%). We believe that the impact of sampling methods on prevalence rates is in need of further investigation. In our analyses, unambiguous classification was not always possible and the prevalence rates generated for less common sampling methods may be less reliable. We therefore recommend more comprehensive investigations of the impact of sampling methods in transgender studies.

In our meta-analyses, we also explored the potential role of PrEP availability by comparing studies conducted in the US where data was collected prior to and after the introduction of PrEP. No effect of PrEP could be established yet in our analyses. In fact, we found a higher HIV prevalence rate following the introduction of PrEP. This may be because there were only six studies done following the introduction of PrEP and the total sample after PrEP introduction was smaller and possibly less representative than the 18 studies conducted before PrEP was introduced. It is possible that no reduction in prevalence due to PrEP is the result of PrEP not yet reaching trans individuals. The inclusion of transgender individuals in PrEP trials has been low and access to PrEP for transgender individuals has been limited.[20, 21, 135] However, a qualitative study on PrEP acceptability among transgender women in San Francisco showed that interest was relatively high once participants were informed about the possibilities, thus suggesting that transgender individuals at high risk for HIV need to be informed about PrEP [20]. By the same bio-medical token, future meta-analytic studies should also include Treatment-as-prevention (TasP) effects in their analysis, once sufficiently robust primary data is available.

This systematic review and meta-analysis should be interpreted in light of possible limitations. One is potential sample size biases for studies originating from countries other than the USA, and those of trans masculine individuals. To be able to present a comprehensive, global picture, we set a lower bound for trans feminine individuals, excluding sample sizes of trans feminine individuals less than 40. Yet, we did not apply a minimum sample size for studies among trans masculine individuals as this would have resulted in the exclusion of most studies reporting HIV prevalence among trans masculine individuals. Further, we were not in a position to conduct city-level comparisons and thus acknowledge that our country-level analyses may provide a less precise estimation of the odds ratios, as these do not take into account that, in some countries, the HIV epidemic is more concentrated in certain areas. A third possible limitation is related to our classification of sampling methods. Unambiguous classification was not always feasible and it is possible that the prevalence rates generated for less common sampling methods were less reliable. Fourth, in our meta-analysis, the sample sizes for African regions and Latin America were smaller than the sample sizes for other regions, and this may have impacted the prevalence rates. Additionally, no prevalence rates from Eastern Europe were available. Fifth, our analysis did not account for sexual orientation or the presence or absence of gender reassignment surgery, both of which can impact HIV risk. It is also did not separately ascertain prevalence rates for trans feminine individuals who engage in sex work versus those who do not as primary level data on this is not available on a global scale. We recommend that future research take these potential shortcomings into consideration. Specifically, we recommend that future research explicitly investigate prevalence among subpopulations within the transgender community, and that new studies also take changes in HIV treatment (TasP) and sampling strategies, as well as their interactions, into account, as this will provide an even more comprehensive picture of HIV prevalence and burden among transgender individuals.

Summary and recommendations

That transgender individuals, both trans feminine and trans masculine, are, worldwide, disproportionately burdened by HIV points to the need to pay explicit attention to the unique HIV prevention and care needs of transgender individuals. HIV surveillance and research has traditionally grouped transgender individuals, particularly trans feminine individuals, with men who have sex with men (MSM), thus conflating gender with anatomy. This obscures the unique situation and vulnerabilities to HIV of transgender people [100]. It is therefore necessary to abandon the aggregation of data across MSM and trans feminine women [100, 136]. Additionally, and in line with MacCarthy et al., [11] we also propose disaggregating data across trans feminine and trans masculine individuals [106]. Although some individual and structural risk factors for HIV may be shared by transgender individuals, trans feminine and trans masculine individuals have unique needs [106].

Ascertaining that transgender individuals continue to be disproportionately burdened by HIV is important as it can serve as an impetus for efforts to change this burden. Although transgender individuals in certain regions may more affected by HIV and knowing that transgender processes are diverse across the world, we contend that it is important to, in all regions, target multiple levels of HIV risk, as well as their antecedents and their intersections, while being cognizant of the local context. Targeting individual level risk factors, such as unprotected sex, STI co-infection, and needle sharing, must occur alongside broader efforts to support transgender individuals and reduce stigmatization and marginalization [9, 137, 138].

Paramount to HIV risk reduction is gender affirmation, and in the context of HIV, gender affirmation is particularly important in health care [139–141]. Discrimination, judgment, insensitivity, and a lack of understanding from health care providers prevents many transgender individuals from accessing HIV prevention, testing, treatment, and care services [142]. Gender affirming care is not simply the provision of hormones and gender-affirming surgeries; it also includes using patients' preferred names and pronouns, respecting diversity in gender identities and expressions, employing inclusive intake forms, displaying images that are welcoming to transgender individuals, and creating safe spaces where transgender individuals can be themselves [135, 143]. We recommend integrating HIV prevention and care services in broader gender-affirming care services [6, 135, 142]. This includes actively making PrEP available to transgender individuals [141, 144, 145].

Conclusion

In sum, this systematic review and meta-analyses have served to update our understanding of HIV prevalence over the course of the epidemic as well as HIV burden in both trans feminine and trans masculine individuals using a larger sample than ever before, and has shown that, worldwide, both carry a substantially higher burden of HIV than other individuals over 15 years of age. It has further demonstrated that a by country and year analysis is recommended, that prevalence rates are higher in African and Latin American regions, that sampling methods may impact prevalence rates, and that, at this point in time, the evidence does not suggest that PrEP has played a role in reducing HIV among transgender individuals.

Supporting information

S1 Appendix. Initial meta-analyses.
(DOCX)

S2 Appendix. Fig A2.1. Funnel plot for the countries describing data from trans feminine individuals. Fig A2.2. Funnel plot for the countries describing data from trans masculine

individuals.
(ZIP)

S1 Checklist. PRISMA 2009 checklist.
(DOC)

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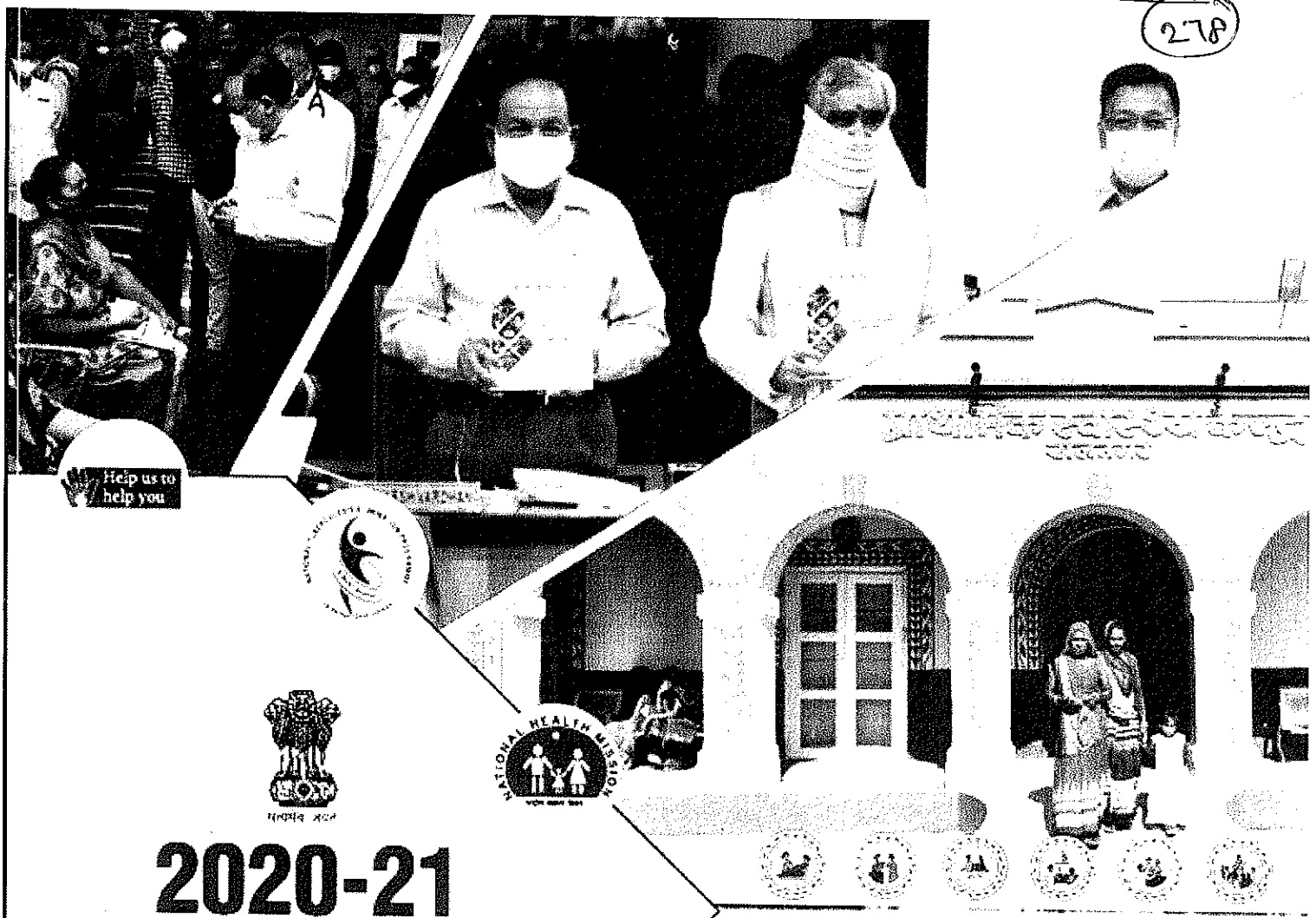
ANNEXURE-A14

