# 血液事業の実態に関する調査報告(シンガポール)

【目的】 献血血液の HIV に対する安全性向上のため、シンガポールにおける献血時の虚偽申告に対する罰則の設定の背景や献血に及ぼす影響等を調査。

【経緯】 平成25年に日本国内で発生した輸血によるHIV 感染例の発生を受け、海外のHIV 対策や献血時の虚偽申告に対する罰則制度を設ける国への訪問調査を開始した。平成25年度のオーストラリアに引き続き、平成26年度はシンガポールを訪問し、情報収集を行った。

【調査期間】 平成27年3月22日 - 3月26日

【訪問施設】 Ministry of Health (MOH) シンガポール保健省

Health Promotion Board (HPB) 健康促進局 Health Sciences Authority (HSA) 保健科学庁

Communicable Disease Center (CDC) 伝染病センター

Singapore Red Cross Society (SRCS) シンガポール赤十字

Japan Green Clinic (JGC) ジャパングリーンクリニック

Blood bank @HSA 保健科学庁内 献血センター

【調査項目】 1. 献血におり

- 1. 献血における HIV スクリーニング方法
- 2. 献血における HIV 陽性者数とその特徴
- 3. 検査目的の献血への対策
- 4. 献血に対する刑事罰の効果

#### 1. 献血における HIV スクリーニング方法

HIV 抗体検査および、個別 NAT によるスクリーニングが実施されている。献血受付時の写真付き ID による本人確認が徹底されている。問診票には、検査により感染が判明しない期間(ウィンドウ・ピリオド)に関する知識の有無や、原因不明の体重減少や寝汗、熱、下痢、リンパ節腫脹など HIV 感染を疑う症状の有無(過去 12 ヶ月間)だけでなく、知り合って 6 ヶ月未満のパートナーがいるか、パートナーが複数いるかなど、性行動に関しての具体的な内容も含まれている。重要な質問項目には、医師によるチェック欄もあり、問診時に再度確認されている。回答内容が真実であることの宣誓署名欄が最後にある。

別添1:シンガポール問診票

#### 2. 献血における HIV 陽性者数とその特徴

シンガポールの献血者における 2013 年の HIV 陽性率は(約 10/10 万件)と日本の陽性率(1.24/10 万件)よりも高く、シンガポール人口 10 万人当たりの新規 HIV 陽性率(11.81 人 /10 万人)とほぼ同じである。また初回献血者の HIV 陽性率は(約 20/10 万件)で複数回献血者の HIV 陽性率(6/10 万件)よりも高い。

#### 3. 検査目的の献血への対策

#### a) 献血時の対策

医師による問診では、HIV 陽性者が献血してはいけない理由を理解しているかの確認を徹底している。多民族国家であるため、問診票および医師の問診は4カ国語(英語、中国語、マレー語、タミル語)に対応している。コールバック制度があり、献血後に発熱した場合や、正確な申告ができずに献血した場合は、ホットラインへ連絡し、自らの血液の不使用を申し立てることができる。

#### b) 匿名検査へのアクセスと匿名性

HIV の匿名迅速検査は、特定の10箇所の医療機関で行われており、朝10時から夜8時まで、予約なしでも受診可能な医療機関がある。問診は、プライバシーが確保された環境で行われ、匿名性が高い。検査方法も口腔粘膜採取や指先からの採血など、侵襲性の少ない方法で行われている。多くの診療所で匿名検査は有料であるが、MSMの集団や性産業従事者、移民者などハイリスクグループに対してはHIV検査クーポンが配布されており、格安で検査を受けることも可能となっている。

#### c) HIV 検査の義務化

人口の約3割を占める non-resident (非居住者) やブルーワーカーには、定期的な HIV 検 査が義務付けられている。なお外国人長期滞在者も2年毎のビザ更新時に、HIV と結核が 陰性であることの申告・宣誓が必要である。

