

assay to detect HHV 8 genomes from DNA extracted from purified CD19+ B lymphocytes from randomly selected US whole blood donors. Blood specimens were stored at 4°C overnight prior to processing. CD19+ B lymphocytes were selected within 24 hours of specimen collection. Cellular target for the GAPDH gene was used to quantify cell-equivalent DNA in order to determine the DNA input into the HHV 8 PCR reaction. Real-time HHV 8 PCR was run in duplicate for each donor specimen along with an HHV 8 genomic copy standard. Five-fold dilution series of a calibrated HHV8 DNA provided 200, 40, 8 and 1.6 copies for a standard curve. Two sets of standard DNA were run with each plate, the 8 copy HHV 8 genome standard was always detected; the 1.6 copy control was detected at greater than 50% of the time. Results: Specimens were obtained from 950 blood donors and purified DNA from greater than  $1 \times 10^6$  B cell-equivalents was obtained from 684 donors. DNA of lesser amount was obtained from 168 donors. The remaining 98 specimens did not produce sufficient DNA for HHV 8 PCR. The quantity of cellular DNA from each donor was measured with a real-time PCR target amplifying cellular GAPDH target. Cellular DNA equivalent to  $3 \times 10^6$  B cells (which approximates total B cells from 1 ml whole blood) was used as input material for each real-time HHV8 PCR reaction. No HHV 8 DNA was detected from any of the blood donor specimens. For the 684 donors from whom sufficient DNA were obtained, HHV 8 genomes were not detected in the DNA-equivalent of 3 to  $6 \times 10^5$  CD19+ B lymphocytes with real time PCR which has a detection limit of 8 copies per PCR reaction (95% CI: 0-3/684). Negative results from the 168 donors were potentially confounded by insufficient input DNA into the PCR reactions. Conclusions: HHV8 genomes were not detected from 684 blood donors using DNA equivalent of 3 to  $6 \times 10^5$  CD19+ B lymphocytes with a real-time PCR, which has a detection limit of 8 copies per PCR reaction. Therefore, the prevalence of detectable HHV8 genomes in healthy blood donors is very low.

#### Disclosure of Conflict of Interest

Lirong Qu, Darrell Trutzli: Nothing to Disclose

#### SP201

##### Identification of a Parvovirus B19 Genotype 3 Isolate in the United States

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Background: Parvovirus B19 (B19V) is a human pathogen frequently detected in plasma donations through the detection of nucleic acids. Three B19V genotypes have been defined based on isolates having greater than 10% divergence in overall DNA sequence. B19V genotype 3 is a rarely occurring genotype that has been detected primarily in Ghana with sporadic reports in Brazil and France. B19V genotype 3 has not been previously reported in North America. Methods: A multi-probe fluorogenic PCR assay has been developed to ensure broad specificity for the detection of B19V. A detection probe specific for genotype 1 contains the DNA sequence of the B19V Au<sub>1</sub> prototype strain and a second probe contains a DNA consensus sequence derived from the A6 (genotype 2) prototype strain and the V9 and D91.1 (genotype 3) isolates. The assay was used to evaluate over 400,000 clinical samples. Determinations of the B19V virus titer and antibody concentration were performed on samples of interest. Results: This evaluation identified a series of 8 plasma donations spanning 28 days from a single donor in the United States. DNA sequence analysis of nucleic acids isolated from the index donation indicates significant homology with B19V genotype 3. The B19V titer of this series of donations showed virus titers that peaked at greater than  $10^{11}$  International Units (IU)/mL. The virus titer decreased significantly over the next several donations coinciding with an increase in IgM levels. The IgG levels also increased but lagged approximately 7 days after the IgM levels. Conclusions: Recent reports surrounding the incidence of the B19V genotype 3 infection among blood and Source Plasma donors indicate that the prevalence of this genotype is quite low. Our data corroborate these reports since testing over 400,000 clinical samples yielded only one donor that tested positive for genotype 3. Analysis of the viral load through the course of infection for this donor suggests an infection cycle similar to that associated with B19V genotype 1 infection. The significance of detecting this rare B19V genotype 3 and its importance to public health is unclear.