278



2020-21
ANNUAL REPORT

Department of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India

consumption of adequately iodized salt (>15ppm) at the household level. No State /UT is free from IDD.

1.7.4.1 Significant achievements of NIDDCP

1) **Enhanced Levels of Production**: Iodized salt production and supply during FY 2020–21 (upto September, 2020) was 38.88 lakh tonnes and 37.90 lakh tonnes respectively;

2) **Establishing Special Cells**: For effective implementation of NIDDCP, 34 States/UTs established Iodine Deficiency Disorders Control Cells in their State Health Directorate;

3) **Setting up Monitoring Labs**: In order to monitor quality of iodized salt and Urinary Iodine Excretion (UIE), 34 States/UTs set up Iodine Deficiency Disorders monitoring laboratories;

4) **Observance of Special Days**: Global IDD Prevention day was observed throughout the country on 21.10.2020. IDD Messages were released on the Ministry of HFW's GoI Twitter handle;

5) **Increase in Estimations of Iodine Content in Salt:** For estimation of iodine content in salt, during FY 2020-21 (upto September, 2020), 8847 salt samples were collected and analysed, out of which 7846 (89%) salt samples were up to the standards (Iodine content > 15 ppm);

6) **Increase in Estimations of UIE**: For estimation of UIE, during FY 2020-21(upto September, 2020), 1668 urine samples were collected and analysed out of which 1551 (93%) samples had urinary iodine level > 100µg/L (optimal); and

7) **Improving Quality of Iodized Salt**: At consumption level, during FY 2020-21 (upto September, 2020), 28,67,418 salt samples were tested and presence of iodine (adequate) found in 25,57,154 salt samples (89%).

1.7.4.2 IEC Activities through State Health Directorates

State/UT Governments have been provided Grants-in-aid for undertaking IEC activities at the local level in their regional languages to ensure impact of IEC activities more effective, including celebration of Global IDD Prevention Day in all Districts. Most States/UTs conducted a range of IEC activities during the year to observe Global IDD Prevention Day on 21.10. 2020.

1.8 NATIONAL AIDS CONTROL ORGANISATION (NACO)

Through its flagship National AIDS Control Programme (NACP), NACO provides leadership to human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS) prevention and control in India through 36 State AIDS Control Societies (SACS) and one Mumbai District AIDS Control Society in States/UTs. NACO has implemented four phases of NACP and currently, NACP Phase-IV (Extension), 2017-21 is under implementation as a 100% central sector scheme. NACP response to HIV/AIDS epidemic in India comprises a comprehensive strategy of prevention, testing, treatment, retention in care and viral suppression. Each of these are supported through critical enablers of IEC, Laboratory Services and Strategic Information Management. Communities which are at the centre of response and equity, gender and respect for rights of communities which have been continuously adopted as guiding principles.

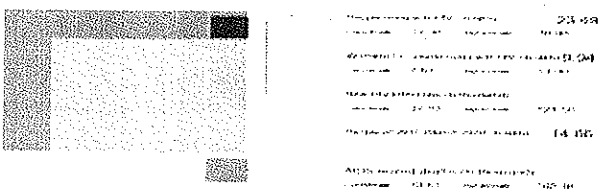
Prevention: Targeted community led interventions for High Risk Groups namely Female Sex Workers (FSW), Men who have Sex with Men (MSM), Transgender/Hijra (TG/H), Injecting Drug

Stigma and Discrimination: The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 towards protecting and securing human rights of persons infected or affected by HIV/AIDS or vulnerable to the disease is under implementation. The Act prohibits discrimination or unfair treatment of HIV-infected people on any grounds.

1.8.1 Overview of HIV Epidemic in India

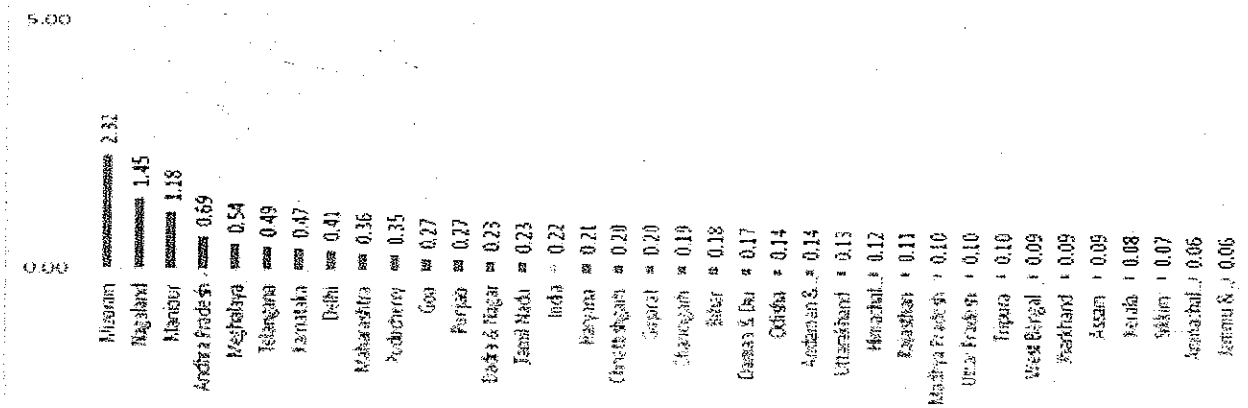
As per India HIV Estimation 2019 report, national adult (15–49 years) HIV prevalence in India is estimated at 0.22% (0.17-0.29%).

Figure 1.8.1: Overview of HIV/AIDS in India, HIV Estimation, 2019



Among the States/UTs, in 2019, Mizoram has shown the highest estimated adult HIV prevalence of 2.32% (1.85-2.84%), followed by Nagaland 1.45% (1.15-1.78%) and Manipur 1.18% (0.97-1.46%).

Figure1.8.2: State/UT-wise Adult (15-49 years) HIV Prevalence in 2019, HIV Estimation, 2019



India is estimated to have around 69.22 (37.03-121.50) thousand new HIV infections in 2019, showing new HIV infections having decreased by 37% since 2010. Nationally, 58.96 (33.61-102.16) thousand AIDS-related deaths in the year 2019 showing 66.00% change in annual AIDS-related deaths since 2010. India is estimated to have had 20.52 thousandmothers who would require ART to prevent MTCT of HIV.

