# EPIDEMIOLOGIA NAZIONALE E REGIONALE DELLE MALATTIE TRASMISSIBILI CON IL SANGUE

GENOVA, 31 OTTOBRE 2007

GIOVANNI IMBERCIADORI

# RISCHI CLASSICI DA TRASFUSIONE

TABLE 1. Risks of transfusion (the classics)*

| Risk | Incidence |
|---|---|
| 1. Hepatitis B | 1/5,800-1/150,000 units |
| 2. Hepatitis C | 1/872,000 units |
| 3. HIV | 1/1.4-2.4 million |
| 4. HTLV | 1/1.5 million |
| 5. TTV | 52% |
| 6. West Nile virus | 1/1.4 million |
| 7. Cytomegalovirus conversion | 7% |
| 8. Epstein-Barr virus | 0.5% |
| 9. TRALI | 1/5,000-10,000 |
| 10. ABO-Rh mismatch | |
| Occurrence | 1/6,000-20,000 |
| Mortality | 1/100,000-500,000 |
| 11. Delayed hemolytic reaction | 1/2,500 |
| 12. Alloimmunization (PLTs and WBCs) | 1/10 |
| 13. Alloimmunization (RBCs) | 1% |
| 14. Allergic reactions | 1%-4% |
| 15. Febrile reaction | 0.1%-1% |
| 16. GVHD | 1/400-1/10,000 |
| 17. Volume overload | 10%-40% |
| 18. Depressed erythropoiesis | Universal |

* Some of the reported risks of transfusion. Data are reported either as risk per number of units transfused or as percentage.