#### d) その他の対策

国民が HIV を含めた性感染症全般に関して、正しい知識を持ってもらう啓発活動が、職場や学校などで行われている。

#### 4. 献血に対する刑事罰の効果

1997年、シンガポール国内にて、抗体検査陰性献血者からの輸血による HIV 感染事例 あり、公的機関に対する偽証罪が適用された。厳罰化を望む世論の高まりを受け、1999年、虚偽申告に関しての条文が感染症法11条の中に規定された。1999年以降、感染症法11条が適用されたケースは11件あり、8~15ヶ月の懲役刑が確定している。なおこの11件は全員男性で、偽証内容はすべて性行為の事実に関するものであった。HIV 感染の事実を知った上で献血した場合に、感染症法24条に条文が設けられたが、まだ適用されたケースはない。刑事罰導入後、献血行動に対する萎縮効果は見られず、献血者数は増加傾向が続いている。

別添2:シンガポールの感染症法(11条と24条の抜粋)

【結論】 シンガポールの HIV 対策は、HIV の定期検査や申告の義務があること、献血 時の問診スクリーニングを重視している点である。なお虚偽申告に対する刑事罰の厳罰化は、マグネット効果(献血時に HIV 感染の有無がわかることから、検査目的で献血する者が集まる効果)の抑止につながっていると推測されている。





# Bloodbank@HSA Blood Services Group

Health Sciences Authority 11 Outram Road Singapore 169078

# DONOR HEALTH ASSESSMENT QUESTIONNAIRE and DECLARATION FORM

# AN IMPORTANT MESSAGE TO BLOOD DONORS

The purpose of this DHAQD Form is to confirm your suitability as a blood donor. If there is a possibility of an infection being transmitted to the recipient of your blood, your donation cannot be proceeded with.

Please read the following section carefully. If you have any of the following conditions now or in the past, you cannot donate blood.

#### Conditions That Make Your Blood Unsuitable For Donation

#### 1. High Risk Behaviours

Certain persons are at an increased risk of being exposed to blood borne diseases such as Human Immunodeficiency Virus (HIV) and must not donate blood (include whole blood and apheresis donation). They are:

- Persons who have engaged in sexual activity\* with multiple partners, including prostitutes and persons who engaged in casual sexual activity\*,
- Persons who have ever injected themselves with addictive drugs.
- All men who have ever had sex with another man,
- Persons who are or have ever worked as prostitutes,
- Persons who have ever had sex with someone with HIV/AIDS

If you have engaged in <u>any of the above activities or suspect that you may have been otherwise exposed to blood borne diseases such as HIV, DO NOT DONATE BLOOD.</u>

You are also advised to undergo testing for blood borne diseases, which is available at polyclinics and at the Department of STI Control.

Anonymous HIV testing is also available in Singapore (please see link <a href="http://www.hpb.gov.sq/HOPPortal/dandc-article/2144">http://www.hpb.gov.sq/HOPPortal/dandc-article/2144</a>)

#### 2. Medical Conditions – IF YOU HAVE THESE CONDITIONS DO NOT DONATE BLOOD

#### a. Acquired Immune Deficiency Syndrome (AIDS) / HIV infection

HIV infection is caused by the Human Immunodeficiency Virus (HIV I & II). The end stage of this disease is called AIDS. HIV infection is mostly spread through:

- Engaging in sexual activity\* with an infected person
- sharing contaminated needles like those used by intravenous drug abusers
- transfusion of contaminated blood
- a pregnant woman to her unborn baby

The early stage of HIV infection is called the "window period". During the window period, you may feel and look well and test results will be negative for infection. However, as you are carrying the virus in your blood stream, recipients of your blood will become infected with HIV.

The signs and symptoms suggestive of HIV/AIDS include weight loss, swollen glands in the neck, armpits or groins, persistent diarrhoea or rare cancers (eg.Kaposi Sarcoma, non-Hodgkin lymphoma). You must not give blood, (a) if you have been tested positive for HIV or have AIDS, and/or (b) have engaged in any of the above activities and/or (c) suspect you have been exposed to HIV.

#### b. Hepatitis

Hepatitis is a viral disease that affects the liver. Carriers of the Hepatitis B or C virus cannot donate blood. For persons who <u>ever</u> had Hepatitis A, the doctor must assess the safety of your blood for donation purposes. As a precautionary measure if you have had close contact with any person who has had hepatitis, you should not donate blood for at least 12 months.

