Original article

Bloodborne infection risk in men who have sex with men (MSM)

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Abstract:

Introduction: *The decline in HIV prevalence and availability of nucleic acid testing have allowed men who have sex with men (MSM) to donate blood in some countries based on research evidence.* ***Objective:*** *This study assessed the risk of blood-borne disease transmission from Thai MSM compared to normal male donors.* ***Materials and Methods:*** *MSM participants were recruited from the National Blood Centre (NBC), Thai Red Cross Society, and 9 Regional Blood Centres, Thai Red Cross Society. MSM with partners were included and MSM who used pre-exposure/post-exposure prophylaxis for HIV were excluded from the study. MSM who had only one partner and were not exposed to sex workers or illicit drugs were classified as low-risk, while MSM with more than one partner or had other sexual risk behaviors were classified as high-risk. Eligible participants had blood sampling to test for transfusion-transmitted infection (TTI): HIV, HBV, HCV, and syphilis, twice, 3 months apart. The low-risk MSM were advised to refrain from having sexual relations during the 3-month study period. The infection pressure of TTI was compared with the control age-matched male donors using a two proportion Z-test with a significance level (α) of 0.05.* ***Results:*** *Seventy-three MSM participants were eligible, 32 were low-risk and 41 were high-risk. Blood tests were positive for 2 in the high-risk group (syphilis and HBV), 1 in the low-risk group (syphilis) and there were no TTI in matched regular donor controls. The infection pressure in the high-risk group is significantly higher than regular donors (4.88% vs. 0.00%, p-value = 0.0285). The low-risk group has little difference in infection pressure to the high-risk group (3.12% vs. 4.88%) with no statistical significance. The MSM participants also have significantly higher infection pressure compared with general Thai male donors (4.10% vs. 0.95%, p-value = 0.0028), with 3.28 times higher in the low-risk group (clinical significant). There was no new TTI positivity on the 3-month follow-up blood test.* ***Conclusion:*** *Despite the limited number of participants, it can be concluded that Thai people with MSM continue to be a clinically significant risk group for transfusion-related infection.*

Keywords : ● *Men who have sex with men* ● *Transfusion-transmitted infection* ● *Blood donation* ● *Deferral criteria*

