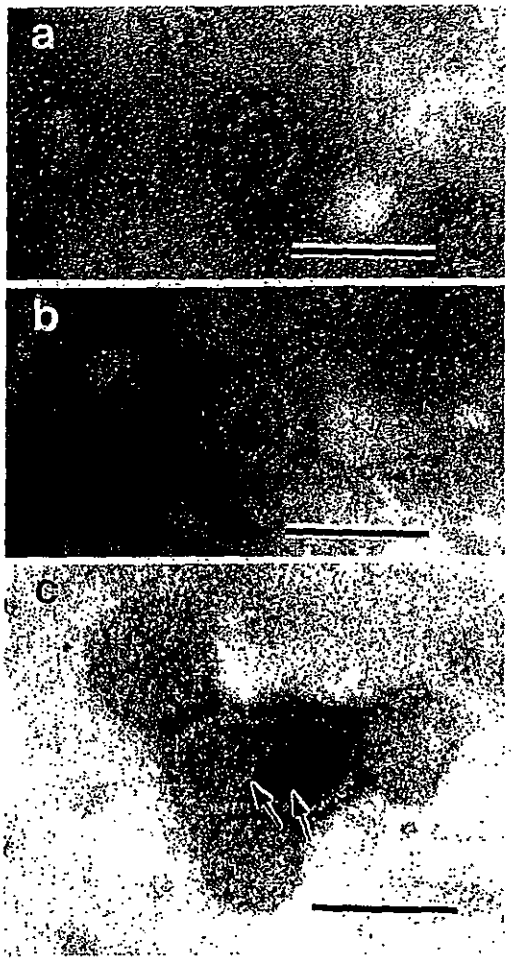

Fig. 3. Electron micrographs of positively stained VLPs showing internal corelike structures. Spherical VLPs from sample no. 6 (a) and sample no. 3 (b) and rodlike VLPs from sample no. 7 (c) are shown. a A 65-nm spherical VLP with a 35-nm inner core and surface spikelike projections; b 80-nm spherical VLP with a 45-nm core; c rodlike VLP 130 nm in the major axis and 70 nm in the minor axis containing two corelike structures (*arrows*) within an outer coat 10 nm thick. *Bar* 100 nm

spherical VLPs barely detectable despite careful observation. Thus, although the presence of the virus-like particles in the blood was significantly ($P < 0.001$) associated with the elevation of plasma ALT levels, indicating that these virus-like particles do cause liver cell necrosis, the nucleic acids of parenterally transmissible known hepatitis viruses were not detected in any tested plasma samples.

A novel DNA virus, which was designated TT virus (TTV), has been successfully cloned from serum of a patient with posttransfusion hepatitis of unknown etiology.[13] TTV particles are 30- to 32-nm spherical particles with a density of 1.31–1.35 g/ml in cesium chloride.[14] The morphology and buoyant density of TTV were quite different from the VLPs described in this article. Recently, a novel single-stranded DNA virus, which was named NV-F, has also been successfully cloned from the serum of a patient with non-A–E hepatitis without isolation of the virus particles.[15] NV-F DNA was detected in 17 (24.6%) of 69 patients with non-A–E and in 5 (2.8%) of 180 healthy individuals. Therefore, further morphological study and genomic study of NV-F should be carried out to evaluate whether the circulating VLPs were closely related to NV-F.

In conclusion, the presented VLPs, which morphologically resembled togaviruses or coronaviruses, may be a causative candidate virus of bloodborne non-A–G hepatitis, and details of the etiological implications should be further elucidated.

Acknowledgments The authors thank Drs. H. Okamoto and M. Mayumi, Immunology Division, Jichi Medical School, Tochigi, Japan, for testing the GBV-C genomic RNA. This study was supported in part by Grants-in Aid for Scientific Research (C) 17590632 from the Ministry of Education, Science and Culture of Japan.