#### c. Other sexually transmitted diseases

Persons who have been diagnosed or treated for sexually transmitted diseases (STD), should not donate blood for at least 12 months. Symptoms of sexually-transmitted diseases include genital ulcer, discharge, or swollen glands in the groin.

#### d. Malaria

Malaria is a parasitic infection transmitted through the bite of an infected Anopheles mosquito. It can also be transmitted by blood transfusion. First-time donors with a history of malaria will be deferred indefinitely. Please inform us if you have visited a malaria endemic area in the last 12 months or lived in a malaria endemic area for more than 6 months. If you have returned recently (less than 4 months) from a malaria endemic area, you will be deferred for at least 4 months from the date of return. Donors who test positive for malaria will be deferred indefinitely.

#### e. Other Conditions

In addition to these infections that can be transmitted through blood transfusion, there are new conditions that may have the potential to infect patients receiving blood or blood products. Examples of such emerging infectious diseases include the West Nile Virus (WNV), dengue virus, chikungunya virus, and variant CreutzfeId-Jacob disease (vCJD). There may also be immune factors present in blood that can adversely affect the health of the patient receiving the blood transfusion. Although these conditions do not currently pose a serious threat to the safety of blood supply in Singapore, we need to monitor them closely and additional tests may therefore be performed on your blood donation to protect the patient receiving the blood transfusion.

#### 3. Other Ways Your Donation Can Help

Residual blood components and samples of your donation (by-products such as white blood cells) may occasionally be used for research and development work rather than being discarded. Our research and development work aims to enhance public health by improving the safety of the blood supply and advancing medical knowledge and healthcare. Samples will not be linked to your identity. All research projects involving these samples must receive formal ethics approval.

#### \*"sexual activity" means:-

- (a) sexual activity occasioned by the introduction into the vagina, anus or mouth of any person of any part of the penis of another person; or
- (b) cunnilingus.

#### What should I do to ensure my blood is safe to donate?

The following sections of this document are required to be completed to help both you and Bloodbank@ HSA ensure the safety of your blood for donation purposes

- 1. Donor Registration
- 2. Donor Health Assessment Questionnaire
- 3. Donor Declaration

Any information you give us is strictly confidential.

#### **DONOR REGISTRATION**

NRIC/FIN/PASSPORT NUMBER			FIRST TIME	30 9053 003	DONATION #	DONATION #					
NAME (AS IN NR	IC/PASSPORT)				REPEAT	AS TOUR HOLES	COLLECTION	SITE		ASSOCIA	TION
							DONATION D	ATE			
HOME ADDRESS		bieca Leatral		iio,	AT LIGH	feet van do			DAY	MONTH	YEAR
	313 (300)	V LINES	estrare.		POSTAL COD	DE	DEFERRAL CO	DE		START DA	TE / END DATE
HOME PHONE	MOBILE PHON	E BL	JSINESS PH	HONE	OCCUPATION	NEWS LOVE	PH ID		PH TYPE		PH STATUS
BIRTH DATE	MONTH YEAR	(65)(32)	SI	EX F	С	RACE O					
EMAIL ADDRESS				DEFER		НВ	GROSS QTY (	Gms)		START	NATION TIME STOP
WEIGHT (kg)	TEMP (°C)	PULSE (/	/min)	B.P. (m	nm Hg)	SCREENER ID	BAG TYPE	LOT #		RES	CODE
COMMENTS (For C	] Official Use Only)	Totales less of c longing?	leteat	ipiev							

## **DONOR HEALTH ASSESSMENT QUESTIONNAIRE**

The questions below cover your health, travel and sexual history and are designed to help assess whether you are at risk of an infectious disease or a non-infectious health condition that would render you unsuitable to donate blood (for example, a history of auto-immune disorders like Rheumatoid Arthritis, as well as the presence of injurious agents in the blood and implication in Transfusion-Related Acute-Lung-Injury or TRALI).