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นิพนธ์ต้นฉบับ

ความเสี่ยงของการถ่ายทอดเชื้อทางโลหิตในชายที่มีเพศสัมพันธ์กับชาย

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บทคัดย่อ

บทนำ *จากการลดลงของความชุก HIV ร่วมกับมีการตรวจวิเคราะห์ด้วยวิธี nucleic acid test บางประเทศจึงเริ่มให้ผู้มีพฤติกรรมเพศสัมพันธ์แบบชายกับชาย (MSM) ที่มีความเสี่ยงต่ำบริจาคโลหิตได้ ตามผลการวิจัยที่สนับสนุน* ***วัตถุประสงค์*** *โครงการวิจัยนี้มีวัตถุประสงค์ในการศึกษาความเสี่ยงของการติดเชื้อที่ถ่ายทอดทางเพศสัมพันธ์ผ่านโลหิตของ MSM ในประเทศไทย เปรียบเทียบกับผู้บริจาคโลหิตชาย* ***วัสดุและวิธีการ*** *ทำวิจัย prospective cohort study โดยรวบรวมอาสาสมัคร MSM จากทั่วประเทศ ณ ศูนย์บริการโลหิตแห่งชาติ และภาคบริการโลหิตแห่งชาติ สภากาชาดไทย รวม 10 แห่ง ในช่วงระหว่างวันที่ 15 มีนาคม พ.ศ. 2566 ถึงวันที่ 15 กันยายน พ.ศ. 2566 คำนวนจำนวนตัวอย่างได้ 159 คนต่อกลุ่ม โดยมีเกณฑ์คัดเข้า คือ MSM ที่มีคู่ และไม่ใช้ยา PrEP/PEP จำแนกอาสาสมัครเป็นกลุ่มความเสี่ยงต่ำ คือ มีคู่คนเดียว ไม่มีเพศสัมพันธ์กับผู้ให้บริการทางเพศหรือใช้สารเสพติด กับกลุ่มความเสี่ยงสูงที่มีคู่มากกว่า 1 คน หรือมีพฤติกรรมทางเพศสัมพันธ์ที่เสี่ยงอื่นๆ มาดำเนินการตรวจเลือดเพื่อหาการติดเชื้อ transfusion transmitted infection (TTI) ได้แก่ HIV, HBV, HCV และ syphilis จำนวน 2 ครั้ง ห่างกัน 3 เดือน โดยกลุ่มความเสี่ยงต่ำต้องงดการมีเพศสัมพันธ์ตลอด 3 เดือน ส่วนกลุ่มความเสี่ยงสูงให้มีเพศสัมพันธ์ได้ นำผลการติดเชื้อมาคำนวณค่า infection pressure เปรียบเทียบกับผลเลือดของกลุ่มควบคุม คือ ผู้บริจาคโลหิตเพศชายของศูนย์บริการโลหิตแห่งชาติ และภาคบริการโลหิตแห่งชาติ สภากาชาดไทย ที่มีช่วงอายุและอาศัยอยู่ในภูมิภาคเดียวกันในช่วงเวลาเดียวกัน วิเคราะห์ข้อมูลที่ได้ด้วยสถิติ two proportion Z-test กำหนดให้ระดับนัยสำคัญ (α) เท่ากับ 0.05* ***ผลการศึกษา*** *มีผู้สมัครเข้าร่วมโครงการทั้งหมด 192 คน มีคุณสมบัติเข้าเกณฑ์ 73 คน อายุระหว่าง 19-46 ปี เป็นกลุ่มเสี่ยงต่ำ 32 คน กลุ่มเสี่ยงสูง 41 คน ตรวจเลือดครั้งแรกพบการติดเชื้อในกลุ่มเสี่ยงสูง 2 คน (syphilis และ HBV) กลุ่มเสี่ยงต่ำ 1 คน (syphilis) โดยกลุ่มเสี่ยงสูงมี % infection pressure สูงกว่ากลุ่มควบคุมที่เป็นผู้บริจาคโลหิตประจำอย่างมีนัยสำคัญ (4.88% vs. 0.00%, p-value = 0.0285) สัดส่วนการติดเชื้อของกลุ่มเสี่ยงต่ำกับกลุ่มเสี่ยงสูงต่างกันเล็กน้อย (3.12% vs. 4.88%) ซึ่งไม่สามารถสรุปได้ว่าแตกต่างกันทางสถิติ (จำนวนตัวอย่างน้อย) และพบว่าอาสาสมัคร MSM มีสัดส่วนการติดเชื้อสูงกว่าผู้บริจาคโลหิตเพศชายทั่วไปอย่างมีนัยสำคัญทางสถิติ (4.10% vs. 0.95%, p-value = 0.0028) โดยกลุ่มเสี่ยงต่ำมีค่าการติดเชื้อสูง กว่าผู้บริจาคเพศชาย 3.28 เท่า ซึ่งมีนัยสำคัญทางคลินิก ไม่พบการติดเชื้อเพิ่มในการตรวจเลือดครั้งที่ 2* ***สรุป*** *มีอาสาสมัครเข้าร่วมวิจัยน้อยกว่าเป้าหมายมาก (73 คน จาก 318 คน) ซึ่งอาจมีเหตุปัจจัย เกี่ยวกับวัฒนธรรม ทัศนคติส่วนบุคคลและเกณฑ์การวิจัยที่ต้องไม่ใช้ยา PrEP ทำให้มีผลต่อการวิเคราะห์ จนไม่สามารถสรุปเพื่อตอบโจทย์วิจัยได้ทั้งหมด อย่างไรก็ดี ข้อมูลที่ได้แสดงให้เห็นว่า MSM ในประชากรชาวไทย ยังคงจัดเป็นความเสี่ยงทางคลินิก เพราะมีโอกาสที่ผู้ป่วยจะได้รับโลหิตติดเชื้อที่แฝงอยู่ในช่วง window period ได้ ด้วยเหตุนี้จึงยังไม่สามารถเปลี่ยนเกณฑ์การคัดเลือกที่เหมาะสมให้ MSM เป็นผู้บริจาคโลหิตได้ จำเป็นต้องศึกษาเพิ่มเติมต่อไป เพื่อให้มีข้อมูลที่สามารถสร้างความมั่นใจด้านความปลอดภัยของผู้รับโลหิต*

คำสำคัญ : ● *ชายที่มีเพศสัมพันธ์กับชาย* ● *การติดเชื้อที่ติดต่อทางโลหิต* ● *การบริจาคโลหิต*
● *เกณฑ์คัดกรองการบริจาคโลหิต*

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต. 2567;34:173-85.

Introduction

In the past, due to the medical evidence showing the relationship between behaviors of men who have sex with men (MSM) and Human Immunodeficiency virus infection (HIV), MSM behaviors were universally a permanent blood donation deferral criterion since 1997[1,2]. However, at present there is nucleic acid testing (NAT) that can be applied to blood screening which helps in decreasing the window period[3] as well as a study that found the difference of sexually transmitted diseases in ones with MSM behaviors such as monogamous MSM having lower risk than polygamous MSM for an example. For this reason, some countries reduce the blood donor criteria for MSM such as allowing donation if they have no sexual intercourse with men in the last 3 months or allowing donation for MSM who do not have anal sex or have anal sex but only have one partner within 3 months[4,5]. For Thailand, the report of the population with MSM behaviors in 2020 found the HIV prevalence to be 7.3%[6,7] which is higher than many other countries. This is the reason for keeping the permanent deferral policy for MSM until there is evidence to support safe blood donation for MSM.