#### Disclosure of Conflict of Interest

Michael Gray, Lori Rinckel, Todd Gierman, Douglas Lee: Nothing to Disclose

#### SP202

##### Methoxypoly (Ethylene Glycol) Modification of Viruses or Host Cells: A Broad Spectrum Antiviral Prophylactic

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Background: Nosocomial viral infections (both transfusion and non-transfusion associated) pose a risk to patients. Previously, we have demonstrated that covalent grafting of methoxypoly (ethylene glycol) (mPEG; pegylation) to the surface of RBC and WBC prevented cell-cell interaction, allorecognition, and cell activation. Thus, as a novel means of viral inactivation, we evaluated the efficacy of mPEG-modification of respiratory syncytial virus (RSV) or its host cells as a model system. Methods: Four mPEG linker chemistries (cyanuric chloride mPEG (CmPEG), benzotriazole carbonate mPEG (BTCmPEG), succinimidyl propionate mPEG (SPAmPEG) and succinimidyl carbonate mPEG (SCmPEG)) were tested. These mPEGs were assessed via syncytia formation and immunostaining using two polymer sizes (2 and 5 kDa) and at concentrations ranging from 0-15 mM mPEG. For direct viral modification, ~120 syncytia forming units of RSV were modified with mPEG, overlaid on Vero cells, and examined over 5 days. For host cell modification, Vero cells were similarly modified with mPEG, challenged with unmodified-RSV and followed for 5 days. Results: For all linker chemistries examined direct modification of RSV significantly reduced the number of syncytia. For example, modification with 15 mM, 5 kDa SCmPEG significantly reduced the number of syncytia from 12612 to 145 ( $p < 0.001$ ) per well (1.9 cm). Furthermore, at the same concentration, modification with 2 kDa SCmPEG showed complete inhibition of viral infection. For host cell modification, 5 kDa CmPEG and 2 kDa SCmPEG grafting also inhibited infection, resulting in a 33 and 45% reduction in the number of syncytia, respectively ( $p < 0.001$ ). Immunostaining over 96 hours further demonstrated the efficacy of pegylating either the virus or host cells. Pegylation of RSV with 15 mM SCmPEG (2 kDa) resulted in a >95% reduction in RSV infection at 24 hours ( $p < 0.001$ ). Conclusions: Our findings demonstrate that mPEG modification of RSV or its host cell can effectively limit or prevent viral invasion. Application of this technology to blood products could prove to be a valuable method for inactivating known and unknown blood-borne viruses. Furthermore, additional studies demonstrate that pegylation of viruses, or their host cells provide, a broad spectrum anti-viral prophylaxis effective against both enveloped and non-enveloped viruses.

#### Disclosure of Conflict of Interest

Troy Sutton, Mark Scott: Nothing to Disclose

#### SP203

##### Prevalence of Transfusion Transmitted Infections in Brazilian Blood Donors as Determined by a Dual EIA Strategy

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Background: Representative data on prevalence of infection markers among Brazilian blood donors are scarce due to the lack of common informational systems infrastructure and because confirmatory assays are not routinely performed on reactive samples at the time of screening. Here we describe infectious marker prevalence results obtained in Brazil during the first year of the study. Methods: Donation data including supplemental testing results were collected and compiled from 3 Brazilian blood centers located in states of São Paulo, Minas Gerais and Pernambuco for 2007. Donation samples that tested EIA repeat reactive were tested with alternative EIA assays to confirm infection. Prevalence of transfusion transmissible infections (TTI) were calculated using the number of donors reactive on the confirmatory EIA at their index donation divided by the total number of donors screened for that disease in 2007. Results: There were 307,085 blood donations collected from 245,445 donors at these three blood centers. Thirty-five percent were first time (FT) donors ( $n = 85,954$ ). HIV prevalence was 2x higher in FT compared to repeat donors. Whereas for the other markers prevalence was 10x or more higher in FT donors. Stratified prevalence in FT donors is reported in the lower portion of the table. Strong differences were noted by demographic characteristics for all agents. For example HIV prevalence in FT donors in Pernambuco is over 2x that of Sao Paulo. Patterns of the epidemic for each agent were dramatically different