# HIV:60 MIL. INFETTI,20 MIL. MORTI

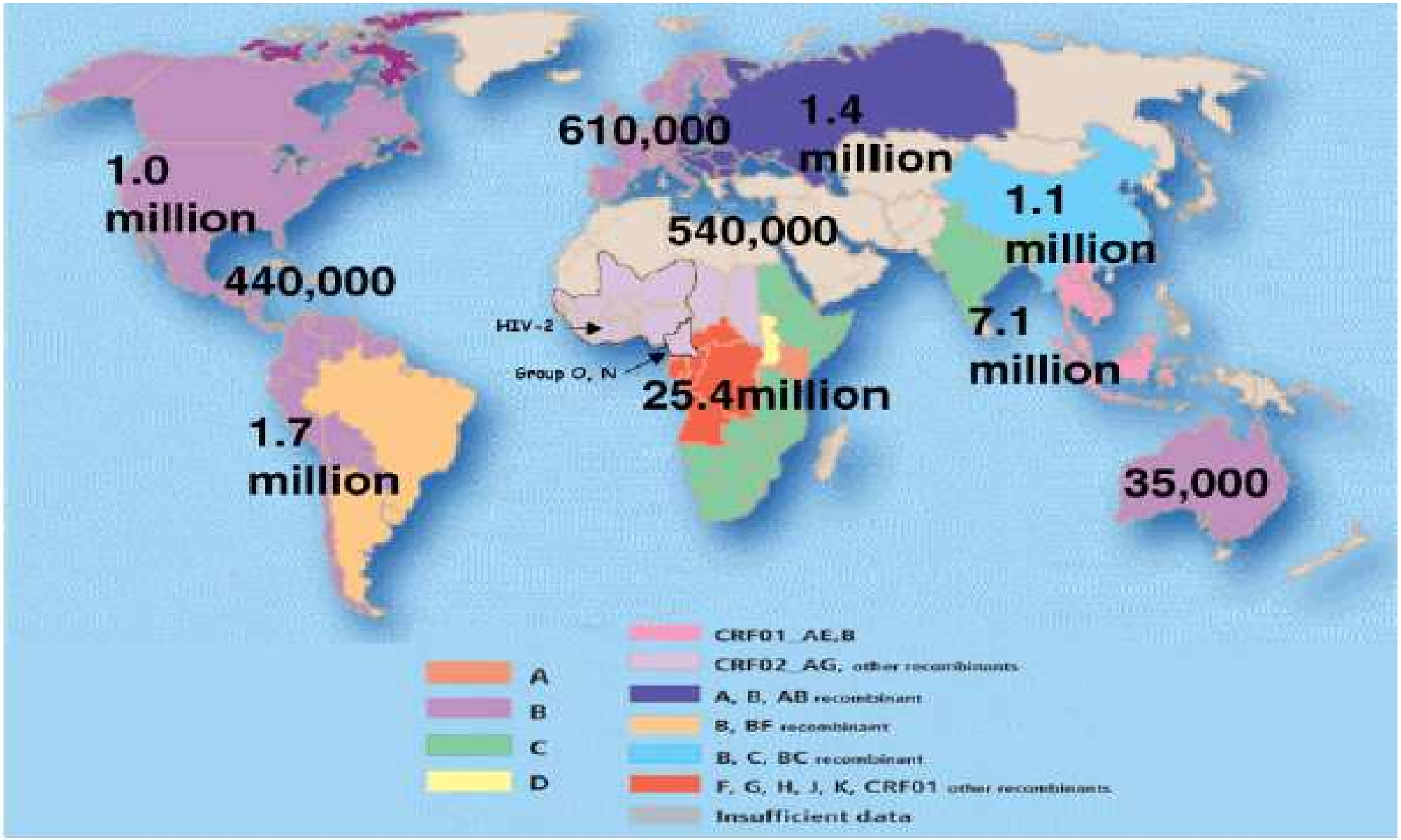



Fig. 1. Global HIV prevalence and distribution. The estimated numbers of HIV-infected individuals in North America, the Caribbean, South America, Western Europe, Central Asia, East Asia, Southeast Asia, North Africa and the Middle East, sub-Saharan Africa, and Australia are indicated. The colors depict regional patterns of HIV variation as follows: subtype A in East Africa; subtype B in the America, Europe, and Australia; subtype C in Southern and Eastern Africa, and in India; subtype D in East Africa; CRF01_AE and subtype B in Southeast Asia; CRF02_AG and other recombinants in West Africa; A, B, and AB recombinants in Central Asia; subtype B and BF recombinants in South America; subtype B and C, and BC recombinants in East Asia; rare subtypes, CR01_AE, and other recombinants in Central Africa and areas where there is insufficient data. The principal concentrations of HIV-1 groups O and N in Cameroon, and of HIV-2 in West Africa, are indicated by arrows.

# 170.000.000 DI PZ. CON INFEZIONE CRONICA DA **HCV** NEL MONDO. OLTRE 1.000.000 IN ITALIA

**Table 1**

**Summary of studies that have used epidemiological and molecular evolutionary approaches to trace the patterns of HCV transmission in different countries**

| Country | HCV subtype(s) | Estimated year of first appearance of HCV | Estimated year of start of major HCV outbreak(s) | Main social and historical events associated with the start of HCV outbreak(s) | References |
|---|---|---|---|---|---|
| Egypt | 4a | 1902 | 1930s | Parenteral antischistosomal therapy campaign | [4–6] |
| Japan | 1b (1st wave) | 1812 | 1920 | Parenteral antischistosomal therapy campaign | [5–8] |
| Japan | 1b (2nd wave) | 1918 | 1940s | World War II | [5] |
| Spain | 1b | 1892 | Late 1930s | Spanish Civil War | [5] |
| France | N.R. | N.R. | 1940s | World War II | [9] |
| Former Soviet Union | 3a | 1958 | 1960s | Unsafe measles vaccination campaigns – increasing IVDU | [5] |
| USA | 1a,1b | 1920 | 1960s | Increasing IVDU (predominant) and unscreened blood transfusions | [5,8] |
| China | 1b | 1966 | 1970s | Chinese Cultural Revolution; increasing blood transfusion and other invasive treatments | [10] |
| South Africa | 5a | 1937 | Late 1950s | Increasing use of unsafe medical procedures | [5] |
| Vietnam | 1a | 1920 | Late 1960s | Vietnam War | [8] |

HCV, hepatitis C virus; IVDU, intravenous drug use.

# HBV

- 2 MILIARDI DI PERSONE VENUTE IN CONTATTO CON HBV
- 360 MILIONI DI PORTATORI CRONICI DEL VIRUS
- **500.000** MORTI / ANNO HBV CORRELATE

# EPATITE B OCCULTA:
# HBSAG- HBV DNA+

**Table 1. Typical serological profiles in patients with hepatitis B infection**

| Serological tests | Hepatitis B immunisation | Acute HBV | Recovered from HBV | Chronic hepatitis B | Healthy or inactive carrier | Occult hepatitis B |
|---|---|---|---|---|---|---|
| HBsAb | + | − | + | − | − | −/+ |
| HBcAb total | − | + | + | + | + | −/+ |
| HBeAb | − | − | + | − | + | −/+ |
| HBsAg | − | + | − | + | + | − |
| HBeAg | − | + | − | + | − | −/+ |
| HBV DNA | − | + | − | +, $>10^5$ copies | +, $<10^5$ copies | +, $<10^3$ copies |

HbsAb=hepatitis B surface antibody; HBcAb=hepatitis B core antibody; HBeAb=hepatitis B e antibody; HBsAg=hepatitis B surface antigen; HbeAg=hepatitis B e antigen