The National Blood Centre, Thai Red Cross Society therefore did the study of bloodborne infectious risk in men who have sex with men to study a course to improve deferral criteria for Thai MSM to create understanding in society as well as incorporating transfusion-transmitted disease residual risk analysis to create an appropriate risk-assessment criteria that is fair to all gender while causing no harm to the blood recipient.

Project preparation

Due to the blood donor screening criteria having the attention of the country, the National Blood Centre prepared a communication plan to create understanding in society and ask for the cooperation of the targeted LGBTQIA+ group from all regions by holding the conference between:

The Research Team comprised of experts in transfusion medicine, virology and sexually transmitted diseases from the National Blood Centre, Royal College of Pathologists of Thailand, Faculty of Medicine Siriraj Hospital, Faculty of Medicine Ramathibodi Hospital, and King Chulalongkorn Memorial Hospital, Division of AIDs and sexually transmitted disease, Department of Disease Control, Ministry of Public Health, Thai AIDS Society and the Thai Society of Hematology.

Research expert advisors (2 persons) in the field of blood donation risk in MSM from the Department of Blood-borne Infections, Sanquin, Amsterdam, Netherlands.

Human rights advisor and medical council representative (2 persons).

Stake-holders from the public consist of the president and the secretary of Rainbow Sky Association of Thailand and the representative in Cholburi, Ubolratchatani, Nakhonsawan and Songkla, LGBTQIA+ alliance networks such as Ratchaburi Rainbow group, Nakhonratchasima and Chiang Mai MPLUS group, Khonkan Act Team group, Chiang Mai CAREMAT group and Phuket Andaman Power group. Four onsite and online conferences were held from every stated region in February and May 2023. There was an invitation for project participants via multiple social media with the president of the Rainbow Sky Association of Thailand giving an interview to invite participants from every region.

The project was approved by the Research Ethics Committee, National Blood Centre, Thai Red Cross Society on Nov 28, 2022 with Certificate of Approval No. NBC 14/2022 and the research fund committee of the Health System Research Institute (HSRI) in 2023.

Materials and Methods

Conceptual framework

This study was concerned with the risk of transfusion-transmitted infection (TTI) such as Hepatitis B virus (HBV), Hepatitis C virus (HCV), HIV and Syphilis in MSM populations from every region in the country. The participants were separated into 2 groups according to their risks: low-risk and high-risk, then they were appointed for blood testing two times in 3 months to

get the statistics of prevalence, incidence and residual risk to be compared with Thai male blood donors in the same age range and region. The result can be used for risk assessment on each population group to determine the appropriate blood donation deferral period for sexual risk behavior that would cause no harm to the blood recipient.

One of the study's objectives was to measure TTI prevalence, incidence and residual risk in MSM. The study also aimed to compare the infection pressure between low-risk and high-risk MSM and between MSM participants and control groups consisting of male first-time donors and regular donors in the same age range and region randomized from the Thai Red Cross Blood Information System (TBIS).

Sample size calculations

This study separated participants into 2 groups; low-risk and high-risk, to compare the incidence of TTI between MSMs with the potential to donate blood and current male blood donors. In 2021, the incidence of TTI in Thai blood donors was 115.55 per 100,000 donations for HIV, 1,289.23 per 100,000 donations for HBV, 533.79 per 100,000 donations for HCV and 803.48 per 100,000 donations for Syphilis. The sample size was calculated from these incidences.

However, due to the limitation of data as the TTI incidence in MSM blood donors is unknown, we opted to use the TTI incidence in current male blood donors which for HIV is 0.1155%. We estimated MSM to have a two-fold higher TTI risk than current male donors, which is 0.2311%. Then we calculated the sample size of a two proportion z-test with the significance level (α at 0.05 and power at 80% using STATA version 14.2 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LLC.). The hypothesis was that MSM had TTI incidence higher than current male donors (one-sided test), The calculated sample size was 159 people per group. Therefore, the sample size of this study needed to be at least 159 MSMs and 159 controls.

After a conference with Rainbow Sky Association of Thailand and alliances from around the country and received outstanding co-operation, we planned to increase the participants to 1,250 people to cover all the participants of the country with 1,000 MSM participants in the low-risk group and 250 in the high-risk group. For the control group, we planned for 2,000 infectious profiles from TBIS which were 1,000 first-time donors and 1,000 regular donors. We originally planned the study duration to be 4 months. However after the first 2 months, we found that fewer participants joined than expected, therefore we adjusted the strategy by having the president of Rainbow Sky Association be a presenter to invite the MSM to recruit more participants in provincial area and extend the study duration to 6 months. However, there were no new participants after adjusting the strategy and duration extension.