## 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 2009. 1. 20	新医薬品等の区分 該当なし	総合機構処理欄
一般的名称	人血清アルブミン	研究報告の公表状況	van de Laar MJ, Likatavicius G, Stengaard AR, Donoghoe MC. Euro Surveill. 2008 Dec 11;13(50). pii: 19066.	公表国	
販売名(企業名)	赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社)			WHO	
研究報告の概要	<p>○欧州のHIV/AIDS調査:2007年最新データ</p> <p>ヒト免疫不全ウイルス(HIV)感染症はヨーロッパの公衆衛生にとって重要な問題であり、複数の国でHIV感染増加のエビデンスが示されている。本稿は、HIVおよび後天性免疫不全症候群(AIDS)の調査データの概要を提供し、ヨーロッパにおいて症例報告された人口100万人当たりの新規HIV感染率が、2000年以降にほぼ2倍となったことを示す。</p> <p>2007年は、当該地域53カ国中49カ国から合計48,892例のHIV感染が報告され、エストニア、ウクライナ、ポルトガルとモルドバ共和国で感染率が最も高かった。欧州連合(EU)および欧州自由貿易連合(EFTA)諸国において、HIV感染の主要感染経路は男性間の性行為であり、次いで異性間接触である。WHO欧州地域東部では、現在も静注薬物使用が主な感染経路であるが、中部では異性接触が主要な感染経路である。2007年のAIDS診断症例の報告件数は、東部を除く全域で減少した。</p> <p>HIV/AIDS調査データは、HIV流行の傾向をモニターし、公衆衛生の対応を評価するために不可欠である。</p>				使用上の注意記載状況・ その他参考事項等
					赤十字アルブミン20 赤十字アルブミン25
報告企業の意見		今後の対応			
<p>ヨーロッパにおいて症例報告された人口100万人当たりの新規HIV感染率は、2000年以降ほぼ2倍となった。2007年は、当該地域53カ国中49カ国から合計48,892例のHIV感染が報告され、エストニア、ウクライナ、ポルトガルとモルドバ共和国で感染率が最も高かったとの報告である。</p> <p>これまで、本剤によるHIV感染の報告はない。また本剤の製造工程には、平成11年8月30日付医薬発第1047号に沿ったウイルス・プロセスバリデーションによって検証された2つの異なるウイルス除去・不活性化工程が含まれている。さらに最終製品についてHIV-NAT陰性であることを確認していることから本剤の安全性は確保されていると考える。</p>		<p>本剤の安全性は確保されていると考えるが、今後も情報の収集に努める。なお、日本赤十字社ではHIV抗体検査にこれまでの凝集法と比べてより感度の高い化学発光酵素免疫測定法(CLEIA)を導入したことに加え、20プールNATについてもHIV-2及びHIVグループOの検出が可能な新NATシステムを導入し、陽性血液を排除している。また、輸血感染症対策として、男性と性的接触を持った男性は1年間献血不適としている。</p>			

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## Rapid communications

# HIV/AIDS SURVEILLANCE IN EUROPE: UPDATE 2007

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Human immunodeficiency virus (HIV) infection remains of major public health importance in Europe, with evidence of increasing transmission of HIV in several countries. This article provides an overview of HIV and acquired immunodeficiency syndrome (AIDS) surveillance data, and indicates that since 2000 the rate of newly reported cases of HIV per million population has almost doubled in Europe. In 2007, a total of 48,892 cases of HIV infection were reported from 49 of 53 countries in the Region, with the highest rates in Estonia, Ukraine, Portugal and the Republic of Moldova. In the European Union (EU) and European Free Trade Association (EFTA) countries, the predominant mode of transmission for HIV infection is sex between men followed by heterosexual contact. Injecting drug use is still the main mode of transmission in the eastern part of the WHO European region, while in the central part heterosexual contact is the predominant mode of transmission. In 2007, the reported number of AIDS cases diagnosed decreased in the Region overall, except in the eastern part. HIV/AIDS surveillance data are vital to monitor the trends of the HIV epidemic and evaluate public health responses.