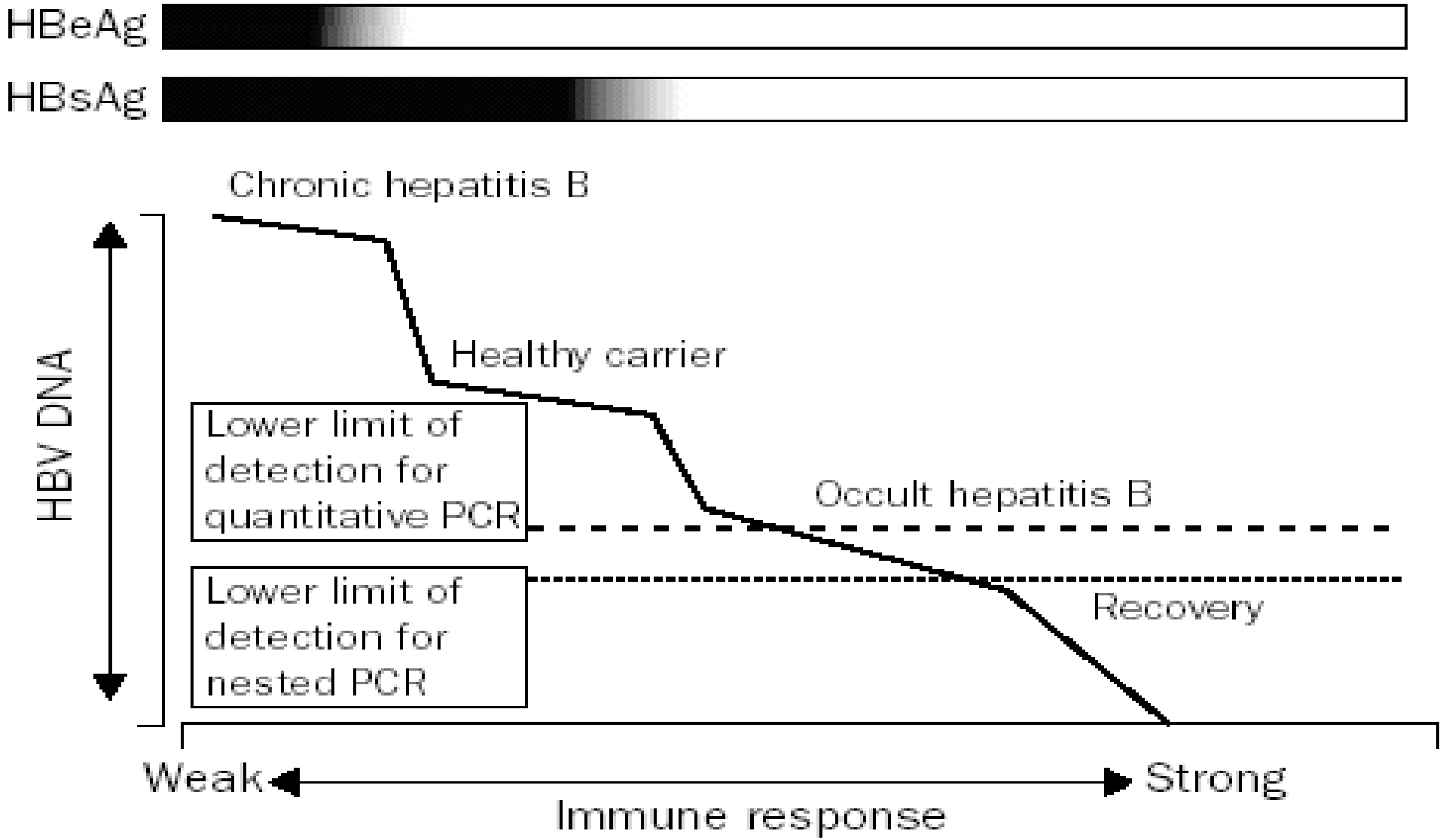



*Figure 2. A model of occult hepatitis B highlighting the potential role of the immune system. Other factors such as HBV mutations and co-infection with HCV also appear to have a role.*

Table 1
Summary of critical data on HBV infection according to genotype

| Geno-type | Geographic areas | Main mode of transmission | %chronic infection | Median age of HBe conversion | % Viral load >10E4 copies/ml [a] |
|---|---|---|---|---|---|
| A | W Europe<br>N America<br>S Africa | Sexual<br>IVDU | <1 | 20 | 40.3 [b] |
| B | Far East<br>SE Asia | Vertical | 1–12 | 40 | 64.3 [c] |
| C | Far East<br>SE Asia | Vertical | 1–10 | 30 | 64.3 [c] |
| D | India<br>Middle East<br>Mediterranean | Vertical<br>Sexual<br>Nosocomial | <1–5 | 20 | |
| E | Africa | Horizontal<br>Nosocomial | 3–25 | <10 | 27.5 [d] |
| F | S America<br>Polynesia | Sexual<br>Vertical? | 1 | ? | |