Research participants were invited from the National Blood Centre, Thai Red Cross Society and 9 Regional Blood Centres, Thai Red Cross Society according to the determined region with 100 low-risk participants and 25 high-risk participants per region.

Data collection

This research was a prospective cohort study conducted at the National Blood Centre, Thai Red Cross Society and Regional Blood Centres, Thai Red Cross Society with a total number of 10 centres. The participant goal was 125 people per centre;

1. National Blood Centre (NBC), Bangkok
2. Regional Blood Centre III, Chon Buri Province (RBC 3)
3. Regional Blood Centre IV, Ratcha Buri Province (RBC 4)
4. Regional Blood Centre V, Nakhon Ratchasima Province (RBC 5)
5. Regional Blood Centre VI, Khon Khan Province (RBC 6)
6. Regional Blood Centre VII, Ubol Ratchathani Province (RBC 7)
7. Regional Blood Centre VIII, Nakhon Sawan Province (RBC 8)

8. Regional Blood Centre X, Chiang Mai Province (RBC 10)
9. Regional Blood Centre XII, Songkhla Province (RBC 12)
10. Regional Blood Centre, Phuket Province (RBC Phuket)

Participant qualifications (n = 73)

MSM aged 18 to 50 years (MSM without a sexual partner would not be included in the study as they had no sexual risk behaviors and could donate blood normally) and no history of taking pre-exposure prophylaxis/post-exposure prophylaxis (PrEP/PEP) in one year as well as consenting to participate in the study to the end. The participants were separated into 2 groups;

Group 1 low-risk MSM (n = 32)

- Monogamous status for at least 3 months prior to the study.
- The participant and his partner had no sexual risk behaviors such as providing or receiving sexual service or taking addictive or stimulant drugs during sex for at least 3 months.

Group 2 high-risk MSM (n = 41)

- Multiple partners in 3 months OR
- The participant or his partner had sexual risk behavior such as providing or receiving sexual service or taking addictive or stimulant drugs during sex in the last 3 months.

Exclusion criteria

- MSM in the low-risk group who had sex 3 months before the second blood testing appointment by interviewed.
- The participant took PrEP/PEP during the study
- The participant could not participate in the study to the end

Control group (n = 73)

The data of current Thai male blood donors were randomly chosen according to the same age range (18-22, 23-25, 26-31, 32-46 and 47-50 years old), region and time with participants to have the control's characteristic most similar to their respective MSM participants, and had their profiles retrieved from Thai Red Cross Blood Information System (TBIS). The donor controls consisted of two groups:

- First-time donor: The donor who has never donated before
- Regular donor: The donor who has donated blood in the last 2 years according to the European Medicines Agency's Guideline on epidemiological data on blood transmissible infections[8].

The rationale for having two donor control groups was first-time donors had higher TTI risk than regular donors due to their tendency to use blood donation as personal health examination after high-risk sexual behaviors, therefore didn't reflect the TTI risk of the general blood donor population.

Research procedure

The participants who informed their interest in the study online and passed the preliminary interview would be invited to join the study on the appointed date at the National Blood Centre, Thai Red Cross Society or Regional Blood Centres, Thai Red Cross Society. After the research staff explained the study objectives and procedures in detail, the participants who decided to enter the study had to sign an informed consent form and then enter their data about sexual risk behaviors and other personal information in the electronic application form via the National Blood Centre computer system which had data access protection according to the Personal Data Protection Act 2019 and there would be no further correction. The result from the information would determine whether the participant was in the low-risk or high-risk group, but the research staff wouldn't know the sorting result of the participant. After that, the participants had 24 milliliters of their blood taken and received a 3-month appointment card and research incentive fee before they returned home.

The low-risk MSM group must abstinate from anal sexual intercourse for 3 months before second blood testing while the high-risk group could have sex normally. Neither group must take PEP or PrEP.

Every participant had their blood taken to test for TTI twice; at the first appointment and the second appointment 3 months later. Tests done were listed below:

1. Preliminary screening test
   - Serological test for antigen and antibodies; HIV-1/2 antigen and antibodies, hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (anti-HCV), and antibodies to Treponema pallidum (anti-TP) by chemiluminescent microparticle immunoassays (Alinity i, Abbott Laboratories)
   - Nucleic acid test (NAT) for HIV-1/2 RNA, HBV DNA and HCV RNA by using real-time PCR (COBAS 6800 MPX assay, Roche Diagnostics)
2. Confirmatory and supplementary tests in case of a positive preliminary screening test
   - Immunochromatographic strip for HIV-1/2 antibodies (Alere determine HIV-1/2, Abbott) and Geenius™ HIV 1/2 confirmatory assay (Bio-Rad) for HIV-1/2 antibodies
   - HBsAg neutralization test and hepatitis B core antigen (anti-HBc) to detect HBV infection (Alinity i, Abbott Laboratories)
   - Geenius™ HCV supplemental assay (Bio-Rad) to detect hepatitis C virus antibodies
   - Immunochromatographic strip for *Treponema pallidum* HIV-1/2 antibodies (Alere determine syphilis TP, Abbott) and rapid plasma reagin to test for the phase of infection