### Introduction

Since January 2008, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization Regional Office for Europe have been jointly carrying out the HIV/AIDS surveillance in Europe [1]. This article presents the main findings for the whole WHO European Region, the three geographical regions of the WHO European Region (West, Centre and East)\* and the European Union (EU) and European Free Trade Association (EFTA) countries.

### HIV case reports in WHO European Region

In 2007, 48,892 newly diagnosed HIV cases (76 per million population) were reported from 49 of the 53 countries in the WHO European Region (no data from Austria, Italy, Monaco and the Russian Federation). In the three parts of the WHO European Region, the rate of newly reported cases of HIV, per million population was highest in the East (Table 1); whereas among individual countries, the highest rates were reported in: Estonia (472 per million), Ukraine (285 per million), Portugal (217 per million) and the Republic of Moldova (204 per million). Between

TABLE 2

Characteristics of newly diagnosed cases of HIV infection reported in the EU/EFTA countries<sup>a</sup>, 2007

	EU/EFTA countries <sup>a</sup>
Number of HIV cases	26 279
Rate per million population	64.1
Percentage of cases:	
Age 15–29 years	28%
Female	31%
Transmission mode <sup>b,c</sup>	
Heterosexual <sup>b,c</sup>	29%
Men who have sex with men	39%
Injecting drug users	9%

<sup>a</sup> Missing data: Italy, Austria.

<sup>b</sup> Transmission group unknown is excluded in the percentages.

<sup>c</sup> Excludes persons originating from countries with generalised epidemics (4 422 in total).

TABLE 1

Characteristics of newly diagnosed cases of HIV infection reported in the WHO European Region and by geographical area, 2007

	WHO European Region <sup>a</sup>	West <sup>a</sup>	Centre	East <sup>a</sup>
Number of HIV cases	48 892	24 202	1 897	22 793
Rate per million population	76.4	77.0	10.1	164.8
Percentage of cases:				
Age 15–29 years	33%	26%	41%	40%
Female	33%	31%	24%	36%
Transmission mode <sup>b,c</sup>				
Heterosexual <sup>b,c</sup>	36%	29%	53%	42%
Men who have sex with men	20%	40%	30%	0.4%
Injecting drug users	32%	8%	13%	57%

<sup>a</sup> Missing data: Austria, Italy, Monaco, Russian Federation.

<sup>b</sup> Transmission group unknown is excluded from the percentages.

<sup>c</sup> Excludes persons originating from countries with generalised epidemics (4 555 in total; 4 540 in West).

2000 and 2007, the annual rate of newly reported cases of HIV per million population has increased from 39 to 75 per million (90% increase) among the 44 countries that have consistently reported.

#### HIV case reports in the EU/EFTA

In 28 of the 30 EU/EFTA countries, 26,279 cases of HIV infection (64 per million) were reported in 2007 (Table 2), with the highest rates reported in Estonia (472 per million), Portugal (217 per million) and Latvia (149 per million). The predominant mode of transmission is sexual contact between men (39%), followed by heterosexual contact (29%), when persons originating from countries with generalised epidemics are excluded. Injecting drug use accounted for 9% of newly reported infections. Among the countries that have consistently reported, the rate has increased from 44 per million in 2000 to 58 per million in 2007. Rates of reported HIV infection have doubled in Bulgaria, Czech Republic, Hungary, the Netherlands, Slovakia, Slovenia, Sweden and the United Kingdom.

The number of HIV reports among men who have sex with men (MSM) has increased by 39% between 2003 and 2007 (Figure 1). The number of heterosexually acquired cases has remained fairly stable at around 6,000 cases (although higher numbers were reported in 2004-2006). Further, the number of cases originating from countries with generalised epidemics amongst heterosexually acquired cases varied between 5,000 in 2005 and 4,400 in 2007. The number of HIV reports among injecting drug users (IDUs) has declined by 30% between 2003 and 2007.

#### HIV case reports by geographical area

The HIV epidemics across the three geographical areas show remarkable differences (Figure 2).