**Table 1** Key Emerging Infections That Are, or May Be, Transmissible by Blood Transfusion

| Organism (disease) | Normal Transmission Route | Transmissibility by Transfusion/Transfusion Risk | Transfusion Cases in US | Treatment for Disease | Intervention for Transfusion |
|---|---|---|---|---|---|
| Parasites | | | | | |
| *Babesia* | Ticks | Known/moderate | >50 | Yes | NA |
| *Leishmania* | Sandflies | Anecdotal | 0 | Partial | Q |
| Malaria | Mosquitoes | Known/low | 1–2 per year | Yes | Q, T (unlicensed) |
| *T cruzi* (Chagas) | Reduvid bugs | Known/low | 5 | Partial | T (unlicensed) |
| Bacteria | | | | | |
| Anaplasma (ehrlichiosis) | Ticks | Probable/infrequent | 1 (presumed) | Yes | NA |
| Gram$^+$ & gram$^-$ species | Multiple | Known/High | 1:75,000 apheresis platelets | Partial | T |
| Spirochetes | | | | | |
| *Borrelia burgdorferi* (Lyme disease) | Ticks | Theoretical | 0 | Yes | NA |
| Viruses | | | | | |
| Avian influenza | Respiratory, droplet | Theoretical | 0 | Partial | NA |
| Dengue (dengue fever) | Mosquitoes | Known/low | 0 (1 in Hong Kong) | No | NA |
| HHV-8 (Kaposi's sarcoma) | Saliva, sexual contact | Probable/low | 0 | No | NA, (LR?) |
| Parvovirus B19 [erythrovirus] (aplastic crises, RBC aplasia) | Respiratory | Known/low | 3–6 | Yes | (T) |
| SARS-coronavirus | Respiratory, fecal-oral | Theoretical | 0 | No | Q |
| Simian foamy virus (No known disease) | Primate contact | Theoretical | 0 | No | Q, (LR) |
| TTV/SEN-V [circoviruses] (No known disease) | Parenteral | Known/high | Very frequent (up to 25% of recipients) | None required | NA |
| GBV-C/HGV [flaviviruses] (No known disease) | Parenteral | Known/high | Very frequent (up to 7% of recipients) | None required | NA |
| New variants of established agents (e.g. HBV, HIV) | Parenteral | Known/low | Rare | Partial | Q, (T) |
| Prions | | | | | |
| vCJD | Oral | Known | 0 (3 in England) | No | (F) |
| Chronic wasting disease | ? oral | Unknown | 0 | No | NA |

Abbreviations: NA, not available; Q, donor questioning; T, laboratory test; (T), test may be partially effective; (LR), leukoreduction thought to reduce infectivity, (F), affinity filters under development.

# ALCUNI DATI ITALIANI

- **MALARIA** 1986 -1996: 7 CASI DA TRASFUSIONE (VOX SANG. 2004)
- **T. CRUZI, BABESIA: NESSUN CASO** NOTIFICATO FINO AL 2004 (VOX SANG. 2004)
- **LEISHMANIOSI**: 2002 218 CASI (174 VISCERALI, 44 CUTANEI) MA NESSUN CASO DI TRASMISSIONE TRASFUSIONALE (VOX SANG. 2004)
- **TTV DNA**: 5% DONATORI ITALIANI POS (BJH 1999)
- **HGV DNA**: 1,5% DONATORI CON ALT NORMALI (TRANSF.1997)