References

1. Choo QL, Kuo G, Weiner AJ, Overby LR, Bradley DW, Houghton M (1989) Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 244:359–362
2. Simons JN, Leary TP, Dawson GJ, Pilot-Matias TJ, Muerhoff AS, Schlauder GG, Desai SM, Mushahwar IK (1995) Isolation of novel virus-like sequences associated with human hepatitis. Nat Med 1:564–569
3. Linnen J, Wages JJ, Zhang-Keck ZY, Fry KE, Krawczynski KZ, Alter H, Koonin E, Gallagher M, Alter M, Hadziyannis S, Karayiannis P, Fung K, Nakatsuji Y, Shih JWK, Young L, Piatak M Jr, Hoover C, Fernandez J, Chen S, Zou JC, Morris T, Hyams KC, Ismay S, Lifson JD, Hess G, Foung SKH, Thomas H, Bradley D, Margolis H, Kim JP (1996) Molecular cloning and disease association of hepatitis G virus: a transfusion-transmissible agent. Science 271:505–508
4. Alter MJ, Gallagher M, Morris TT, Moyer LA, Meeks EL, Krawczynski K, Kim JP, Margolis HS, for The Sentinel Counties Viral Hepatitis Study Team (1997) Acute non-A-E hepatitis in the United States and the role of hepatitis G virus infection. N Engl J Med 336:741–746
5. Alter HJ, Nakatsuji Y, Melpolder J, Wages J, Wesley R, Shih WK, Kim JP (1997) The incidence of transfusion-associated hepatitis G virus infection and its relation to liver disease. N Engl J Med 336:747–754
6. Kaito M, Watanabe S, Tsukiyama-Kohara K, Yamaguchi K, Kobayashi Y, Konishi M, Yokoi M, Ishida S, Suzuki S, Kohara M (1994) Hepatitis C virus particle detected by immunoelectron microscopic study. J Gen Virol 75:1755–1760
7. Ishida S, Kaito M, Kohara M, Tsukiyama-Kohara K, Fujita N, Ikoma J, Adachi Y, Watanabe S (2001) Hepatitis C virus core particle detected by immunoelectron microscopy and optical rotation technique. Hepatol Res 20:335–347
8. Kaito M, Ohba H, Chiba J, Kohara M, Tanaka H, Fujita N, Gabazza EC, Watanabe S, Konishi M, Adachi Y (2006) The ultrastructural morphology of native hepatitis B virus. Med Mol Morphol 39:136–145
9. Kaito M, Ishida S, Tanaka H, Horiike S, Fujita N, Adachi Y, Kohara M, Konishi M, Watanabe S (2006) Morphology of hepatitis C and hepatitis B virus particles as detected by immunogold electron microscopy. Med Mol Morphol 39:63–71
10. Yoshiba M, Okamoto H, Mishiro S (1995) Detection of the GBV-C hepatitis virus genome in serum from patients with fulminant hepatitis of unknown aetiology. Lancet 346:1131–1132
11. Coursaget P, Maupas PH, Levin P, Barin F (1979) Virus-like particles associated with non-A, non-B hepatitis. Lancet 2:92
12. Fagan EA, Ellis DS, Tovey GM, Lloyd G, Portmann B, Williams R, Zuckerman AJ (1989) Toga-like virus as a cause of fulminant hepatitis attributed to sporadic non-A, non-B. J Med Virol 28:150–155

13. Nishizawa T, Okamoto H, Konishi K, Yoshizawa H, Miyakawa Y, Mayumi M (1997) A novel DNA virus (TTV) associated with elevated transaminase levels in posttransfusion hepatitis of unknown etiology. Biochem Biophys Res Commun 241:92–97
14. Itoh Y, Takahashi M, Fukuda M, Shibayama T, Ishikawa T, Tsuda F, Tanaka T, Nishizawa T, Okamoto H (2000) Visualization of TT virus particles recovered from the sera and feces of infected humans. Biochem Biophys Res Commun 279:718–724
15. Yeh CT, Tsao ML, Lin YC, Tseng IC (2006) Identification of a novel single-stranded DNA fragment associated with human hepatitis. J Infect Dis 193:1089–1097