While overall HIV prevalence is low, there are population groups which are more affected by HIV than the rest. The Figure below depicts HIV prevalence among population group of ANC attendees, inmates in central jails, FSWs, MSMs, IDUs, H/TGs, single male migrants (SMM) and long-distance truckers (LDT). For ANC and inmates in central jails, the last round of surveillance was conducted in 2019 while for FSW, MSM, IDU, H/TG people, migrants and LDTs in 2017. As evident, HIV epidemic in India continues to be concentrated among high-risk population. HIV prevalence among IDU is almost 28 times higher than that of overall adult prevalence. Similarly, HIV prevalence among H/TG, MSM and FSW has HIV prevalence which is 6 to 13 times higher than the adult prevalence. Among inmates in central jails, where population with high-risk behaviour are over-represented, HIV prevalence is almost nine times higher than the adult prevalence.

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ANNEXURE A-15

281

ORIGINAL ARTICLE

Blood donor deferral policies across Europe and characteristics of men who have sex with men screened for human immunodeficiency virus in blood establishments: data from the European Men-who-have-sex-with-men Internet Survey (EMIS)

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Background. The predominant mode of transmission of human immunodeficiency virus (HIV) in Europe is male-to-male transmission. Men who have sex with men (MSM) are deferred from donating blood in many countries, but nevertheless do donate blood. Based on data from 34 countries, we estimated the proportion of MSM screened for HIV in the context of a blood donation and identified individual factors associated with this HIV screening in order to propose possible public health interventions.

Materials and methods. In 2010, the first European MSM Internet Survey (EMIS) collected self-reported data on HIV testing from >180,000 MSM in 38 European countries. Using logistic regression, demographic and behavioural factors associated with screening for HIV in blood establishments were identified. Stratified by European sub-region, we analysed the proportion of MSM screening in blood establishments by time elapsed since last negative HIV test.

Results. Donor eligibility criteria for MSM vary across Europe with most countries using permanent deferral. The Western region had the lowest (2%) proportion of MSM screened in blood establishments and the Northeastern region had the highest (14%). Being <25 years old, not disclosing sexual attraction to men, never having had anal intercourse with a man, having a female partner, living in a rural area, and certain European sub-regions or countries of residence increased the likelihood of being screened in blood establishments.

Discussion. In spite of deferral policies, MSM are screened for HIV in the context of blood donations. Gay-friendly testing services are rare in rural areas, and young men might be reluctant to disclose their sexual orientation. Recent developments, such as home sampling, might offer new testing possibilities for those not reached by established services yet wishing to know their HIV status. Donor selection procedures should be improved. Both interventions might help to further reduce the risk of transfusion-transmitted infections.

Keywords: men who have sex with men, blood donation, HIV, screening, behavioural surveillance.

Introduction

In the early 1980s, national authorities established measures to prevent human immunodeficiency virus (HIV) from entering the blood supply. Permanent deferral of men who have sex with men (MSM) from donating blood was an attempt to increase blood safety in response to the AIDS epidemic in the 1980s. In 1985, tests to detect the virus became available. Nevertheless, a residual risk of transfusion-transmitted HIV remains. This is mainly due to undetected infectious donations in the window period of an infection when infectious disease markers are not yet detectable. In 1985, the first generation HIV antibody tests had a window period of approximately 56 days[1]. To reduce the residual risk of transfusion-transmitted HIV infections, HIV nucleic acid amplification testing to screen blood donations was implemented in most European countries starting in 1997[1,2]. This reduced the window period for potentially infectious donations from approximately 56 to less than 14 days[3]. Many countries worldwide retain the permanent deferral of potential donors with a sexual behaviour that puts them "at high risk" of acquiring

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282

infectious diseases which are transmissible by blood, including HIV[4].

In addition to donor screening, donor history questionnaires and donor interviews are used to identify eligible donors according to defined donor deferral criteria. These criteria aim to minimise the risks for donors as well as for recipients and include for instance medical conditions, travelling, invasive procedures such as tattooing, and sexual exposures.

With respect to sexual exposures, European Union (EU) legislation[5] distinguishes behaviour "at risk" and "at high risk" linked to temporary and permanent deferral from blood donation, respectively. No further definition of "risk" and "high risk" is given, nor are risk categories defined. Member States are required to transfer European regulations into national law. In order to comply with the EU directive, most member states kept the permanent deferral for MSM that was already in place since the identification of the HIV, mainly because of the epidemiological situation. In 2012, the predominant mode of HIV transmission in European countries was male-to-male sexual transmission, accounting for 40% of all new HIV diagnoses[6]. While MSM constitute approximately 3% of the adult male population[7,8], they represented more than 30% of all people newly diagnosed with HIV in ten countries and more than half of all newly diagnosed people in another nine countries[6]. The rate of HIV diagnoses per 100,000 population decreased slightly from 6.4 per 100,000 in 2006 to 6.2 per 100,000 in 2012 and yet the burden of new diagnoses attributed to sex between men increased by 11% since 2006[6].

The permanent deferral of MSM from donating blood is discussed intensively[9]. Irrespective of deferral criteria, some MSM donate blood. The first pan-European MSM Internet Survey (EMIS) in 2010 included questions on HIV testing sites within the context of HIV screening or diagnosis. We estimated the proportions of MSM who reported that they were last screened for HIV in the context of a blood donation for 34 European countries in the EMIS dataset and identified associated individual factors. Based on these findings we propose and discuss possible public health interventions to reduce the use of blood establishments for HIV test-seeking by groups with increased risk of HIV infection.

Materials and methods

Review of current practices

We searched literature in PubMed and Scopus as well as the grey literature to generate an overview of the implementation of the European Council directive 2004/33/EC with respect to MSM and blood donation in 2010 and expanded the search to other countries with participants in EMIS.

Population and data collection

The EMIS survey sample and methods have been fully described in detail elsewhere[10,11]. In short, five primary and 77 secondary partners active in public health or in the MSM community developed a questionnaire in 25 different languages which was featured in gay online social media and by gay community organisations. Users of gay online media were invited by instant messages or banner advertisements to participate in an anonymous online survey. The core slogan to promote the survey was "Be part of something huge". It was intended to promote the benefits to the community of taking part in the study and to be intriguing and mildly suggestive of the sexual content of the survey. The questionnaire explored sexual health, access to healthcare, behaviours as well as socio-economic factors. The typical completion time was 20 minutes. No financial incentives were given. No IP addresses were collected. The survey was accessible online from June 6 to August 31, 2010. More background information, including the English version of the questionnaire, is available at www.emis-project.eu.

Questionnaire items used for this study

The questions on blood donation depended on the respondent's answer regarding his HIV status. Men who indicated that they were HIV-positive were asked for the year of the diagnosis. Men who replied that they had screened negative were asked when they had had their last test. All respondents were asked about the setting and could choose from ten options: primary care, private practice, hospital outpatient clinic, hospital as an inpatient, HIV testing service, blood donation, home testing, bar/pub/club/sauna, mobile medical unit, or elsewhere.

Data analysis

We explored the regulations regarding MSM and blood donation in effect in the various countries in 2010, classifying them as permanent deferral, deferral for six or 12 months, deferral based on individual risk assessment, no MSM-specific rule, and information unavailable (if no or contradictory information was found). We calculated the proportions of participants using blood establishments among all testing sites regardless of HIV status.

We classified replies on time of last HIV screening into three categories -more than five years previously, between one and five years previously, and within the preceding year- and stratified countries by nine geographic regions, as proposed by the EMIS investigators[11]. We classified testing venues into two groups: blood establishment versus all others. The dataset had already been checked for consistency.

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Participants had provided informed consent and were at or above the age of homosexual consent in their country of residence. Respondents who did not express sexual preference for other men or who did not report sexual contacts with other men had already been excluded[11]. However, we further excluded people who gave inconsistent answers on their age or their HIV testing history. In addition, participants who had never been tested for HIV, had not received their results or did not indicate where they had been tested were excluded. Those tested while hospitalised were excluded because most HIV tests would not have been self-initiated in this setting. Finally, we excluded countries with less than 100 valid questionnaires.