# ANTI HHV-8 E DONATORI:ITA.USA UK

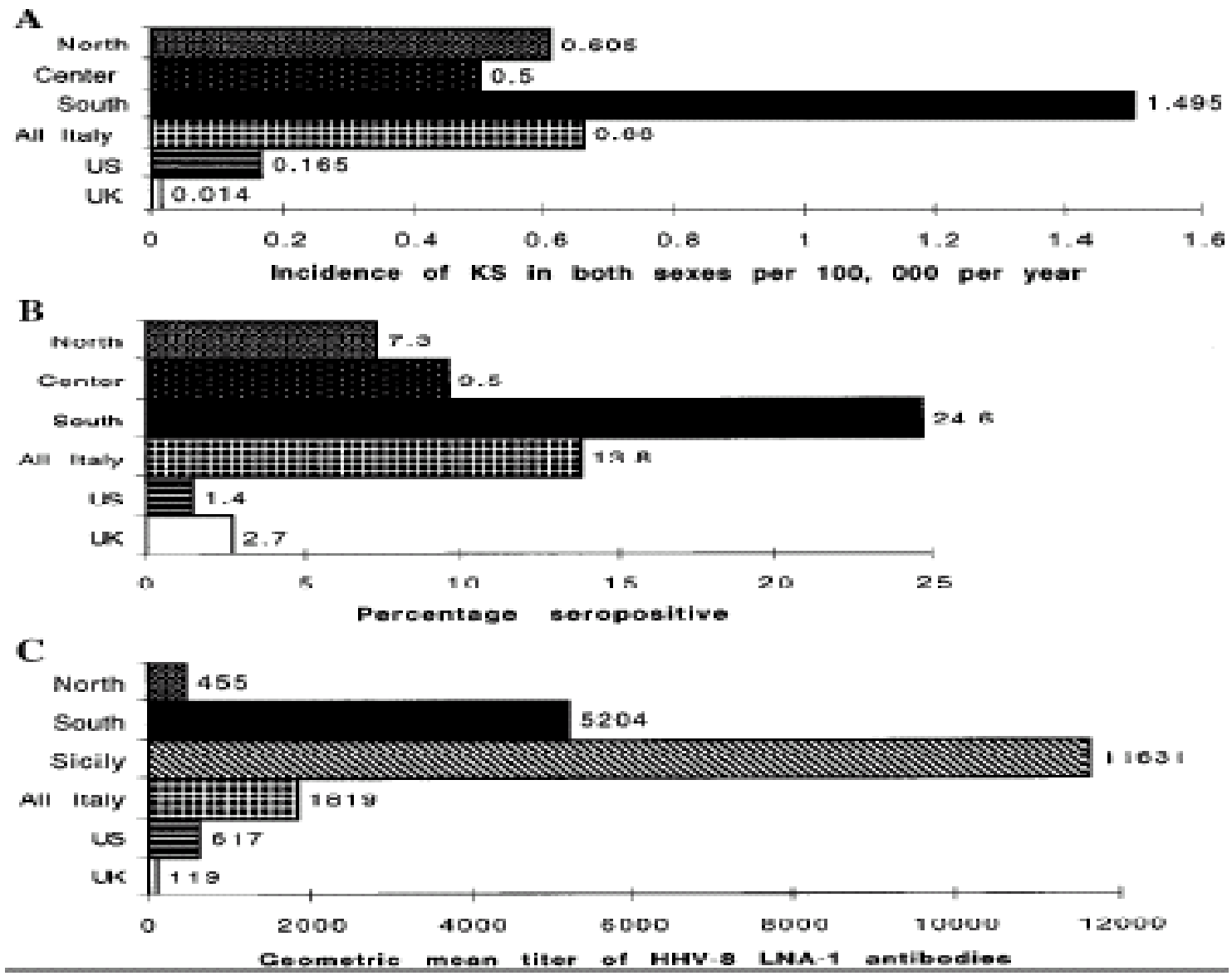



**Fig. 1.** Incidence of Kaposi's sarcoma (KS) and prevalence of serum antibodies against human herpesvirus 8 (HHV-8) latent nuclear antigen (LNA-1). **A)** Incidence of KS in both sexes per 100 000 per year in Italy, the U.K., and the United States [from *(17, 19, 20)*]. **B)** Prevalence of antibodies against HHV-8 in blood donors from Italy, the U.K., and the United States. **C)** Geometric mean titers of antibodies against HHV-8 LNA-1 in Italy, the U.K., and the United States.