医薬品　研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
一般的名称	－		研究報告の公表状況	http://www.fda.gov/cber/faq/msmdonor.htm	公表国 米国	
販売名(企業名)	－					

研究報告の概要

男性間性交渉者(MSM)からの供血に関する米国食品医薬品局(FDA)の政策は、米国でAIDSが流行し始めた1977年以降に他の男性と性交渉を行ったことがある男性の供血は見合わせており、これは米国独自のものではなく、多くのヨーロッパ諸国も、この政策を維持しており、MSMからの供血永久停止を科学と倫理の両面から再検討している。
米国赤十字によると、1977年以降に男性間性交渉歴を持つ男性のHIV有病率は、一般集団の60倍、初回供血者の800倍、リピート供血者の8000倍高いとされる。HIVに感染している男性間性交渉者の75%は、すでに自分がHIV陽性であることを自覚しており、供血する可能性は低いことを考慮に入れても、男性間性交渉歴を有する潜在的供血者のHIV有病率は、初回供血者よりも200倍高く、リピート供血者よりも2000倍高い。
現在の高感度検査がHIV感染供血者を検出できない割合は100万人中1人未満であるものの、米国で全血、赤血球濃縮製剤、血漿、血小板が輸血される件数は年間2000万件以上にのぼることに留意しなければならない。
非常に低レベルのウイルスが血中に存在する時期、いわゆる「ウインドウ期」では、HIV感染を検出することが特に難しい。
現在、輸血や血漿分画製剤からHIVが伝播するリスクは米国ではほぼ排除されている。
また、男性間性交渉者は、輸血により伝播され得る他の感染症を有するリスクも高い。例えば、男性間性交渉者は、一般集団よりも、B型肝炎ウイルス感染は約5～6倍多くみられ、C型肝炎ウイルス感染は約2倍多くみられる。さらに、男性間性交渉者の間でヒトヘルペスウイルス8型（HHV-8）の罹患率と有病率も高い。HHV-8は、免疫不全患者にカポジ肉腫と呼ばれる癌を引き起こす。

報告企業の意見	今後の対応
米国において実施されている、HIVをはじめとするウイルス疾患のハイリスクグループであるMSMからの供血制限に関する情報である。 血漿分画製剤では、採血時の問診、スクリーニング検査に加え、製造工程中において各種ウイルスの不活化・除去効果を有する工程が設けられている。	今後とも供血者からのHIV等の感染者排除に関する安全性情報等に留意していく。

使用上の注意記載状況・その他参考事項等

重要な基本的注意
現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病（vCJD）等が伝播したとの報告はない。しかしながら、製造工程において異常プリオンを低減し得るとの報告があるものの、理論的なvCJD等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。

FDA Policy on Blood Donations from Men Who Have Sex with Other Men

---

What is FDA's policy on blood donations from men who have sex with other men (MSM)?

Men who have had sex with other men, at any time since 1977 (the beginning of the AIDS epidemic in the United States) are currently deferred as blood donors. This is because MSM are, as a group, at increased risk for HIV, hepatitis B and certain other infections that can be transmitted by transfusion.

The policy is not unique to the United States. Many European countries have recently reexamined both the science and ethics of the lifetime MSM deferral, and have retained it (See the transcript of the "FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era" at http://www.fda.gov/cber/minutes/nat030806t.htm#7 for further information.). This decision is also consistent with the prevailing interpretation of the European Union Directive 2004/33/EC article 2.1 on donor deferrals.

Why doesn't FDA allow men who have had sex with men to donate blood?

A history of male-to-male sex is associated with an increased risk for the presence of and transmission of certain infectious diseases, including HIV, the virus that causes AIDS. FDA's policy is intended to protect all people who receive blood transfusions from an increased risk of exposure to potentially infected blood and blood products.