Infection pressure, defined as the number of antibody-reactive infections[9], would be calculated from the number of members that tested positive for Syphillis, HIV, HBC or HCV for each group. If one member tested positive for more than one disease, their infection pressure would be a summation of all diseases. For example, a participant who tested positive for both HIV and HBV would have an infection pressure of 2.

Incidence and residual risk (length of window period x incidence of infections in repeat donors) were calculated from the participants' TTI test results from the second appointment in case of a new infection.

Statistical comparison

Infection pressures from low-risk and high-risk groups were compared with the control group; both first-time and regular current male donors with two proportion Z-test with a significant level of 0.05.

Results

The study had started online recruiting on 1st March 2023, started appointing participants on 15th March 2023 and stopped recruiting on 15th September 2023. One hundred and ninety two participants registered for the study via QR code. After inquiring and receiving further explanation via telephone, there were 128 participants left. After the first appointment and entering sexual behavior information via an electronic program, 55 participants were excluded and 73 participants (32 in the low-risk group and 41 in the high-risk group) were left to enter the study as described in Table 1.

The low-risk group consisted of 32 participants with an age range of 19-40 years old and an average age of 27.53 years (standard deviation, SD 1.03 years) while the high-risk group had 41 participants with an age range of 19-46 years old and an average age of 27.29 years (SD 1.10) as shown in Table 2.

TTI test result from the first appointment

- Low-risk group: from 32 participants, found 1 syphilis reactive (34 years old)
- High-risk group: from 41 participants, found 1 syphilis reactive (21 years old) and 1 HBV NAT positive (22 years old)
- Control group first-time donor: from 73 controls, found 1 syphilis reactive (31 years old)
- Control group regular donor: from 73 controls, found no TTI

Data analysis

Infection pressure was calculated for participants and controls were randomized from TBIS. It was found that MSM participants had a total infection pressure of

Table 1 Number of participants spread by region and risk group

Study sites	Number of participants (n)		
	Low risk	High risk	Total
National Blood Centre (Bangkok)	6	11	17
Regional Blood Centre 3 (Chon Buri)	2	6	8
Regional Blood Centre 4 (Ratchaburi)	1	1	2
Regional Blood Centre 5 (Nakhon Ratchasima)	7	9	16
Regional Blood Centre 6 (Khon Kaen)	7	3	10
Regional Blood Centre 7 (Ubon Ratchathani)	0	1	1
Regional Blood Centre 8 (Nakhon Sawan)	6	8	14
Regional Blood Centre 10 (Chiang Mai)	1	1	2
Regional Blood Centre 12 (Songkhla)	0	0	0
Regional Blood Centre (Phuket)	2	1	3
Total	**32**	**41**	**73**

Table 2 Age range of participants

Age (years)	Low risk n (%)	High risk n (%)	*p*-value
18-22	7 (21.87)	13 (31.70)	0.709
23-25	7 (21.87)	8 (19.51)	
26-31	10 (31.25)	10 (24.39)	
32-46	8 (25.00)	10 (24.39)	
47-50	-	-	
Total	**32 (100)**	**41 (100)**	

4.10% with the low-risk group at 3.12% and the high-risk group at 4.88%. For the control group, the infection pressure of the first-time donor was 1.36% and for the regular donor was 0.00% as shown in Table 3.

Due to the total participants number being 73 people while the calculated sample size was 159, the analysis could not conclude the statistically significant difference from the data. Still, the research team analyzed the data according to the objectives as shown below:

- Comparing infection pressure between low-risk and high-risk groups and between 1st time and regular donors as described in Table 3
- Comparing 73 total participants with controls, the results are as described in Table 4
- Comparing 32 participants from the low-risk group with controls as described in Table 5
- Comparing 41 participants from the high-risk group with controls as described in Table 6

A comparison study with the TBIS data of male blood donors in the age range 19-46 years old from National Blood Centre and all Regional Blood Centres in 2023.

There were 234,703 male blood donors aged 19-46 years old from the National Blood Centre and all Regional Blood Centres with infection pressure of 0.95% and 0.24% in regular male donors.

- Comparing infection pressure of participants with male blood donors aged 19-46 years old from the National Blood Centre and all Regional Blood Centres as shown in Table 7.