# LE PIU' IMPORTANTI EPIDEMIE DI WNV NEL BACINO DEL MEDITERRANEO

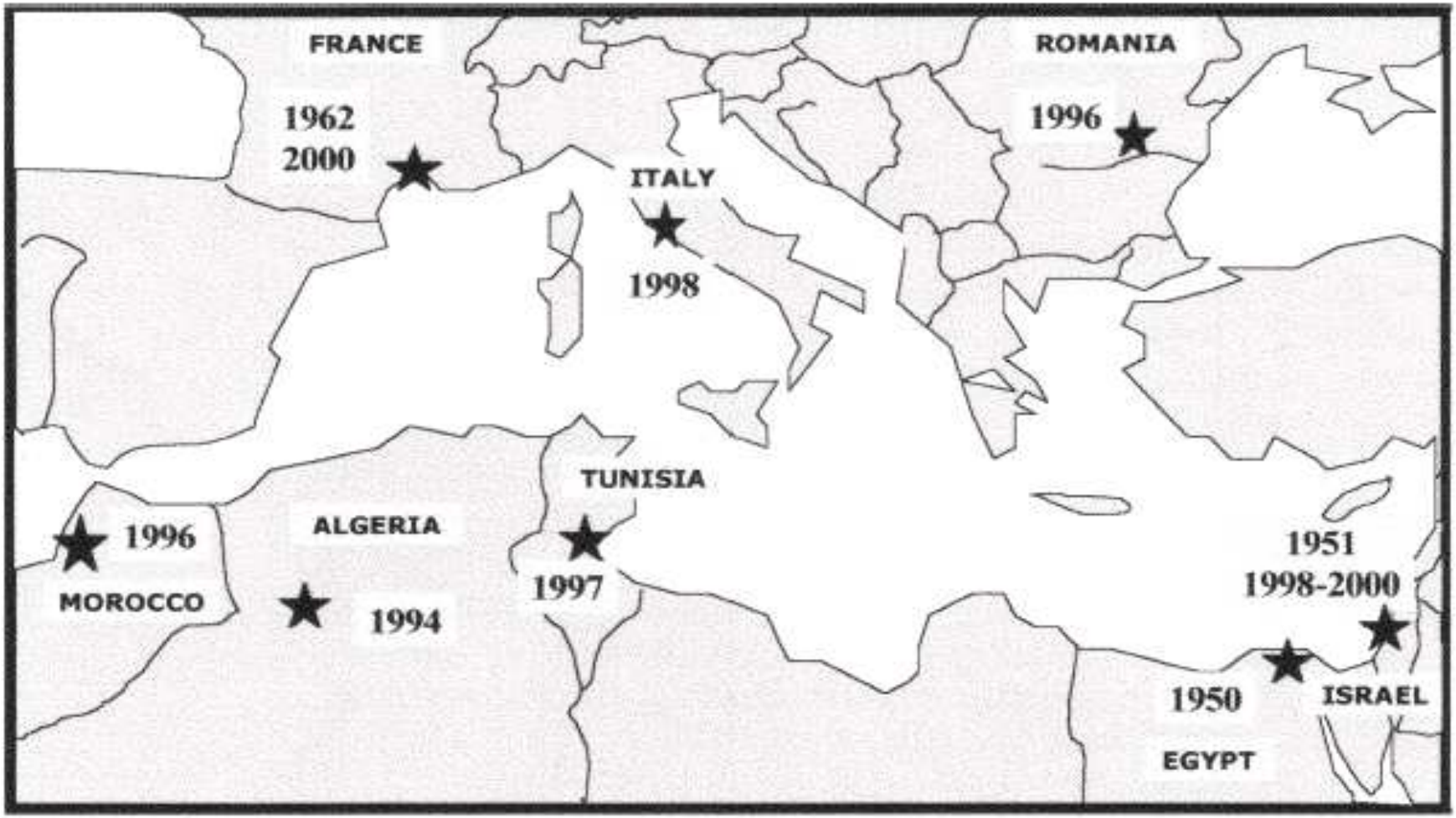
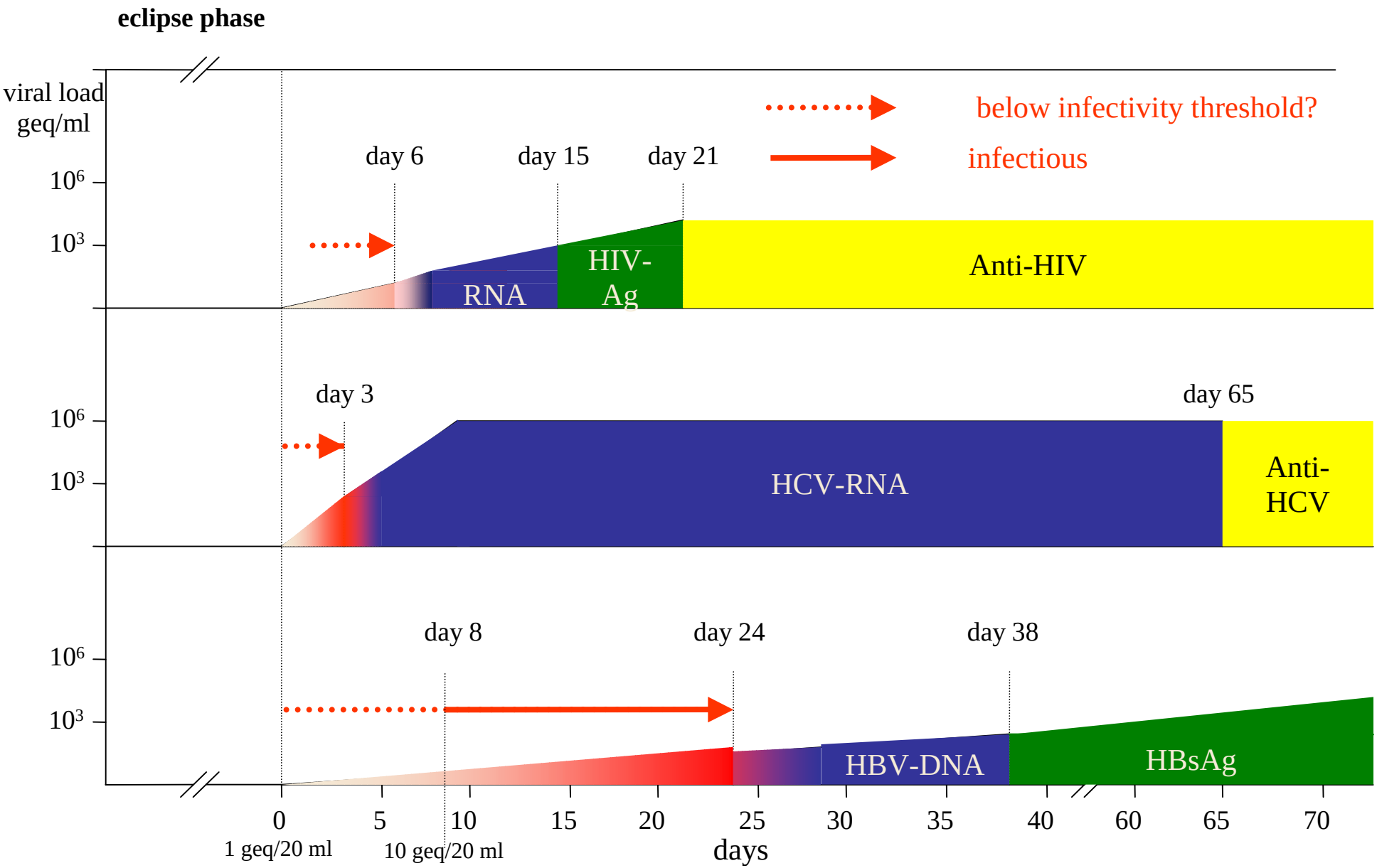