The deferral for men who have had sex with men is based on the following considerations regarding risk of HIV:

- Men who have had sex with men since 1977 have an HIV prevalence (the total number of cases of a disease that are present in a population at a specific point in time) 60 times higher than the general population, 800 times higher than first time blood donors and 8000 times higher than repeat blood donors (American Red Cross). Even taking into account that 75% of HIV infected men who have sex with men already know they are HIV positive and would be unlikely to donate blood, the HIV prevalence in potential donors with history of male sex with males is 200 times higher than first time blood donors and 2000 times higher than repeat blood donors.
- Men who have had sex with men account for the largest single group of blood donors who are found HIV positive by blood donor testing.
- Blood donor testing using current advanced technologies has greatly reduced the risk of HIV transmission but cannot yet detect all infected donors or prevent all transmission by transfusions. While today's highly sensitive tests fail to detect less than one in a million HIV infected donors, it is important to remember that in the US there are over 20 million transfusions of blood, red cell concentrates, plasma or platelets every year. Therefore, even a failure rate of 1 in a million can be significant if there is an increased risk of undetected HIV in the blood donor population.
- Detection of HIV infection is particularly challenging when very low levels of virus are present in the blood for example during the so-called "window period". The "window period" is the time between being infected with HIV and the ability of an HIV test to detect HIV in an infected person.
- FDA's MSM policy reduces the likelihood that a person would unknowingly donate blood during the "window period" of infection. This is important because the rate of new infections in MSM is higher than in the general population and current blood donors.
- Collection of blood from persons with an increased risk of HIV infection also presents an added risk if blood were to be accidentally given to a patient in error either before testing is completed or following a positive test. Such medical errors occur very rarely, but given that there are over 20 million transfusions every year, in the USA, they can occur. That is one more reason why FDA and other regulatory authorities work to assure that there are multiple safeguards, not just testing.
- Several scientific models show there would be a small but definite increased risk to people who receive blood transfusions if FDA's MSM policy were changed and that preventable transfusion transmission of HIV could occur as a result.
- No alternate set of donor eligibility criteria (even including practice of safe sex or a low number of lifetime partners) has yet been found to reliably identify MSM who are not at increased risk for HIV or certain other transfusion

transmissible infections.

- Today, the risk of getting HIV from a transfusion or a blood product has been nearly eliminated in the United States. Improved procedures, donor screening for risk of infection and laboratory testing for evidence of HIV infection have made the United States blood supply safer than ever. While appreciative and supportive of the desire of potential blood donors to contribute to the health of others, FDA's first obligation is to assure the safety of the blood supply and protect the health of blood recipients.
- Men who have sex with men also have an increased risk of having other infections that can be transmitted to others by blood transfusion. For example, infection with the Hepatitis B virus is about 5-6 times more common and Hepatitis C virus infections are about 2 times more common in men who have sex with other men than in the general population. Additionally, men who have sex with men have an increased incidence and prevalence of Human Herpes Virus-8 (HHV-8). HHV-8 causes a cancer called Kaposi's sarcoma in immunocompromised individuals.

What is self-deferral?

Self-deferral is a process in which individuals elect not to donate because they identify themselves as having characteristics that place them at potentially higher risk of carrying a transfusion transmissible disease. FDA uses self-deferral as part of a system to protect the blood supply. This system starts by informing donors about the risk of transmitting infectious diseases. Then, potential donors are asked questions about their health and certain behaviors and other factors (like travel and past transfusions) that increase their risk of infection. Screening questions help people, even those who feel well, to identify themselves as potentially at higher risk for transmitting infectious diseases. Screening questions allow individuals to self defer, rather than unknowingly donating blood that may be infected.

Is FDA's policy of excluding MSM blood donors discriminatory?

FDA's deferral policy is based on the documented increased risk of certain transfusion transmissible infections, such as HIV, associated with male-to-male sex and is not based on any judgment concerning the donor's sexual orientation.