We considered HIV testing at a blood establishment as opposed to other testing sites as an outcome and performed a logistic regression analysing contributing factors including age, population size of place of residence, seeking testing for sexually transmitted infections (STI) within the preceding 12 months and presence of symptoms when doing so, anal intercourse with men, relationships with women, social disclosure of having sex with men (outness) and EMIS geographic region. We performed this analysis for HIV-negative and HIV-positive participants separately because, on the one hand, social, demographic and behavioural factors might have been influenced following the HIV diagnosis and, on the other, because participants who screened negative within the context of a blood donation might return in the future.

To describe regional developments in screening at blood establishments, we calculated the time elapsed (within the preceding year, within one-five years previously, more than five years previously) since the last negative HIV test in the context of a blood donation for MSM divided by geographic region to explore whether the proportion of MSM testing at blood establishments remained stable over time.

We used Stata® 13.1 (StataCorp, College Station, TX, USA) to calculate odds ratio (OR), p-values, standard errors and 95% confidence intervals (95% CI).

Human subject protection

The Research Ethics Committee of the University of Portsmouth, United Kingdom (REC application number 08/09:21) approved EMIS 2010.

Results

Human immunodeficiency testing and blood donation among men who have sex with men

The dataset, cleaned according to the EMIS study protocol[10] and provided for analysis to study partners, contained 174,209 valid questionnaires. The EMIS population has been described fully elsewhere[10,11]. We excluded questionnaires containing discrepant answers on the participant's age or his HIV testing history (n=302, 0.13%). We further excluded participants who did not test for HIV (n=50,629, 29%) or had never received their test result (n=1,216, 0.70%), participants who did not indicate where they tested for HIV (n=204, 1.1%), and participants who tested for HIV as an in-patient (n=6,382, 3.7%). Finally, we excluded those from countries with fewer than 100 valid questionnaires (Bosnia and Herzegovina, Moldova, the former Yugoslav Republic of Macedonia and Malta) (n=264, 0.15%). Our analysis was thus based on 115,212 (66%) questionnaires. General practitioners, family doctors, and doctors in private practice accounted for 38% of test settings, followed by outpatient clinics (27%), dedicated HIV testing services (24%), bars, pubs, clubs, saunas or mobile medical units (0.7%) and home testing (0.7%). Three percent of MSM said they tested without specifying the location ("elsewhere"). Blood donation represented 6.3% of all HIV test settings, with 2.9% among participants diagnosed positive and 6.7% among those tested negative (Table I).

Table I - Number of participants using different settings to test or screen for HIV in 34 European countries, EMIS 2010.

	HIV positive (diagnosis)		HIV negative (last screening)		Total	
	N	%	*N*	%	*N*	%
General practitioner, family doctor, private physician	5,086	43.2	38,908	37.6	43,994	38.2
At a hospital or clinic as an out-patient	3,493	29.7	27,326	26.4	30,819	26.7
At an HIV testing service	2,406	20.4	25,026	24.2	27,432	23.8
At a blood bank, while donating blood	344	2.9	6,950	6.7	7,294	6.3
Used a home testing kit	48	0.4	731	0.7	779	0.7
Mobile medical unit	29	0.3	822	0.8	851	0.7
In a bar or pub, club or sauna	15	0.1	408	0.4	423	0.4
Elsewhere not otherwise specified	359	3.0	3,262	3.2	3,621	3.1
Total	11,780	100	103,432	100	115,212	100

EMIS: European Men-who-have-sex-with-men Internet Survey; HIV: human immunodeficiency virus.

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Implementation of regulations regarding men who have sex with men and blood donation

At the time of the survey in 2010, permanent deferral of MSM was in place in most member states. For the 34 countries represented in EMIS, we could confirm rules regarding MSM in 25 countries: permanent deferral was in place in 20 countries, deferral for six or 12 months after the last sexual contact was used in two EU-member states, two member states implemented an individual risk assessment and one country had no MSM-specific policy in place.

The proportions of participants reporting HIV tests in blood establishments were highest in Lithuania (17%), Latvia (14%), Austria (12%) and Croatia (12%) and lowest in the Netherlands (1.3%), Norway (1%) and the United Kingdom (0.9%). The reported proportions were above 10% in nine countries, between 5-9.9% in 12 countries, between 2-4.9% in six countries and less than 2% in seven countries. When aggregated by regulations in place in each country, the groups were statistically different. The proportions of MSM donating blood were highest in countries with individual risk assessment (9.4% [95% CI: 9.0-9.8%]), somewhat lower in countries with a limited deferral period (7.4% [95% CI: 6.1-8.8%]) and lowest in countries with permanent deferral (5.4% [95% CI: 5.3-5.6%]), yet blood donation took place in spite of the permanent deferral rule and varied greatly among countries (range, 0.9-12.1%) (Table II).

Characteristics of men who have sex with men who last screened human immunodeficiency virus negative or tested positive while donating blood

Compared with those testing elsewhere, MSM diagnosed with HIV at blood establishments were more likely to be under 25 years old, live in a smaller town, be in a steady relationship with a woman and less out about their sexual attraction. The EMIS sub-region of the individual's country of residence increased odds to donate blood in only three regions (Table IIIa).

Compared with those testing elsewhere, MSM who last screened HIV-negative in blood establishments were more likely to be under 25 years old, live in a smaller town, be in a steady relationship with a woman and less likely to have engaged in anal intercourse with a man, to be screened for other STI in the absence of symptoms, and to be out about their sexual attraction. Compared to the EMIS sub-region West, all other sub-regions contributed, in addition to the size of the place of residence, to the likelihood of seeking out blood donation (Table IIIb).

Time lapse since the last negative human immunodeficiency virus screening at a blood establishment by EMIS sub-region

Blood establishments, among all testing locations, play a role ranging from a cumulative 1.4% in the West to 14.2% in the Northeastern sub-region. Stratified by time since last HIV test and region, we observed that in regions with a low proportion of blood establishments as testing sites, the proportion of MSM reporting blood establishments as testing sites remained stable, notably in the West, Northwest and East. However, in regions with a higher proportion of blood establishments as testing sites, we observed that MSM with HIV tests within the preceding year more often reported blood establishments as a testing site than MSM who had tested longer ago. Compared to other testing options, blood establishments were visited proportionally more frequently. The proportion of all HIV screening tests in blood establishments in the EMIS sample exceeded 10% within the preceding year and represented a substantial testing venue for MSM in five sub-regions: Central-West (10.3%), non-EU Southeast (10.4%), Southwest (10.8%), Central-East (11.7%) and Northeast (18.0%) (Figure 1).

Discussion

Despite being based on the same EU directive, regulations regarding blood donation depending on behaviour and risk vary across Europe and range from lifelong deferral of MSM to a temporary deferral after last sex with a man to individual risk assessment by a physician. MSM are the most affected group in the HIV epidemic in Europe[6,12-16]. Nevertheless, the permanent deferral of MSM from blood donation in most European countries is subject to intense debate and legal challenges[17-19]. In order to achieve a harmonised European approach, a working group at the Council of Europe was created to provide scientific grounds for donor deferrals due to different sexual behaviour[20,21]. A Resolution of the Committee of Ministers concluded that countries should only decide on a temporary deferral policy for a given risky sexual behaviour when having demonstrated that this sexual behaviour does not put the donors at high risk of acquiring severe blood-borne infectious diseases[20]. The United Kingdom analysed their HIV surveillance data and initiated a change in deferral policy in 2011 and now restricts only men who have had sex with another man within the preceding 12 months. The United Kingdom is also the country in which MSM were least likely to screen themselves in the context of a blood donation, which indicates that most testing needs are met elsewhere. Donor surveillance and well-designed mathematic modelling of the residual risk will indicate whether the safety of the blood supply has

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Table II - Setting of last HIV test as reported by EMIS participants who had been tested for HIV, 2010 and deferral policies for men who have sex with men in 2010.