The Bloodbank@HSA relies on you to answer the questions truthfully and to disclose information which is relevant to help us determine the safety of your blood.

You must complete and answer ALL the questions. If you are between 16 and 17 years old, parental consent is required prior to making a blood donation.

If your answer is false or misleading, you will be liable to prosecution under the Infectious Diseases Act. Supplying false information is an offence punishable under the Act with a fine of up to \$20,000 and/or with imprisonment of up to 2 years or to both.

Please call us at 1800 226 3320 (24-hour hotline) immediately if you feel that your blood should not be given to any patient. Health, travel, social or sexual histories may expose donors to infectious diseases like HIV, Hepatitis B and C, Syphilis and Malaria. Please help us provide the safest possible blood to our patients by alerting us early if you have any concerns or doubts. Your call will be kept strictly confidential and no questions will be asked. Although your blood will not be used, it will still be subjected to infectious disease testings to monitor the pattern and incidence of blood-transmissible diseases of the donor pool.

-	ou require clarification on any of the questions, please discuss this with ical Screener:	the Medic	al Officer (			
(Please indicate your answer by placing a mark inside the box using a permanent ink pen)						
1(a)	Is your purpose for this donation visit to find out whether or not you are infected with HIV or suffering from AIDS?	Yes	No			
1(b)	There is a window period in the early stage of HIV infection where you may test negative for the virus and you may feel well. Do you know that during this window period you can transmit the virus to someone else?	Yes	No			
1(c)	Is there any reason for you to suspect that you have or could possibly have been infected with HIV or AIDS?	Yes	No			
1(d)	Have you <b>ever</b> offered to anyone sexual activity* services for cash or benefits of any kind?	Yes	No			
2(a)	Male Donors: have you <b>ever</b> engaged in sexual activity* with another male?	Yes	No			
2(b)	Female Donors: in the past twelve (12) months, have you engaged in sexual activity* with a male whom you know or suspect to have engaged in sexual activity* with another male?	Yes	No			
3(a)	In the past twelve (12) months, have you had: unexplained weight loss or persistent night sweats, fever, diarrhoea or swollen glands?	Yes	No			
3(b)	In the last twelve (12) months, have you engaged in sexual activity* with anyone you know or have reason to suspect is infected with HIV or AIDS?	Yes	No			
4	In the last twelve (12) months, have you: (a) received from anyone sexual activity* services for cash or benefits of any kind?	Yes	No			
	(b) engaged in sexual activity* with anyone whom you have known for less than six (6) months?	Yes	No			
	<ul><li>(c) engaged in sexual activity* with more than one partner?</li><li>(d) had been diagnosed for syphilis, gonorrhea or any other sexually</li></ul>	Yes Yes	No No			
,	transmitted disease or had a positive test for syphilis?  (e) engaged in sexual activity* with a person described as in paragraphs 4(a), (b), (c) or (d)?	Yes	No			
	*"sexual activity" means:-  (a) sexual activity occasioned by the introduction into the vagina, anus or person of any part of the penis of another person; or  (b) cunnilingus.	mouth of a	ny			
5	Have you: (a) donated blood, double unit red cells, platelets or plasma in the last 16 weeks?	Yes	No			