Male to male sex has been associated with an increased risk of HIV infection at least since 1977. Surveillance data from the Centers for Disease Control and Prevention indicate that men who have sex with men and would be likely to donate have a HIV prevalence that is at present over 15 fold higher than the general population, and over 2000 fold higher than current repeat blood donors (i.e., those who have been negatively screened and tested) in the USA. MSM continue to account for the largest number of people newly infected with HIV.

Men who have sex with men also have an increased risk of having other infections that can be transmitted to others by blood transfusion.

What about men who have had a low number of partners, practice safe sex, or who are currently in monogamous relationships?

Having had a low number of partners is known to decrease the risk of HIV infection. However, to date, no donor eligibility questions have been shown to reliably identify a subset of MSM (e.g., based on monogamy or safe sexual practices) who do not still have a substantially increased rate of HIV infection compared to the general population or currently accepted blood donors. In the future, improved questionnaires may be helpful to better select safe donors, but this cannot be assumed without evidence.

Are there other donors who have increased risks of HIV or other infections who, as a result, are also excluded from donating blood?

Intravenous drug abusers are excluded from giving blood because they have prevalence rates of HIV, HBV, HCV and HTLV that are much higher than the general population. People who have received transplants of animal tissue or organs are excluded from giving blood because of the still largely unknown risks of transmitting unknown or emerging pathogens harbored by the animal donors. People who have recently traveled to or lived abroad in certain countries may be excluded because they are at risk for transmitting agents such as malaria or variant Creutzfeldt-Jakob Disease (vCJD). People who have engaged in sex in return for money or drugs are also excluded because they are at increased risk for transmitting HIV and other blood-borne infections.

Why are some people, such as heterosexuals with multiple partners, allowed to donate blood despite increased risk for transmitting HIV and hepatitis?

Current scientific data from the U.S. Centers for Disease Control and Prevention (CDC) indicate that, as a group, men who have sex with other men are at a higher risk for transmitting infectious diseases or HIV than are individuals in other risk categories. While statistics indicate a rising infection rate among young heterosexual women, their overall rate of HIV infection remains much lower than in men who have sex with other men. For information on HIV-related statistics and trends, go to CDC's HIV/AIDS Statistics and Surveillance web page.

Isn't the HIV test accurate enough to identify all HIV positive blood donors?

HIV tests currently in use are highly accurate, but still cannot detect HIV 100% of the time. It is estimated that the HIV risk from a unit of blood has been reduced to about 1 per 2 million in the USA, almost exclusively from so called "window period" donations. The "window period" exists very early after infection, where even current HIV testing methods cannot detect all infections. During this time, a person is infected with HIV, but may not have made enough virus or developed enough antibodies to be detected by available tests. For this reason, a person could test negative, even when they are actually HIV positive and infectious. Therefore, blood donors are not only tested but are also asked questions about

behaviors that increase their risk of HIV infection.

Collection of blood from persons with an increased risk of HIV infection also presents an added risk to transfusion recipients due to the possibility that blood may be accidentally given to a patient in error either before testing is completed or following a positive test. Such medical errors occur very rarely, but given that there are over 20 million transfusions every year, in the USA, they can occur. For these reasons, FDA uses a multi-layered approach to blood safety including pre-donation deferral of potential donors based on risk behaviors and then screening of the donated blood with sensitive tests for infectious agents such as HIV-1, HIV-2, HCV, HBV and HTLV-I/II.

How long has FDA had this MSM policy?

FDA's policies on donor deferral for history of male sex with males date back to 1983, when the risk of AIDS from transfusion was first recognized. Our current policy has been in place since 1992.

FDA has modified its blood donor policy as new scientific data and more accurate tests for HIV and hepatitis became available. Today, the risk of getting HIV from a blood transfusion has been reduced to about one per two million units of blood transfused. The risk of hepatitis C is about the same as for HIV, while the risk of hepatitis B is somewhat higher.

Doesn't the policy eliminate healthy donors at a time when more donors are needed because of blood shortages?