FIGURE 1. Major outbreaks reported in the Mediterranean basin: 1950–2000.

# SCREENING

- ANTI HIV1-2
- ANTI HCV
- HBsAg
- ANTI TREPONEMA PALLIDO
- HCV RNA
- ( HIV RNA  HBV DNA )

# Closing the infectious window with Ultrio on Procleix Tigris System



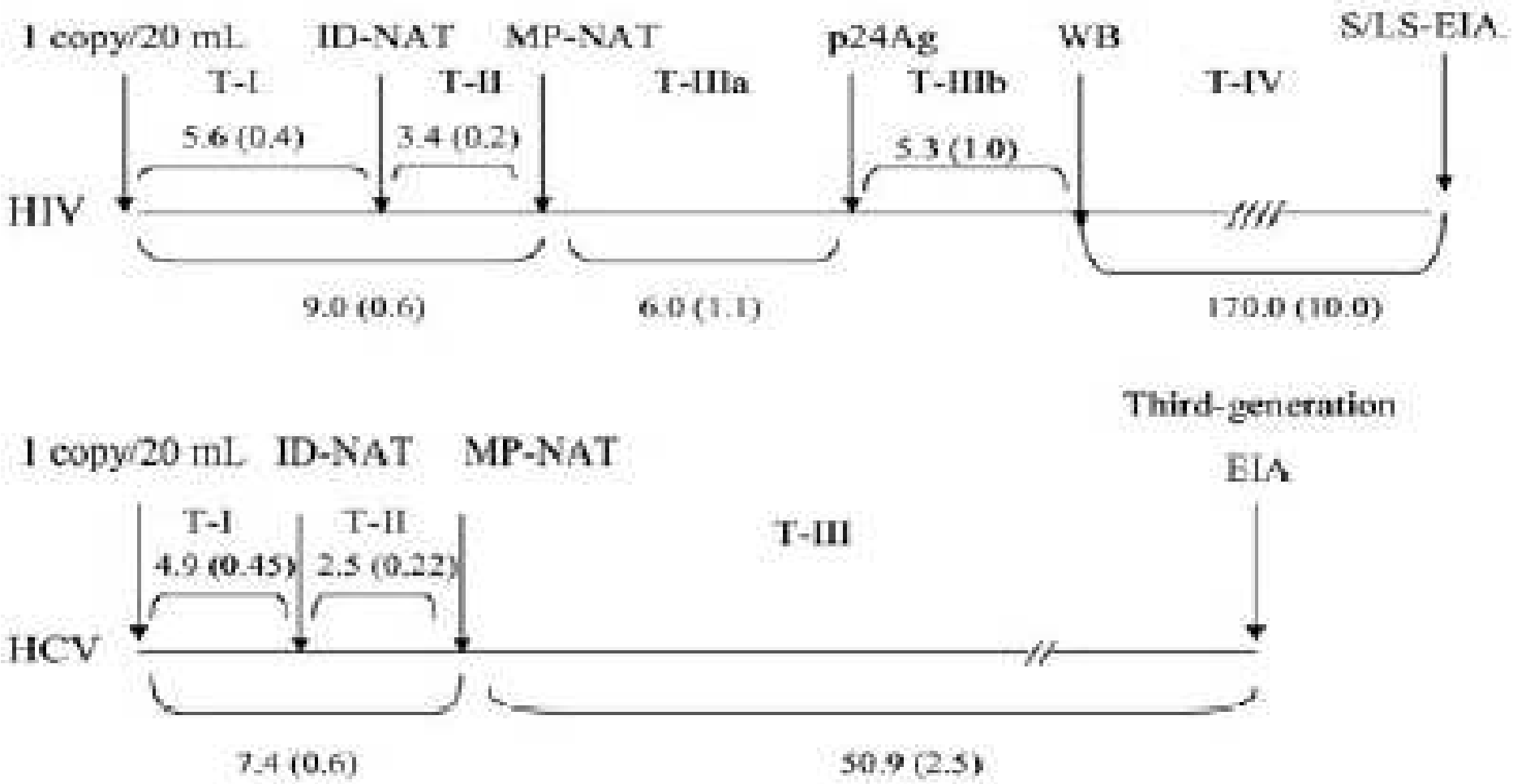



**Fig. 1. Periods in days (SE) for HIV and HCV. Calculations based on the HIV and HCV Gen-Probe transcription-mediated amplification 50 percent sensitivities. WB = Western blot.**