	(b)	ever been told to stop giving blood or been refused as a blood donor?	Yes	No	
	(c)	ever had yellow jaundice or hepatitis or a positive hepatitis test?	Yes	No	
		been in close physical proximity with anyone with yellow jaundice or hepatitis or a positive hepatitis test in the past twelve (12) months?	Yes	No	
	(e)	ever received blood transfusion in UK, Mexico, France, South America and Central America or received plasma derived product in any country (including Singapore)?	Yes	No	
	(f)	received a blood transfusion in any other countries (other than the UK, Mexico, France, South America or Central America) in the last 12 months?	Yes	No	
	(g)	ever taken or been injected with addictive drugs?	Yes	No	
	(h)	within the past twelve (12) months, ever had body piercing (including ear piercing), tattoos, acupuncture done or been accidentally exposed to someone else's blood (including blood contaminated instrument)?	Yes	No	
	(i)	been detained or remanded in prison, approved institutions, approved homes or detention centres/barracks in the past twelve (12) months?	Yes	No	
6(a)	Are	you feeling well today?	Yes	No	
6(b)	Doy	you have any fever today or during the past 3 weeks?	Yes	No	
7		he past twelve (12) months, have you: been hospitalised?	Yes	No	
	(b)	been under a doctor's care regularly?	Yes	No	
	(c)	had a major illness or surgery (including wisdom tooth extraction)?	Yes	No	
	(d)	contracted or been in close contact with contagious infection, e.g. Chickenpox, measles, dengue, Chikungunya or any other viral infections?	Yes	No	
8		e you ever received / are taking: Human Growth Hormone?	Yes	No	
	(b)	cornea / dura mater transplant?	Yes	No	
	(c)	insulin / diabetic medication?	Yes	No	
9		he past three (3) days, have you: taken any medication (including pain killers)?	Yes	No	
	(b)	had a tooth extraction or dental work?	Yes	No	
	(c)	taken any form of traditional medicine (including herbal extract)?	Yes	No	
10		e you ever had: heart trouble, chest pain, shortness of breath, persistent cough?	Yes	No	

	(b)	high blood pressure requiring medication?	Yes	No
	(c)	Disease of the lungs, kidneys, liver or blood?	Yes	No
	(d)	a diagnosis of any cancer?	Yes	No
	(e)	any skin infection?	Yes	No
	(f)	fainting, unconsciousness, fits or mental disorder?	Yes	No
	(g)	malaria, Babesiosis or Chagas disease?	Yes	No
11		ve you received:  any injection or vaccination in the past twelve (12) months?	Yes	No
	(b)	any Hepatitis vaccination before?  If yes, when?	Yes	No
	(c)	In the past eight weeks, have you received smallpox vaccination or have you had close physical contact with (eg, touch) the vaccination site of anyone who received small pox vaccination?	Yes	No
12(a	a) F	emale Donors: Are you currently pregnant?	Yes	No 🔠
12(ŀ	0	emale Donors: Have you ever been pregnant in the past or had an abortion r a miscarriage previously? f so, please provide the number and last date of pregnancy	Yes	No
13(a	1.00	n the past twelve (12) months, have you travelled out of Singapore? f yes, where and when since your last successful donation?	Yes	No
13(t	n	lave you ever lived in a malaria endemic area consecutively for 6 months or nore?  f yes, where?	Yes	No
13(0	5	lave you ever stayed in Mexico, South America or Central America for a ontinuous period of 4 weeks or more?	Yes	No
13(c	fı N	lave you visited or lived cumulatively in Europe for five (5) years or more rom 1980 to the present, or the United Kingdom (England, Scotland, Wales, orthern Ireland, Isle of Man & Channel Islands) for three (3) months or more rom 1980 to 1996?	Yes	No
13(e		o you have any immediate family members who has been diagnosed with reutzfeld-Jacob Disease (CJD)?	Yes	No
14	c: u	o you understand that blood which is infected and donated to another person an cause disease, disability, pain, suffering and even death to him/her? Do you nderstand all the questions and information contained in this form and the onor information presented to you?	Yes	No
15	р	o you know that if you feel that your blood should not be transfused to another erson, you can call the 24-hour hotline at telephone No. 1800-2263320 Toll-Free) to alert HSA immediately?	Yes	No

### DONOR DECLARATION

To: Group Director
Blood Services Group
Health Sciences Authority

I declare that all the answers to the above questions are true.

I agree that my blood donation is made on a fully voluntary and non-remunerative basis as an altruistic gift of life and can be used for such purposes as is deemed fit for the benefit of society.

I consent to you collecting a sample of my blood from the donation for blood group typing and testing it for Syphilis, Hepatitis B, Hepatitis C, the HIV virus which causes AIDS and such other tests as you deem necessary for ensuring transfusion and transplant safety. I understand that, where the sample collected is unsuitable, testing may not be performed and my blood will not be used. I also understand if my blood test for the AIDS virus (HIV) or Hepatitis is not clearly positive or negative, my blood will not be used and my name may be placed on a deferral list.