FDA realizes that this policy will defer many healthy donors. However, FDA's MSM policy minimizes even the small risk of getting infectious diseases such as HIV or hepatitis through a blood transfusion.

Would FDA ever consider changing the policy?

FDA scientists continue to monitor the scientific literature and to consult with experts in CDC, NIH and other agencies. FDA will continue to publicly revisit the current deferral policy as new information becomes available.

On March 8, 2006, FDA conducted a workshop entitled "Behavior-based donor deferrals in the Nucleic Acid Test (NAT) era". The workshop addressed scientific challenges, opportunities, and risk based donor deferral policies relevant to the protection of the blood supply from transfusion transmissible diseases, seeking input on this topic. Participants were given the opportunity to provide scientific data that could support revising FDA's MSM deferral. The workshop provided a very active, open and broad-based scientific dialogue concerning current behavior-based deferrals and explored other options that may be considered and the data needed to evaluate them.

FDA's primary responsibility is to enhance blood safety and protect blood recipients. Therefore FDA would change this policy only if supported by scientific data showing that a change in policy would not present a significant and preventable risk to blood recipients. Scientific evidence has not yet been provided to FDA that shows that blood donated by MSM or a subgroup of these potential donors, is as safe as blood from currently accepted donors.

FDA remains willing to consider new approaches to donor screening and testing, provided those approaches assure that blood recipients are not placed at an increased risk of HIV or other transfusion transmitted diseases.

References:

1. Germain, M., Remis, R.S., and Delage, G. The risks and benefits of accepting men who have had sex with men as blood donors. Transfusion 2003; 43:25-33.
2. Busch MP, Glynn SA, Stramer SL, Strong DM, Caglioti S, Wright DJ, Pappalardo B, Kleinman SH; NHLBI-REDS NAT Study Group. A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. Transfusion 2005, 45:254-264
3. Presentation at FDA Blood Products Advisory Committee Meeting, September 2000.
4. Soldan, K. and Sinka, K. Evaluation of the de-selection of men who have had sex with men from blood donation in England. Vox Sanguinis 2003; 84:265-273.

Updated: May 23, 2007

医薬品 研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	機構処理欄
				2007. 3. 19	該当なし	

一般的名称	解凍人赤血球濃厚液	研究報告の公表状況		公表国
販売名(企業名)	解凍赤血球濃厚液「日赤」(日本赤十字社) 照射解凍赤血球濃厚液「日赤」(日本赤十字社) 解凍赤血球-LR「日赤」(日本赤十字社) 照射解凍赤血球-LR「日赤」(日本赤十字社)		Chen YM, Kuo SH. Lancet. 2007 Feb 24;369(9562):623-5.	台湾

研究報告の概要

○台湾のHIV-1

台湾のHIV-1/AIDS感染拡大は危険な状況に突入しつつある。2006年末までに外国人599名を含む13,702名のHIV-1感染が台湾の疾病対策センター(CDC)に報告された。2003年の初回供血者、徴集兵、妊婦におけるHIV-1感染率は、それぞれ10万人当り5.2人、57.0人、12.0人であった。同年のHIV-1感染率は、静注薬物使用者(IDU)で0.09%、女性風俗従業員で0.2%、性感染症患者で1.9%、男性と性交渉を持つ男性(MSM)で6.7%であった。感染者数は2003年に11%増、2004年に77%増、2005年に123%増と急増したが、感染拡大予防プログラム実施後の2006年には10%減少した。最近の推定では台湾のHIV-1/AIDS感染者数は約3万人で、感染率(2,300万人中3万人;1/767)は中国(13億人中65万人;1/2,000)よりも高い可能性が示されている。

リスク要因分析によると、IDUのHIV-1感染率は、2002年の1.7% (13/772)から2003年の8.1%(70/862)、2004年の41.3%(628/1,520)、2005年の72.4% (2,461/3,399)へと増加し、2006年には68.6% (2,017/2,974)に減少した。台湾のIDU6万～10万人のうち、10～15%はHIV-1のCRF07_BC株に感染していると推定される。