The data suggest that the HIV epidemic in the western part of the WHO European Region is characterised by a continuing

increase in sexual transmission of HIV infection. The distribution of transmission modes largely mirrors that described for the EU/EFTA countries. In 2007, 24,202 new cases of HIV infection (77 million) were reported from 20 countries (Table 1).

The HIV epidemic in the central part of the WHO European Region remains at low and stable levels (1,897 cases; 10 per million), although there is evidence of increasing sexual (both heterosexual and homosexual) transmission in many countries (Table 1). Heterosexual transmission accounted for 53% of all reported cases, followed by 30% cases reported among MSM and 13% cases among IDUs, data on transmission mode were missing for 33% of cases.

In the eastern part of the WHO European Region, in 2007, 14 countries reported 22,793 new HIV cases (165 per million), of which 58% were from Ukraine. The predominant mode of transmission in this region is through IDUs, accounting for 57% of the reported cases. Between 2000 and 2007, the rate of newly reported HIV infections has increased from 54 per million to 160 per million. However, the numbers in this region are greatly underestimated as no data were reported from the Russian Federation.

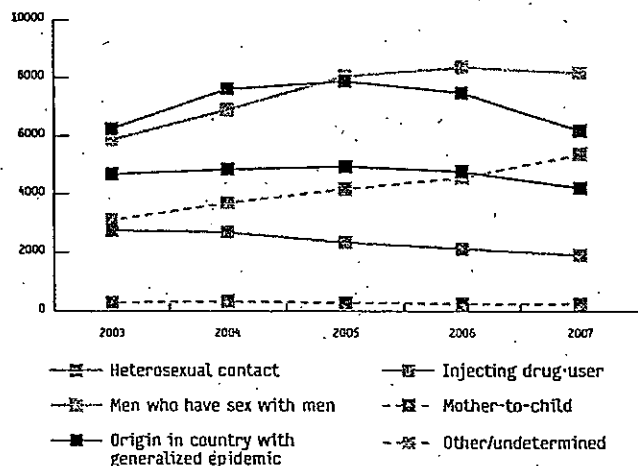
#### AIDS diagnoses

In 2007, 5,244 AIDS cases were reported as being diagnosed in 48 of the 53 countries (9 per million) in the WHO European Region (no data from Italy, Kazakhstan, Monaco, Russian Federation and Ukraine). Due to incomplete reporting and no adjustment for reporting delays the total number of AIDS cases is underestimated.

Trends in AIDS diagnoses per million population (Figure 3) have continued to decrease in the WHO European Region overall, from 16 per million in 2000 to 9 per million in 2007, mainly due to decrease in western and central regions probably due to a combination of reporting delay and the effect of highly active

FIGURE 1

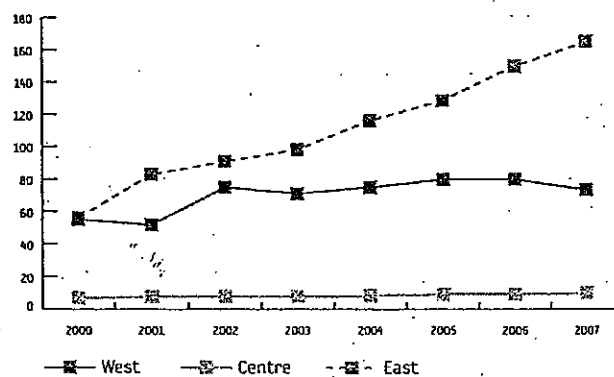
Number of reported HIV infections by transmission mode, origin and year of notification, EU/EFTA, 2003-2007



Data were not available for: Austria, Estonia (except for IDU), Italy, and Malta.

FIGURE 2

HIV cases per million population in geographic areas of the WHO European Region (West, Centre, East) by year of notification, 2000-2007



Data not included from: West: Andorra, Austria, France, Italy, Malta, Monaco, Spain; Centre: Serbia; East: Russian Federation.

antiretroviral therapy (HAART) [2]. However, during the same period, the rate increased in 21 (mainly eastern) countries, with the largest increases in Belarus and the Republic of Moldova.