The infection pressure of low-risk MSM was 3.28 times higher than the total male donors (3.12%: 0.95%) which meant the potential recipient of their blood product would have approximately 3 times higher risk for TTI which could lead to morbidity, increased treatment cost and mortality, therefore had clinical significance. From the second appointment, there was no new

Table 3 Comparing infection pressure between two groups of participant and between two groups of control

Study groups	Number	Infection pressure	% Infection pressure	*p*-value
Total MSM participants	73	3	4.10	
Low risk MSM	32	1	3.12	0.3541*
High risk MSM	41	2	4.88	
Control: 1st time male donors	73	1	1.36	0.3156*
Control: regular male donors	73	0	0.00	

*There was not enough evidence to conclude that the high-risk group had statistically significantly more infectious risk than the low-risk group or the 1st time male donors had statistically significantly more infectious risk than the regular male donors.

Table 4 Comparing infection pressure of total participants with controls

Study groups	Infected n (%)	Non-infected (n)	Total (n)	*p*-value
Total participants	3 (4.10)	70	73	0.1553
Control: 1st time donors	1 (1.36)	72	73	
Total participants	3 (4.10)	70	73	0.0400*
Control: regular donors	0 (0.00)	73	73	

*Total participants had higher infection pressure than regular donors with statistical significance (*p*-value = 0.0400).

Table 5 Comparing infection pressure in the low-risk group with the control group

Study groups	Infected n (%)	Non-infected (n)	Total (n)	*p*-value
Low risk MSM	1 (3.12)	31	32	0.2724*
Control: 1st time donors	1 (1.36)	72	73	
Low risk MSM	1 (3.12)	31	32	0.0646*
Control: regular donors	0 (0.00)	73	73	

*There was not enough evidence to conclude that the low-risk group had statistically significantly more infection pressure than controls.

Table 6 Comparing infection pressure in the high-risk group with the control group

Study groups	Infected n (%)	Non-infected (n)	Total (n)	*p*-value
High risk MSM	2 (4.88)	39	41	0.1307
Control: 1st time donors	1 (1.36)	72	73	
High risk MSM	2 (4.88)	39	41	0.0285*
Control: regular donors	0 (0.00)	73	73	

*The high-risk group had higher infection pressure than regular donors with statistical significance (*p*-value = 0.0285) but not enough evidence to conclude that it was higher than first-time donors.

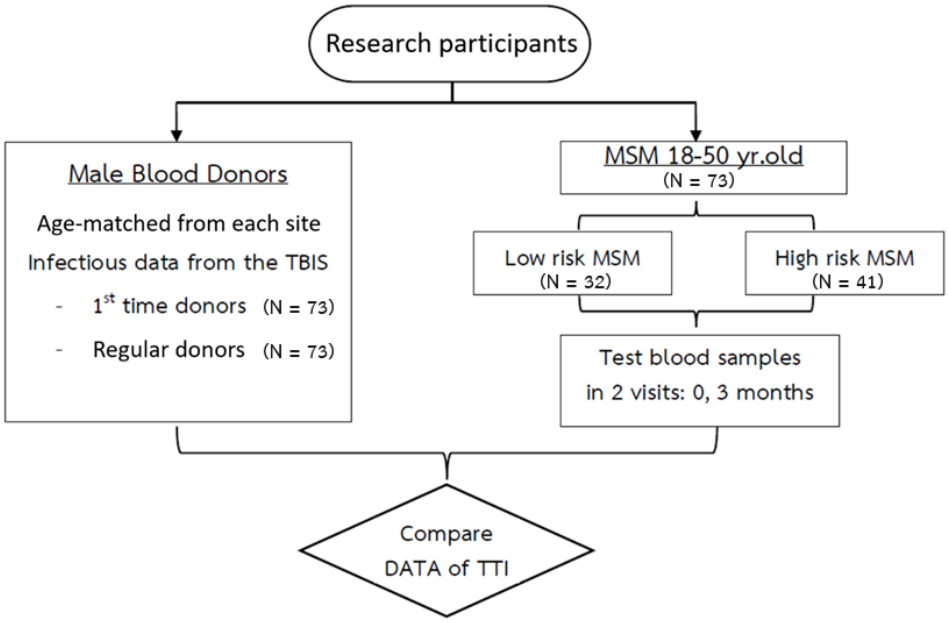
Table 7 Comparing the infection pressure of participants with the TBIS data of male blood donors in an age range 19-46 years old from National Blood Centre and all Regional Blood Centres in 2023

Compare groups	Number	Infection pressure	% Infection pressure	*p*-value
Total male donors (TBIS)	**234,703**	**2,239**	**0.95**	
Low risk MSM	32	1	3.12	0.1033
High risk MSM	41	2	4.88	0.0049*
Total participants	73	3	4.10	0.0028*
1st time & non-regular donors (TBIS)	**72,314**	**1,853**	**2.56**	
Low risk MSM	32	1	3.12	0.4202**
High risk MSM	41	2	4.88	0.1742**
Regular male donors (TBIS)	**162,389**	**386**	**0.24**	
Low risk MSM	32	1	3.12	0.0004***
High risk MSM	41	2	4.88	< 0.0001***
Total participants	73	3	4.10	< 0.0001***

* Infection pressure of all MSM participant groups was higher than male blood donors in the age range 19-46 years (3.12%, 4.88% vs. 0.95%) but due to the small sample size the statistical significance could not be demonstrated in low-risk group.