同性愛者用サウナを利用するMSMのHIV-1感染率は5.2%～15.8%である。MSMのHIV-1/AIDS感染者は、異性愛者と比べて梅毒の有病率も有意に高い。HIV-1/AIDS感染者のうち20歳未満の割合は、異性愛者(1.7%)と比較してMSM(3.0%)では有意に多い。

HIV-1の垂直感染例は、2006年末までに確定例19例が報告された。台湾CDCは、2005年1月に母子感染予防プログラムを開始し、2005年中に5例の垂直感染が報告された。2006年6月までにスクリーニング率は97.4%に達し、妊婦338,452名中47名(10万人当り13.9人)の感染が特定され、母子感染予防のための抗レトロウイルス療法を受けた。

台湾でHIV-1感染の脅威が高まるにつれ、根強い感染の否定、差別再燃の兆候が多くみうけられる。

報告企業の意見	今後の対応
2003年以降急増した台湾のHIV-1/AIDS感染者数は約3万人と推測され、感染率は中国よりも高い可能性が示され危険な状態に入りつつあるとの報告である。	日本赤十字社では、HIVについて20プールでスクリーニングNATを行い、陽性血液を排除している。国内外のHIV感染、AIDS発生の動向やHIV感染に関する新たな知見等について今後も情報の収集に努める。次世代NAT試薬についての評価、検査方法の改良に向けた開発・検討を進める。

使用上の注意記載状況・その他参考事項等

解凍赤血球濃厚液「日赤」
照射解凍赤血球濃厚液「日赤」
解凍赤血球-LR「日赤」
照射解凍赤血球-LR「日赤」

血液を介するウイルス、細菌、原虫等の感染
vCJD等の伝播のリスク

8 American Enterprise Institute, Washington, D.C. Can Asia avoid the AIDS typhoon? Nov 11, 2002: http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=722 (accessed Oct 19, 2006).

9 Ministry of Health, People's Republic of China, Joint United Nations Programme on HIV/AIDS, World Health Organization. Update on the HIV/AIDS epidemic and response in China. 2006: http://data.unaids.org/publications/External-Documents/RP_2005ChinaEstimation_25Jan06_en.pdf (accessed Oct 26, 2006).

10 Hesketh T, Huang XM, Wang ZB, Xing ZW, Cubitt DW, Tomkins AM. Using the premarital examination for population-based surveillance for HIV in China. *AIDS* 2003; 17: 1574–76.

11 Qu S, Sun X, Zheng X, Shen J. National sentinel surveillance of HIV infection in China from 1995 to 2001. XIV International AIDS Conference, Barcelona, Spain, July 7–12, 2002: WePeC6072 (abstr). http://gateway.nlm.nih.gov/MeetingAbstracts/102250025.html (accessed Oct 26, 2006).

12 Hong L, Mo LH, Liu H. Prevention of HIV transmission from mother-to-child in Yunnan. *Mod Prev Med* 2001; 28: 68–69.

13 Wang L, Kong L, Wu F, Bai Y, Burton R. Preventing chronic diseases in China. *Lancet* 2005; 366: 1821–24.

HIV-1 in Taiwan

Taiwan is entering a new and dangerous phase of its HIV-1/AIDS epidemic. By the end of 2006, 13 702 individuals (including 599 foreigners) had been reported as infected with HIV-1 to the Centers for Disease Control of Taiwan.[1] In 2003, HIV-1 rates in first-time blood donors, military conscripts, and pregnant women were measured at 5·2, 57·0, and 12·0 per 100 000, respectively.[1] Data from that year indicated HIV-1 rates of 0·09% for intravenous drug users, 0·2% for female sex workers, 1·9% for patients with sexually transmitted infections, and 6·7% for men who have sex with men in saunas or bath houses.[1] Since then, the number of people living with HIV-1/AIDS in Taiwan has jumped sharply, from an 11% increase in 2003 to a 77% increase in 2004 and a 123% increase in 2005 (figure 1).[1]