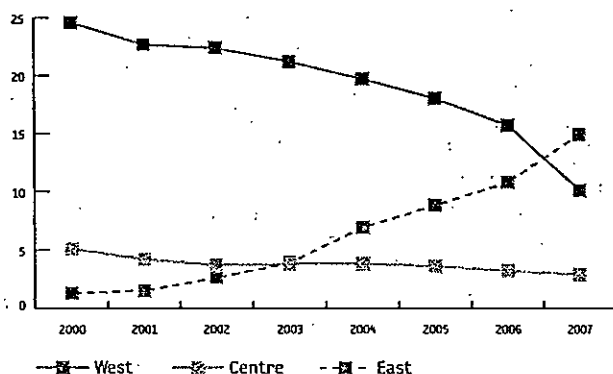
#### Discussion and conclusion

HIV infection remains of major public health importance in Europe with a continued increase in the number of HIV cases reported [1,3]. In contrast, the number of AIDS cases diagnosed (not adjusted for reporting delays) has continued to decline, except in the eastern part of the WHO European Region. The data suggest evidence of increased transmission of HIV in many countries. However, the predominant transmission group varies by country and geographical area and the data illustrate the wide diversity in the epidemiology of HIV in Europe.

In 2007, in the EU/EFTA countries, also reflecting the western part of the WHO European Region, the highest proportion of HIV cases was reported among MSM. National prevention programmes aimed at reducing HIV transmission within Europe should have a strong focus on MSM [4]. Migrant populations should also be targeted in national prevention programmes and access to treatment and care services should be ensured. Although there seems to be a decline in the number of new diagnoses among IDUs, this is still the predominant transmission group in the Baltic States. In the central part of the WHO European Region, levels of HIV remain low and stable, although there is evidence of increasing sexual transmission in many countries. In the eastern part, the number of HIV cases has increased substantially, mainly driven by an increase in cases acquired through IDU but also by an increase in heterosexually-acquired cases. Interventions to control HIV among IDUs should be the cornerstone of HIV prevention strategies in the eastern part but measures should also be strengthened to prevent heterosexual transmission, especially targeted at those with high-risk partners.

FIGURE 3

Number of diagnosed AIDS cases per million population in the geographic areas of WHO European Region (West, Centre, East) by year of diagnosis, 2000-2007



Data not included from: West: Andorra, Italy, Monaco; East: Kazakhstan, Russian Federation, Ukraine

In interpreting the presented data, it should be taken into account that data are incomplete due to non-reporting from a few large countries. Therefore the findings and conclusions are limited to the surveillance data reported by these 49 countries. Had all data from all countries been available, the total number of reported HIV infections could have doubled to almost 100,000 cases in 2007.

Surveillance of HIV/AIDS is essential to monitor the epidemic and evaluate the public health response to control the transmission of infections. Countries in Europe need to ensure that surveillance data is of high quality by implementing case-based reporting systems for HIV and AIDS cases and ensuring its completeness, especially regarding the probable mode of transmission. Achieving full coverage of reporting from all countries in Europe is of utmost importance.

#### The WHO European Region comprises:

The West, 23 countries: Andorra, Austria (EU), Belgium (EU), Denmark (EU), Finland (EU), France (EU), Germany (EU), Greece (EU), Iceland (EFTA), Ireland (EU), Israel, Italy (EU), Luxembourg (EU), Malta (EU), Monaco, the Netherlands (EU), Norway (EFTA), Portugal (EU), San Marino, Spain (EU), Sweden (EU), Switzerland (EFTA), United Kingdom (EU).

The Centre, 15 countries: Albania, Bosnia and Herzegovina, Bulgaria (EU), Croatia, Cyprus (EU), Czech Republic (EU), Hungary (EU), the Former Yugoslav Republic of Macedonia, Montenegro, Poland (EU), Romania (EU), Serbia, Slovakia (EU), Slovenia (EU), Turkey.

The East, 15 countries: Armenia, Azerbaijan, Belarus, Estonia (EU), Georgia, Kazakhstan, Kyrgyzstan, Latvia (EU), Lithuania (EU), Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.

#### Acknowledgements

We would like to thank all participating countries and national institutions of the European network for HIV/AIDS surveillance for their important contributions.

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