Regulation in 2010	Country	Test in blood establishment	Test in other setting	Number of participants reporting testing	% blood establishment	% CI
Permanent deferral	Austria	338	2,462	2,800	12.1%	10.9-13.3%
	Croatia	31	226	257	12.1%	8.6-16.7%
	Greece	176	1,541	1,717	10.3%	8.9-11.8%
	Turkey	81	765	846	9.6%	7.8-11.8%
	Estonia	32	308	340	9.4%	6.7-13.0%
	Czech Republic	121	1,166	1287	9.4%	7.9-11.1%
	Germany	2,879	32,170	35,049	8.2%	7.9-8.5%
	Slovenia	32	455	487	6.6%	4.7-9.2%
	Portugal	235	3,374	3,609	6.5%	5.8-7.4%
	Switzerland	163	3,647	3,810	4.3%	3.7-5.0%
	Finland	42	1,162	1,204	3.5%	2.6-4.7%
	Luxemburg	6	207	213	2.8%	1.3-6.2%
	Sweden	54	2,160	2,214	2.4%	1.9-3.2%
	Belgium	54	3,048	3,102	1.7%	1.3-2.3%
	France	154	8,773	8,927	1.7%	1.5-2.0%
	Denmark	19	1,204	1,223	1.6%	1.0-2.4%
	Ireland	20	1,315	1,335	1.5%	1.0-2.3%
	Netherlands	37	2,851	2,888	1.3%	0.9-1.8%
	Norway	13	1,307	1,320	1.0%	0.6-1.7%
	United Kingdom	107	12,135	12,242	0.9%	0.7-1.1%
	Subtotal	4,594	80,276	84,870	5.4%	5.3-5.6%
6- or 12-month deferral	Slovakia	33	228	261	12.6%	9.1-17.3%
	Hungary	72	1,092	1,164	6.2%	4.9-7.7%
	Subtotal	105	1,320	1,425	7.4%	6.1-8.8%
Individual risk assessment	Italy	1,145	9,452	10,597	10.8%	10.2-11.4%
	Spain	725	8,599	9,324	7.8%	7.2-8.3%
	Subtotal	1,870	18,051	19,921	9.4%	9.0-9.8%
No specific rule	Russian Federation	177	3,064	3,241	5.5%	4.7-6.3%
Unavailable information	Lithuania	42	197	239	17.6%	13.2-23.0%
	Latvia	46	272	318	14.5%	11.0-18.8%
	Poland	194	1,446	1,640	11.8%	10.4-13.5%
	Serbia	58	496	554	10.5%	8.2-13.3%
	Romania	110	1,000	1,110	9.9%	8.3-11.8%
	Bulgaria	42	581	623	6.7%	5.0-9.0%
	Cyprus	9	137	146	6.2%	3.2-11.5%
	Ukraine	40	881	921	4.3%	3.2-5.9%
	Belarus	7	197	204	3.4%	1.6-7.1%
	Subtotal	548	5,207	5,755	9.5%	8.8-10.3%
Total		7,294	107,918	115,212	6.3%	6.2-6.5%

HIV: human immunodeficiency virus; EMIS: European Men-who-have-sex-with-men Internet Survey; 95% CI: 95% confidence interval for the EMIS dataset.

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Table IIIa - Factors associated with having been tested for HIV in the context of a blood donation, participants with HIV-positive test outcomes in 34 countries in Europe, logistic regression analysis, EMIS 2010.

Characteristics		OR	95% CI
Age	>25 years	ref	
	≤25 years	**2.3**	1.6-3.5
Being out about sexual preference(s)	Generally out	ref	
	Out to a few people	**1.6**	1.2-2.2
Relationship with female partner(s)	Not in a relationship with a female partner	ref	
	In a relationship with female partner(s)	**2.3**	1.3-4.0
Anal intercourse with a male partner	Ever	ref	
	Never	1.1	0.13-8.1
Symptoms when STI screening (<12 months)	STI test due to symptoms	ref	
	No STI test	1.3	0.9-1.9
	STI test without symptoms	0.6	0.8-1.6
Population size of place of residence	≥1,000,000	ref	
	500,000-999,999	1.1	0.8-1.6
	100,000-499,999	**1.7**	1.2-2.3
	10,000-99,999	**1.6**	1.2-2.3
	<10,000	**1.8**	1.2-2.6
Region of residence (EMIS region)	West	ref	
	Southeast (EU)	0.9	0.1-6.8
	Northwest	1.1	0.4-2.9
	East	1.6	0.7-3.7
	Central East	1.7	0.7-4.1
	Southeast (non-EU)	2.3	0.5-9.7
	Central West	**2.3**	1.6-3.3
	Southwest	**3.6**	2.4-5.0
	Northeast	**8.6**	2.9-26.1

HIV: human immunodeficiency virus; EMIS: European Men-who-have-sex-with-men Internet Survey; OR: odds ratio (bold: p≤0.05); 95% CI: 95% confidence interval; ref: reference category; STI: sexually transmitted infection; EU: European Union.

been affected; preliminary data covering the first two years following the change in deferral period showed no increase in HIV-positive blood donations[22].

Although MSM are banned from donating blood in most European countries, the EMIS survey showed that 6.3% of participants reported having had their last HIV test within the context of a blood donation. In countries with a permanent deferral policy in place, 5.4% of the reported last HIV tests took place in the context of a blood donation. This finding varies greatly among countries (range, 0.9-12.1%) and might reflect the availability, acceptance and ease of access to HIV testing services.

The majority of participants (65%) reported testing in traditional medical settings such as general practitioners' and family doctors' offices, in private practices or as outpatients. In our study, these settings were more often reported by HIV-positive participants. By contrast, dedicated HIV testing services, mobile medical units, home testing, testing at bars, pubs, clubs and saunas, as well as blood establishments were more often reported as testing sites by HIV-negative participants. This finding might be attributable to more frequent screening and thus fewer diagnoses because, with the exception of blood establishments, these settings emphasise HIV screening.

EMIS data allowed us to determine characteristics of MSM who had either received their HIV diagnosis at a blood establishment or last tested HIV negative there. In many aspects, HIV-positive and -negative men did not differ. Compared to their peers who tested in regular settings, MSM who tested at blood establishments were younger and less open about their sexual preference. Notably, they were also more likely to be in a relationship with a woman. MSM frequenting blood establishments more commonly came from smaller towns and rural areas, suggesting -among other things- fewer regular testing sites and a lack of perceived anonymity/confidentiality at regular HIV testing sites

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Table IIIb - Factors associated with having been tested for HIV in the context of a blood donation, participants with HIV-negative test outcomes in 34 countries in Europe, logistic regression analysis, EMIS 2010.

Characteristics		OR	95% CI
Age	>25 years	ref	
	≤25 years	**2.3**	2.1-2.4
Being out about sexual preference(s)	Generally out	ref	
	Out to a few people	**1.8**	1.7-1.9
Relationship with female partner(s)	Not in a relationship with a female partner	ref	
	In a relationship with female partner(s)	**1.6**	1.4-1.7
Anal intercourse with a male partner	Ever	ref	
	Never	**1.9**	1.7-2.1
Symptoms when STI screening (<12 months)	STI test due to symptoms	ref	
	No STI test	**2.9**	2.5-3.4
	STI test without symptoms	**2.3**	2.0-2.7
Population size of place of residence	≥1,000,000	ref	
	500,000-999,999	**1.2**	1.1-1.4
	100,000-499,999	**1.4**	1.3-1.5
	10,000-99,999	**1.8**	1.6-1.9
	<10,000	**1.8**	1.6-1.9
Region of residence (EMIS region)	West	ref	
	Northwest	**1.5**	1.2-1.9
	East	**3.9**	3.2-4.7
	Southeast (EU)	**5.0**	4.0-6.2
	Central West	**6.0**	5.3-6.8
	Central East	**6.7**	5.7-6.8
	Southwest	**6.9**	6.0-7.8
	Southeast (non-EU)	**7.0**	5.7-8.7
	Northeast	**9.5**	7.4-12.0

OR: odds ratio (bold: p≤0.05); 95% CI: 95% confidence interval; ref: reference category; STI: sexually transmitted infection; EMIS: European Men-who-have-sex-with-men Internet Survey; EU: European Union.