However, after the implementation of a harm-reduction programme, a 10% decrease was seen in 2006 (figure 1). The current estimated number of HIV-1/AIDS cases in Taiwan is about 30 000, which suggests that the infection rate there could be greater than that in China: 30 000 per 23 million (1/767) compared with 650 000 per 1·3 billion (1/2000).[2]

A risk-factor analysis of reported cases showed that the proportion of intravenous drug users infected with HIV-1 increased from 1·7% (13/772) in 2002, to 8·1% (70/862) in 2003, to 41·3% (628/1520) in 2004, to 72·4% (2461/3399) in 2005, and dropped to 68·6% (2017/2974) in 2006 (figure 2).[1] The most important risk factor for Taiwanese intravenous drug users is needle-sharing, followed by the sharing of heroin diluents.[3] A molecular epidemiological study showed that more than 95% of intravenous drug users with newly diagnosed HIV-1 in 2004 and 2005 were infected with CRF07_BC, a circulating recombinant form of subtypes B′ and C.[4,5] Previously, several studies suggested that CRF07_BC originated in China's Yunnan province as a mix of subtype B′ from Thailand and subtype C from India. The subtype is believed to have moved to Xinjiang province in China's northwest along a major heroin-trafficking route.[6]

See Editorial page 616
See Comment page 621

Of the 60 000–100 000 intravenous drug users in Taiwan, 10–15% may be infected with CRF07_BC. If so, they probably represent the largest group of such intravenous drug users in northeast Asia. The circulating recombinant form might have followed a separate drug-trafficking route to Taiwan from Yunnan

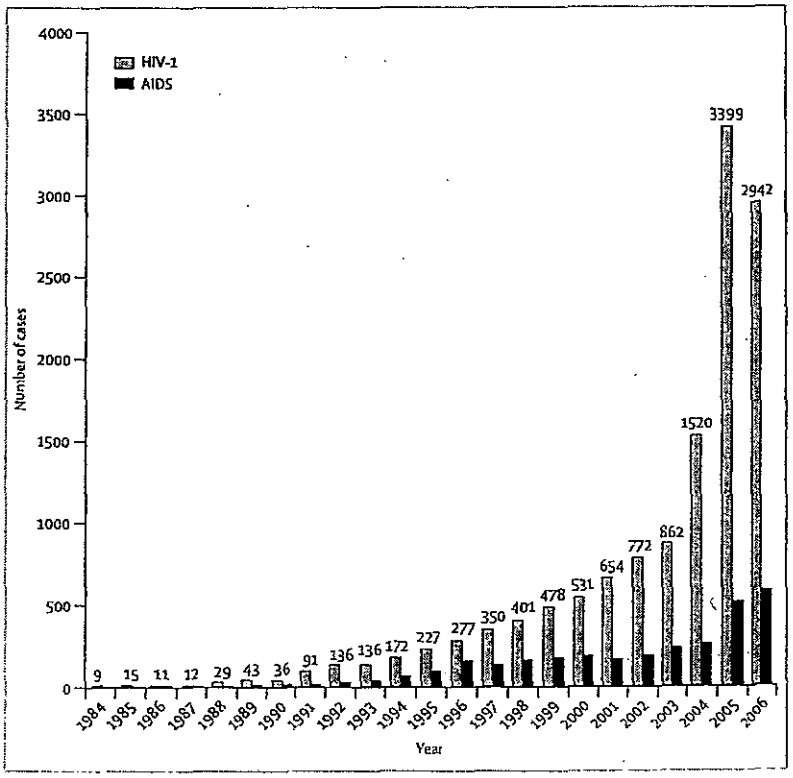

Figure 1: Annual numbers of HIV-1 seropositive cases and AIDS patients reported to Taiwan Centers for Disease Control[1]