** Not enough evidence to conclude that participants have significantly higher infection pressure than first-time and repeat donors (3.12%, 4.88%, 2.56%).

*** Infection pressure of both low-risk and high-risk group were higher than regular male donors with statistical significance (*p*-value = 0.0004, *p*-value < 0.0001).



TTI = Transfusion transmitted infection such as HIV, hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis
The research participants consisted of MSM participants aged 18-50 years old, who were further divided into low-risk and high-risk group, and the control group consisted of age-matched male blood donor from each site with their infectious data taken from Thai Red Cross Blood Information System (TBIS). The data of TTI will then be compared between each group.

Figure 1 Research flowchart

infection in both groups of participants which was due to the number of participants being much smaller than planned, therefore incidence and residual risk of Thai MSM who are potential blood donors could not be calculated.

Discussion

This study collected data of participants from all around the country, therefore the data is complete and not limited to only one region or Bangkok. There was also an interview and cooperation with important public stakeholders consisting of LGBTQIA+ representatives from the Rainbow Sky association and alliance network around the country. However, there was still a limitation of much fewer participants than planned with 73 participants from the calculated sample size of 318 (22.95%) and much less than the target of 1,250 estimated for data completion. The important reason that affected participant decisions to join the study was Thai culture or local values that make Thai people uncomfortable with sensitive personal information disclosure such as sexual preference and sexual risk, as well as blood donation with an agenda to test for infection which may result in a higher positive result in the population. Some regions also had very few participants such as Songkhla province which had no participants. Some participants were also excluded due to their history of taking PrEP within 1 year. There was an observation that there were fewer low-risk participants than high-risk (32 vs 41 participants) which may be due to the 3-month abstinence criteria which may affect participants' decision to opt out of the study. An insufficient number of participants affected the statistical analysis.

As PrEP usage was found to be prevalent in MSM populations, it was shown that MSM still had a high risk for HIV infection/transmission. This group of drugs could decrease HIV amount in the bloodstream to an undetectable level with NAT during incubation or window period which caused false negative results. Therefore, the study criteria excluded participants who used PEP/PrEP during the research period.

The low-risk group's 3-month abstinent period was to ensure there were not any infectious risks including syphilis which may have an incubation period as long as 3 months[10] as well as other countries using 3-month deferral period for MSM behaviors[11,12]. The 3-month deferral period was used in many countries for years before changing to a risk-assessment questionnaire[13-15], or was still used in some countries such as Australia[16] and New Zealand[17].

In terms of age distribution, the total participants have an age range of 19-46 years old with no participants in an age range of 47-50 years old, which may reflect more interest in blood donation in younger MSM than older. In a high-risk group, there were more participants in the age range 18-22 years old than low-risk group (31.7% vs. 21.87%) which may reflect the higher risk in younger MSM that was in concordance with two participants that found TTI in high-risk group (age 21 and 22 years old) while in low-risk group the participant with TTI was 34 years old.

In this research, we chose to compare the infection pressure which was the summation of all TTI; syphilis, HIV, HBV, and HCV to cover all the significant TTI in the country that must be screened in donated blood. In the current Thai population, syphilis prevalence is increasing which can also represent HIV risk as they share a similar transmission route[18] and have infection synergy[19] as syphilis facilitates transmission and acquisition of HIV which in turn accelerates the natural history of syphilis. Infection pressure was also used in the past study of the Netherlands by Bilson et al.[9]

As 3 participants with TTI were found from a total of 73, the calculated prevalence was 4.10% which was lower than 7.3%, the prevalence of HIV in MSM reported by the Centers for Disease Prevention and Control in the year 2020[7]. This may be due to the study participants paying more attention to their health than MSM in general populations. Meanwhile, the TTI prevalence of the same age-range blood donor in 2023 was 1.24%.

From the TTI infection pressure comparison between low-risk and high-risk groups, no statistically significant difference between infection pressure was found (3.12% vs. 4.88%, *p*-value = 0.3541). There was also no statistically significant difference between total participants and first-time donors (4.10% vs. 1.36%, *p*-value = 0.1553) which may be due to the insufficient number of participants. The total participants however have statistically significantly higher infection pressure than regular blood donors (4.10% vs. 0.00%, *p*-value = 0.0400).