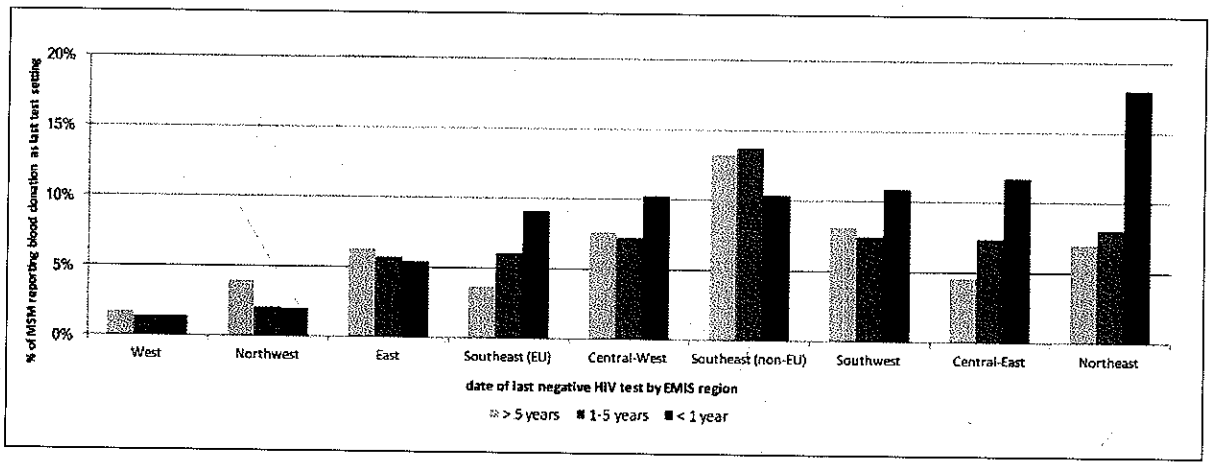

Figure 1 - Proportion of participants who had their last negative HIV test at a blood establishment by time elapsed since last test and EMIS Region, EMIS 2010.
West (Belgium, France, Republic of Ireland, the Netherlands, United Kingdom); Northwest (Denmark, Finland, Norway, Sweden); East (Belarus, Russia, Ukraine); Southeast (EU) (Bulgaria, Cyprus, Romania); Central-West (Austria, Switzerland, Germany, Luxembourg); Southeast (non-EU) (Croatia, Serbia, Turkey); Southwest (Spain, Italy, Portugal, Greece); Central-East (Czech Republic, Hungary, Poland, Slovenia, Slovakia); Northeast (Estonia, Lithuania, Latvia). HIV: human immunodeficiency virus; EMIS: European Men-who-have-sex-with-men Internet Survey.

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as possible reasons for seeking HIV screening while donating blood. Difference in HIV status affected two factors: HIV-negative MSM at blood establishments were less likely to self-report ever having had anal intercourse and were also less likely to have screened for STI other than HIV within the preceding 12 months.

These findings were not significant among those diagnosed HIV-positive in the context of a blood donation. This may be explained by the fact that STI testing, irrespectively of symptoms, is part of routine HIV care; it does not imply that men who tested positive within the context of a blood donation had already been screened for STI before being diagnosed with HIV. Routine annual STI testing, including HIV screening, is recommended to sexually active MSM in most countries by responsible authorities to identify infections early and prevent transmission[23,24]. Our results suggest that HIV-negative MSM using blood establishments as testing sites are less well reached by this recommendation or do not have easy access to such combined testing sites or perceive barriers to access them and are, therefore, less likely to be screened for STI when asymptomatic. They also reported fewer STI tests due to symptoms within the preceding 12 months.

An important factor characterising MSM testing at blood establishments was the country of residence, which we summarised by EMIS regions. Compared to the West region, the other regions ranged from having a small impact (testing 1.5 times more likely in the countries forming the Northwest region) to being the single largest predisposing factor (OR=9.5 in the Northeast). For HIV-negative men, the region of residence was a statistically significant factor, while only three regions (Central-West, Southwest, Northeast) remained significant in the analysis of HIV-positive men.

We expected to find that MSM frequenting blood establishments would report having no or limited access to HIV screening. Instead, this assumption was not confirmed, even among those who had been screened recently at blood establishments. This question was not significant in preliminary analysis and thus excluded from the regression model presented here. Blood establishments might be perceived as alternative HIV test settings. This should be discouraged because HIV testing in blood establishments is done for product safety and is not, therefore, accompanied by counselling. Although the residual risk of transfusion-transmitted HIV infections is very low, test-seeking donors with sexual risk exposures might pose a risk to blood safety because of window period donations or test failures. The fact that blood establishments are used as HIV testing sites underlines the need to improve donor selection.

Donor selection could be refined by better donor questionnaires, by educating potential donors and by ensuring a confidential environment at the donation site[9]. Studies on unreported deferrable risks among donors demonstrated that the personal perception of risk is a key to non-compliance with donor selection criteria[25,26]. Well-designed donor history questionnaires and appropriate donor education material are, therefore, needed to prevent donations from individuals at risk of acquiring transfusion-transmissible infections[9]. In a recent study in Italy, 8.3% of HIV-positive repeat tested donors reporting a risk behaviour <4 months before donation stated that they had donated blood in order to be tested for HIV[27]. In another survey in Australia, the proportion of HIV-negative test-seekers among non-compliant donors was lower (0.74%) but test-seeking donors had a significantly greater likelihood of non-disclosure during the pre-donation assessment (adjusted OR, 2.39; 95% CI: 1.14-5.04) in the logistic regression[28].

To assess whether blood establishments have become more or less popular testing sites among those screening negative, we compared the proportions of MSM reporting their last HIV screening from this setting among all test settings within three time frames (more than five years previously, between one and five years previously, within the preceding one year). We found that in the West, Northwest and East the proportions of men who tested at a blood establishment within the preceding year were lower than those of men living in the same regions who had tested longer ago. We do not, however, know why they chose other test settings. By contrast, in the Southeast (EU), Central-West, Southwest, Central-East and Northeast the proportions of MSM who had tested at blood establishments among all sites within the preceding year were higher compared to the proportions who last tested longer ago. Regions in which the use of blood establishments was generally higher were also those in which larger proportions of MSM screened at blood establishments more recently. As discussed above, MSM who tested at blood establishments were not more likely to report a lack of testing facilities and they might have considered blood donation an appropriate setting. Yet in countries with more recent or less pronounced epidemics[29-31], blood establishments play a more important role, possibly because these countries tend to have a less well or more recently established network of testing facilities. It is also possible that the recommendation for sexually active MSM to screen for HIV has reached this group and some might use blood donation to follow this advice in an easily accessible and stigma-free setting. The need to disclose sexual risk behaviours to get tested in other test settings may be a barrier for some MSM, particularly if there is no easy access to gay-friendly and anonymous testing services. This of course points to the need for public health actions to provide appropriate and acceptable test settings to meet these prevention needs and also safeguard the allogeneic blood supply.