I consent to the results of the above tests being stored in a computerised file. The results may be used for statistical and academic purposes provided that I shall not be identified as the subject of the tests without my express consent.

I understand that the results of tests made on my blood donation are solely for the purpose of ensuring safe blood for transfusion and the test results will not be released for insurance, employment or for any other purpose.

If I feel that my blood should <u>not be</u> transfused to another person, I shall call telephone No. 1800-2263320 (Toll-Free) to alert HSA immediately. I understand no reasons need to be provided but my donated blood will still be subjected to infectious disease testings such as HIV, Syphilis Hepatitis B and Hepatitis C viruses for epidemiological assessment of the donor pool.

repaired b and repaired e virages for epidemiological assessment of the donor pool.						
I confirm that I fully understand all the quisleading answers. **I confirm that I fully unto me in the(language/di(name)	questions above and the consequences of giving false or nderstand all the questions above which were explained alect) by NRIC/Passport No./FIN No. before I give my answers.					
I UNDERSTAND THAT I SHALL BE PROSECU THE ANSWERS TO THE ABOVE QUESTIONNAIR MISLEADING.	TED AND MAY BE IMPRISONED, AND/OR FINED IF ANY OF RE OR ANY OF THE STATEMENTS ABOVE IS FALSE OR					
Consent to use my residual blood components and blood sample for research  I consent to the use of residual blood components and samples from my donation for medical and health related research and development, on the basis that this will not be linked to my personal details and all research projects involving these samples have received formal ethics approval.						
	Yes No No					
NAME OF DONOR (IN BLOCK LETTERS)	SIGNATURE OF DONOR					
NRIC/FIN/PASSPORT NUMBER	DATE					

SIGNATURE OF MEDICAL SCREENER (WITNESS)

This form is the property of HSA Effective date: 2 May 2014

\*\*delete where appropriate

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Donating blood is an act of great human kindness.

NAME OF MEDICAL SCREENER (WITNESS)

# BLOOD SERVICES GROUP HEALTH SCIENCES AUTHORITY

Supplementary Questions (Infectious Disease Outbreak)

1.	Have you visited or lived in Guinea, Liber the last 8 weeks?	ia or Sierra Leone within	Yes No
2:	Have you ever been infected or diagnose	d with Ebola infection.	Yes No No
3.	Have you had close contact with a per /probable or confirmed of having Ebola in (Close contact – having cared for or live confirmed, probable or suspected EVD, or blood, secretions or other body fluids of suspected case of EVD. This includes him involved in providing care to patients with handling human bodies, and bats, rodent endemic areas.)	Yes No No	
NA	ME OF BLOOD DONOR	NRIC / PP NO.	SIGNATURE
		• • • •	
NA	ME OF MEDICAL SCREENER	DATE	SIGNATURE
BL	OOD UNIT NO.		

#### INFECTIOUS DISEASES ACT (感染症法)

#### PART III

#### CONTROL OF INFECTIOUS DISEASES WITHIN SINGAPORE

#### Offence for supplying false or misleading information

**11.**—(1) Any person who —

(a)

donates any blood or blood product at any blood bank or hospital in Singapore for any use or purpose; and

(b)

directly in connection with such donation of blood or blood product, supplies any material information which he knows to be false or misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both.

(2) In this section, "material information" means any information directly relating to the likelihood of transmission of an infectious disease by the use of any blood or blood product.

#### PART IV

#### CONTROL OF AIDS AND HIV INFECTION

#### Blood donation and other acts by person with AIDS or HIV Infection

**24.**—(1) Any person who knows that he has AIDS or HIV Infection shall not —

(a)

donate blood at any blood bank in Singapore; or

(b)

do any act which is likely to transmit or spread AIDS or HIV Infection to another person.

- (1A) For the purposes of this section, a person shall be deemed to know that he has AIDS or HIV Infection if a serological test or other test for the purpose of ascertaining the presence of HIV Infection carried out on him has given a positive result and the result has been communicated to him.
- (2) Any person who contravenes <u>subsection (1)</u> shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 10 years or to both.