When analyzing TTI infection pressure by risk group, the high-risk MSM group has statistical-significantly higher infection pressure than regular blood donor controls (4.88% vs. 0.00%, *p*-value = 0.0285) while the low-risk MSM group despite the similar infection pressure to the high-risk group couldn't demonstrate statistical significant higher infection pressure to the regular blood donor (3.12% vs. 0.0%, *p*-value = 0.0646) which may be due to insufficient participant number. An inability to demonstrate statistical significance due to an insufficient participant number does not equal statistical indifference (as there may or may not be a difference if the participant number is sufficient). Misinterpreting said result can lead to the risk of implementing blood donor deferral criteria.

The TBIS data shows that Thai first-time donors and non-regular donors have higher infection pressure compared to regular donors. This can be explained by the blood donor behavioral survey reported by the National Blood Centre, Thai Red Cross Society in 2022, presented at the National Scientific Conference on Blood Transfusion Service (NSBT) 2024 which found that some first-time donors enrolled in blood donation to use the National Blood Centre's blood testing as their health inspection or to test their blood after having high-risk sexual behaviors. This data shows how Thai Blood donors have no acknowledgment of the importance of correct history giving to screen for risk before blood donation similar to Hong Kong's report about the non-compliance of blood donors in 2014[20] and 2017[21], this study therefore focused on comparing infection pressure of participants with regular blood donor.

Due to the insufficient participant number, this study did the extended analysis by taking the TBIS data of male blood donors in the same age range as participants from National Blood Centre and Regional Blood Centres in the year 2023 to maximize the weight of analysis (Table 7). The analysis between 234,703 male blood donors in the year 2023 and 73 participants found that both low-risk (3.12%) and high-risk (4.88%) MSM participants had statistically significant (*p*-value = 0.0004 and *p*-value < 0.0001) higher infection pressure than regular male blood donor in the same age range (0.24%) but there wasn't enough evidence to conclude that there is a statistically significant difference between the participant and first-time or non-regular donor (3.12%, 4.88% vs. 2.56%). In Bilsen et al.'s study[9], both low-risk and high-risk MSMs also had statistically significantly higher infection pressure than repeat donors while the statistical comparison with new donors wasn't shown. For each disease's seroprevalence, both MSM groups have statistically significantly higher anti-HBc reactivity compared with either new or repeat donors.

Still, the low-risk group had 3.28 times higher infection pressure than male blood donors (3.12% vs. 0.95%). Even if the statistical significance could not be demonstrated due to insufficient participants, there is still clinical significance due to the risk of transmitting bloodborne infectious diseases. Therefore low-risk MSM despite having safer sexual behavior than high-risk MSM cannot be considered for blood donation yet.

Conclusion

This study was designed to cover important data for analysis to get the result that can answer the question about blood donation criteria change for MSM who

desire to donate blood. However, many fewer participants joined the project than aimed due to multifactorial reasons involving personal culture and attitude as well as a contraindication for using PEP which affected the analysis and therefore unable to conclude and answer all the research questions.

However, the data gained from research can be analyzed and showed that high-risk MSM participants have significantly higher infection pressure than the normal blood donor control group. (4.88% vs. 0.00%, *p*-value = 0.0285) while low-risk MSM could not be demonstrated to have significantly different infection pressure to the high-risk MSM group and first-time donor control.

Moreover, the analysis comparing all male blood donors in 2023 showed that both high-risk and low-risk MSM groups had significantly higher infection pressure than Thai regular male donors (4.88%, 3.12% vs. 0.24%, both *p*-values < 0.0001). While the low-risk MSM group couldn't be demonstrated to have significantly different infection pressure to first-time and non-regular donors, they still have 3.28 times higher infection pressure than normal male donors and therefore the deferral criteria that would allow this low-risk MSM group to donate blood couldn't be implemented yet and need more data that would ensure blood recipient safety including the residual risk which couldn't be calculated in this study.

The obstacle in adjusting deferral criteria for Thai MSM to be allowed to donate blood is their TTI prevalence which is still higher than other sexual risk behaviors[7,8] as well as higher than other countries that have adjusted the criteria. This study found that both low-risk and high-risk MSM have significantly higher infection pressure than male regular blood donors. To solve this, the National Public Health system should implement a policy and measures to control the spread of sexually transmitted diseases earnestly as well as prevention, early examination and early treatment especially in teenagers who have rapidly increasing infectious rates[7]. A policy that promotes population knowledge of self-healthcare and avoidance of risk behaviors via appropriate media for each target group should be implemented.

For a way to improve the study in the future, there needs to be an emphasis on creating awareness on the importance of blood donation and its effect on blood recipients in every region population so blood donor aspirants would be mindful to take care of their health, avoid risk behavior and earnestly give the true history during self-deferral process which would lead to safe blood and more people interested in participating in the study in the future.

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