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Although home testing kits are available in only a few countries, 0.7% of EMIS participants reported having used such kits for their last HIV test. The EMIS survey did not go into details regarding whether home testing (e.g. analysing a specimen with a quick test at home) or home sampling (taking a specimen at home, sending it to a laboratory for analysis) was used. Home sampling may be particularly useful in rural areas in which the demand for specialised services might be too low to offer MSM friendly, convenient, readily accessible, sustainable and cost-effective services[32]. A study in the United Kingdom investigated targeted home sampling, i.e. when a lay-person collects their own specimen to send to a laboratory for analysis, while counselling is by phone and online. This study was promoted specifically for MSM and sub-Saharan migrants. Previously untested black African heterosexual women with more sexual partners and MSM were attracted by the convenience offered through home sampling and were reached successfully with this strategy[33]. Home sampling would have two main advantages: epidemiological data, such as age group and sex, could be sent anonymously to the laboratory to maintain surveillance and individuals seeking testing could be informed about risks and risk management and other needs for prevention (e.g. STI screening) while pointing them to the various appropriate settings. Given the convenience and confidentiality of the home setting, home sampling could be considered as an alternative for MSM who would otherwise screen for HIV by donating blood, in addition to optimising existing or creating new testing possibilities.

Our study has a number of limitations. First, the EMIS sample was not random. The dataset was likely to be biased towards better educated, internet-literate MSM. This sample may have thus been less likely to seek HIV screening by donating blood. As a consequence, our study may underestimate the proportion of MSM who use blood donation centres to seek HIV testing. Second, the EMIS questionnaire did not differentiate MSM who donated blood in order to get tested from those who donated for other, e.g. altruistic, reasons, did not specify the number of past and planned subsequent donations, and did not specify whether donors had used a confidential unit exclusion option to withhold their blood from being used for transfusion. Because EMIS did not collect this information, the impact of these donations on blood safety cannot be estimated.

Conclusions

In conclusion, in most European countries sexually active MSM are permanently deferred from donating blood, and yet such individuals do donate blood and are screened for HIV in this context. MSM who are less open about their sexuality and who have poor access to anonymous or confidential MSM-friendly care in less densely populated areas more often use blood donation to screen for HIV. On the basis of these findings, we can formulate a number of recommendations. We need, first, a closer public health assessment to safeguard the blood supply and to offer appropriate prevention services and, second, local exploration of the reasons for increased proportions of MSM choosing to test at blood donation centres compared to other testing sites. Furthermore, we need to strengthen alternative testing capacities and consider novel testing approaches, such as home sampling for those not reached by existing testing avenues. Public health measures must, therefore, make sure that alternatives are made available to dissuade test seeking during blood donation by meeting screening needs outside this context.

Acknowledgements

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EMIS Associated Partners: Robert Koch Institute (Germany); Sigma Research, London School of Hygiene and Tropical Medicine (United Kingdom); University College, Maastricht (The Netherlands), CEEISCat (Spain), *Regione Veneto* (Italy), *GIZ-Gesellschaft für Internationale Zusammenarbeit* (Germany).

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Authorship contributions

SBS analysed the data and wrote the paper; RO and AJS revised and commented on the paper; UM analysed data, commented and revised the paper. All Authors critically reviewed the text and shared thoughts and inputs.

The Authors declare no conflicts of interest.

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ANNEXURE A16

291

Email **Dr. Anil Kumar**

RESPONSE: Supreme Court Case for discussion tomorrow Re: Some Agenda Papers pertaining to Meeting Re: Meeting Notice of National Blood Transfusion Council (NBTC) on 26.11.2022 at 12:00 PM

From : anubha@thalassemiapag.org Mon, Nov 28, 2022 12:02 PM

Subject : RESPONSE: Supreme Court Case for discussion tomorrow Re: Some Agenda Papers pertaining to Meeting Re: Meeting Notice of National Blood Transfusion Council (NBTC) on 26.11.2022 at 12:00 PM

To : Dr. Anil Kumar <dr.anilkumar@nic.in>

Cc : Secretary NMC office <Secyoffice-nmc@nic.in>, Prof (Dr) Atul Goel <dghs@nic.in>, Atul Goel <atul.goel28@lhmc-hosp.gov.in>, btsnbtc2000@gmail.com, drmegha1603@gmail.com, pagthals@thalassemiapag.org

Dear Dr. Kumar,

Greetings from TPAG!

At the outset, I would like to place on record my heartfelt gratitude on behalf of Thalassemia Patients Advocacy Group (TPAG) for inviting me to the NBTC meeting held on 26th Nov 2022 to represent TPAG. In reference to the agenda discussed in the said meeting, please find below our preliminary response on AGENDA 1 in the interest of time. We shall submit our response on the other agenda items shortly:

Also, please note that further mails to TPAG may kindly be marked to pagthals@thalassemiapag.org INSTEAD OF pagthals@gmail.com.

AGENDA 1

1. We, at TPAG, being a community of patients falling under RPWD Act 2016, completely understand and appreciate the trials and tribulations witnessed by transgenders in the society. We are all for equality and equal opportunity. However, blood donation and rules and guidelines formed therefor may not be the right platform for any particular community to seek equality under. Being from the blood recipient community, we strongly oppose any attempt whatsoever to dilute the NBTC guidelines which have been formulated to ensure safe blood transfusions. Identifying transgender persons, men having sex with men and female sex workers as "at risk" category for the purpose of blood donation should not be seen as an act of discrimination but only as an eligibility criterion for blood donation in line with public health and with the policy of greater good of greater number. Further, such categories of persons have not been identified "at risk" for the first time by NBTC guidelines only. Relevant data may be examined in this regard. Furthermore, notwithstanding anything said before and without prejudice to our interests, it is submitted that even the Constitution of India makes provisions for reasonable

discrimination in certain cases. Relevant parallels may be examined in this regard too. As far as thalassemia is concerned, it is one of the 21 disabilities identified under RPWD Act 2016 and any dilution of NBTC guidelines that has the potential of impacting safety of the community may be in direct contradiction of the Act which is a statute passed by the parliament of the country. Relevant provisions of RPWD Act 2016 may be referred to in this regard.

2. India is a vast country and substantial distance still needs to be covered in terms of implementation of safe blood practices across the country primarily because health is a state subject. NBTC is working on strengthening guidelines and eventually transitioning them to a separate legislation on blood. This will involve exploration of possibility of adopting sophisticated screening methodologies like NAT, leucocyte depletion, extending cross matching, etc. Under these circumstances, diluting the eligibility criteria for donor selection would not only be a regressive step but a step that may cost blood recipients, particularly those in need of blood repeatedly, their lives. Fundamental rights are not absolute and the fundamental rights of one category of citizens cannot be used to take away the fundamental rights of another category of citizens. On a practical level as well, while transgenders, men having sex with men and female sex workers, stand nothing to lose in terms of health while NBTC is strengthening its guidelines and exploring a new law on blood, recipients of blood may be under a huge risk of contracting transfusion transmitted infections (TTIs) if the guidelines are diluted even before a new law is explored with possibility of stricter provisions for screening methodologies, leucocyte depletion, extending cross matching etc. On the contrary, till possibility of such provisions under exisiting or new law is explored, guidelines related to blood transfusion services in general and donor selection and counselling in particular must be further strengthened and not diluted.

Hope the above is in order. We shall be happy to provide any clarifications that may be required in this regard.

Regards
Anubha

From: Dr. Anil Kumar <dr.anilkumar@nic.in>
Sent: Friday, November 25, 2022 7:08 PM
To: bsgsacs@gmail.com <bsgsacs@gmail.com>; directorbloodbank@Indianredcross.org <directorbloodbank@Indianredcross.org>; Anubha Taneja <anubha@thalassemiapag.org>; captvenki@gmail.com <captvenki@gmail.com>; pagthals@gmail.com <pagthals@gmail.com>; sacsgujarat@gmail.com <sacsgujarat@gmail.com>; Dr. V.G. Somani DCGI <dci@nic.in>; abtypmbdd@hotmail.com <abtypmbdd@hotmail.com>; pd upsacs <pd.upsacs@gmail.com>; upsacs@gmail.com <upsacs@gmail.com>; NIB <info@nib.gov.in>; dr priti99 <dr_priti99@yahoo.com>; narinder naidu <narinder.naidu@yahoo.com>; Sangeeta pahuja s <Sangeeta.pahuja.s@gmail.com>; secretary@fibdo.org <secretary@fibdo.org>; Mr Vishal Chauhan <vishal.chauhan@ias.nic.in>; Ms. V. Hekali Zhimomi <dgoffice@naco.gov.in>; palamalendu@gmail.com <palamalendu@gmail.com>; Ms. V Hekali Zhimomi <zhimomiv@ias.nic.in>; poonamcoshic@gmail.com <poonamcoshic@gmail.com>; Dr(Mr) Dr Mandeep Kumar Bhandari <mandeep@ias.nic.in>; Vishal chauhan <jsncd-mohfw@gov.in>; drvijayendrakr@rediffmail.com <drvijayendrakr@rediffmail.com>; Vishal Chauhan Joint Secretary Policy MoHFW <js.policy-mohfw@gov.in>; pandeyhemc@gmail.com <pandeyhemc@gmail.com>; asfa-mohfw <asfa-mohfw@nic.in>; rekhatirkey@gmail.com <rekhatirkey@gmail.com>; drdsc1318 <drdsc1318@gmail.com>; sangeeta pathak <sangeeta.pathak@maxhealthcare.com>
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ANNEXURE-A17

298

Editorial

Nucleic acid testing-benefits and constraints

Rekha Hans, Neelam Marwaha

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Nucleic acid testing (NAT) is a molecular technique for screening blood donations to reduce the risk of transfusion transmitted infections (TTIs) in the recipients, thus providing an additional layer of blood safety. It was introduced in the developed countries in the late 1990s and early 2000s and presently around 33 countries in the world have implemented NAT for human immunodeficiency virus (HIV) and around 27 countries for hepatitis B virus (HBV).[1] NAT technique is highly sensitive and specific for viral nucleic acids. It is based on amplification of targeted regions of viral ribonucleic acid or deoxyribonucleic acid (DNA) and detects them earlier than the other screening methods thus, narrowing the window period of HIV, HBV and hepatitis C virus (HCV) infections. NAT also adds the benefit of resolving false reactive donations on serological methods which is very important for donor notification and counseling. In a recent Malaysian study[2] 1388 donor samples were tested by serology as well as NAT, authors found 1.37% samples reactive on standard serology methods but non-reactive by NAT. These samples were confirmed to be "false reactive" on confirmatory serological tests.

NAT for HCV was first introduced in Germany in 1997 and it was performed on pooled samples of 96 blood donations (Minipool NAT [MP-NAT]).[3] Later on, as other countries adopted this technique there was a progressive decrease in pool size to 16, 8 or 6 donation samples. MP-NAT may have the advantage of being cost-effective, but there are some limitations. The whole size of pooled blood donations is blocked until the NAT report is available. Moreover, as viral nucleic acid concentration gets diluted in the large pool of samples, the sensitivity of NAT might decrease and if a pool is tested reactive, the whole pool requires resolution to identify the single positive unit and this process requires an additional step of handling, additional time for testing and hence delay in the release of units. NAT is also available for testing each donation individually (ID-NAT). This format of NAT seems more sensitive as shown by data from many studies where ID-NAT has been compared to MP-NAT with pools of 16 or 8 or 4 samples[4,5] and if a unit is ID-NAT reactive, donation number is identifiable for performing discriminatory test. That single unit is removed from the inventory, releasing other units on time. However, this has limitations of higher cost. In a study conducted in United States, it was seen that over a 10-year period, approximately 66 million donations were screened with 32 HIV (1:2 million) and 244 HCV (1:270,000) NAT yield donations identified. HCV prevalence among first time donors decreased by 53% for 2008 compared with 1999.[6] The introduction of HBV NAT in the United States, along with the HBV vaccination policy made a measurable contribution to blood safety and decreased residual risk of HBV infection.[7] In United Kingdom, NAT has reduced the risk of HCV by 95% and that of HIV by 10%.[8] The American Red Cross implemented automated triplex NAT for HIV, HCV and HBV in June 2009. They analyzed their results of the initial year of testing and found that the yield of MP-NAT (MP16) had little measurable impact on blood safety in detecting seronegative donations.[9] Other studies showed that sensitive, ID-HBV NAT detects significantly more DNA-positive, hepatitis B surface antigen (HBsAg)-non-reactive donations than MP-NAT, regardless of the anti-hepatitis B core status of the donor.[10,11] In a pilot study of 18 months from China, ID-NAT was compared with enzyme immunoassays. It was observed that HBV yield rate in their population is 1:1056 for blood donations.[12] In a study from Egypt 5 window period HCV donations were identified among 15,655 1st time donors (yield 1:3100).[13] NAT screening may thus prove to be more beneficial where the seroprevalence of transfusion transmissible infectious agents is high, as is the case in most developing countries.

In India, mandatory blood screening for HBV, HIV and HCV is done by serological tests for HBsAg and antibodies to HIV 1/2 and HCV. The screened seronegative donations are still at risk for TTIs and thus, need for a sensitive screening test arises to decrease this residual risk which has been reduced significantly over the last two to three decades in western countries where NAT has been implemented. NAT testing has been started in few centers in India, but it is not a mandatory screening test for TTIs as per Drug and Cosmetics Act, 1940 and the rules therein.[14] Major barriers in implementing routine NAT testing in India is its high cost and lack of technical expertise in most of the blood centers.

In the present issue of the journal three articles on NAT - one review and two original studies highlight the current dilemma for India. The review article by

294

Shyamala draws attention to the high seroreactivity of HBV, HCV and HIV in multitransfused thalassemic patients which indicates window period transmission of TTIs by seronegative units. A case for ID-NAT testing has been put forward. The article by Chatterjee et al. has compared the sensitivity of ID- and MP-NAT testing as assessed by dilution of NAT yield samples. The authors observed that samples with high viral load were detected by all dilutions, but 67% of samples of low viral load are missed by MP-NAT and concluded that ID-NAT is ideal methodology for TTI screening. In a study by Shivaram seronegative samples were tested by in-house MP-NAT, using reverse transcriptase-polymerase chain reaction over a period of 5 years and found a nominal increase in cost per test. Their NAT yield was 0.0006%, low as compared to studies from other parts of India. However, the analytical sensitivity of the in house MP-NAT had not been established and the results may not represent the true yield.

In India blood centers are gradually introducing NAT to provide safe blood to their patients. First multicenteric study was done by Makroo et al.[15] where a total of 12,224 samples along with their serological results were obtained from eight blood banks in India and were tested individually manually by procleix ultrio assay for HIV 1, HCV and HBV. They observed eight NAT yield cases. According to a study from the western part of India combined NAT yield (NAT reactive/seronegative) for HIV, HCV and HBV was 0.034% (1 in 2972 donations)[16] which is high when compared to studies from developed countries. In another study conducted in north India, 18,354 donors were tested by both ID-NAT and fourth generation enzyme-linked immunosorbent assay (ELISA), 7 were found to be NAT-positive but ELISA-negative (NAT yield) for HBV and HCV. The prevalence of NAT yield cases among routine donors was 1 in 2622 donations tested (0.038%).[17] This high yield of NAT is due to the high prevalence of TTIs in India, further highlighting the need for NAT in India. In another study from a tertiary care center from north India ID NAT results were compared to serological method for 73,898 samples, 1.49% were reactive by NAT, HIV-1 (0.09%), HCV (0.25%), 1.05% were reactive for HBV only and around 0.08% were HBV-HCV co-infections with a combined yield of 1 in 610 donations (total 121 NAT yields).[18]

NAT is a highly sensitive and advanced technique which has reduced the window period of HBV to 10.34 days, HCV to 1.34 days and HIV to 2.93 days[19] but it is highly technically demanding, involving issues of high costs, dedicated infrastructure facility, equipments, consumables and technical expertise. The need for NAT depends on the prevalence and incidence rate of infections in blood donor population, available resources and the evidence of benefit added when combined with serology tests. Hence the decision of starting NAT should be considered when basic quality assured blood transfusion system is already in place such as volunteer base for blood donation, provision of donor self-deferral, donor notification and counseling along with quality assured sensitive serological methods for testing TTIs.

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