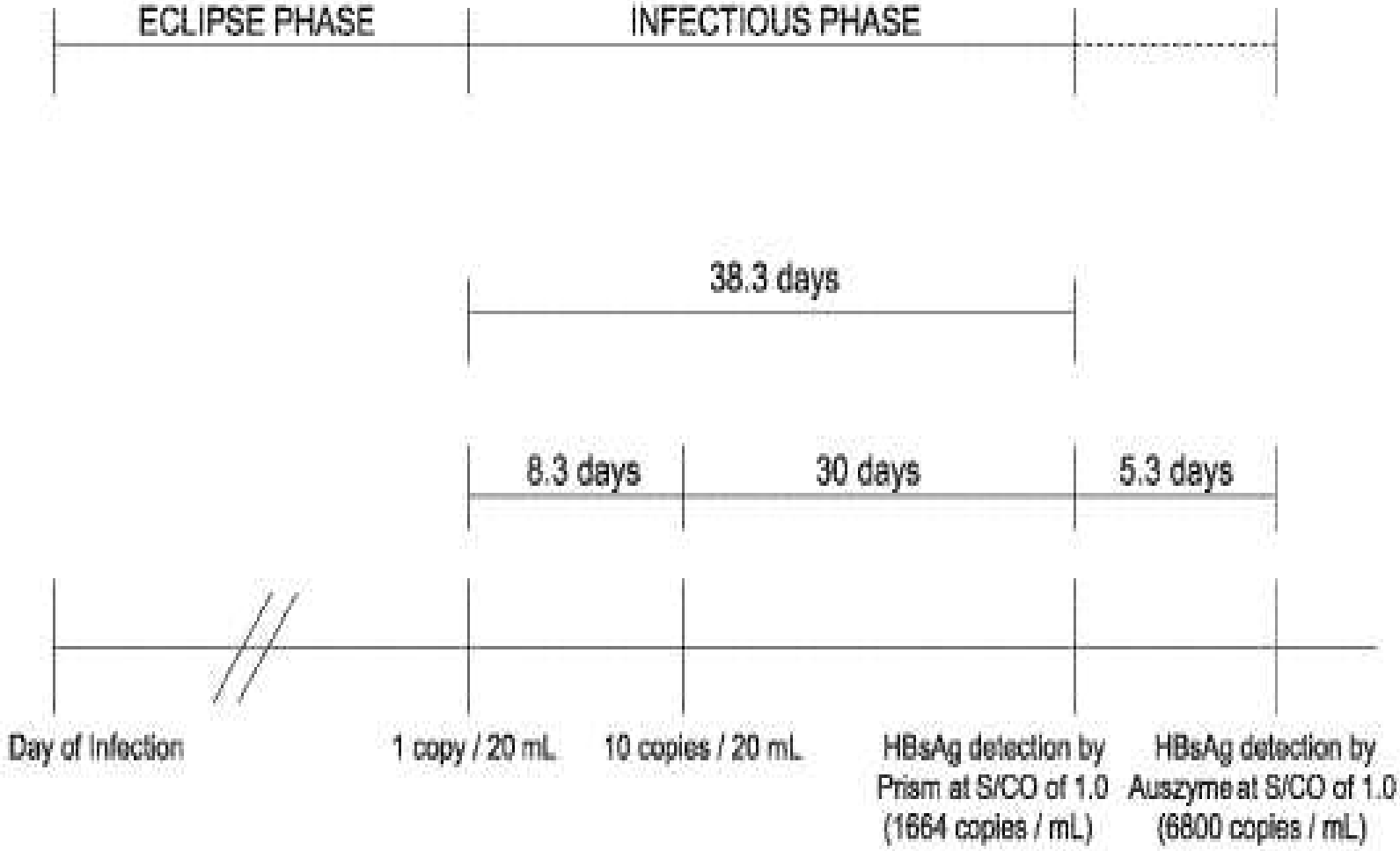



Fig. 3. HBV window period time-line. The durations of theoretically infectious window periods preceding HBsAg detection by Prism and Auszyme are indicated. Note that the infectious window period prior to Prism HBsAg seroconversion is divided into two phases; one where HBV DNA copy number ranges from 1 to 10 copies per 20 mL (lower probability of transmission) and the second where viral load exceeds 10 copies per mL (higher probability of transmission). The duration of the eclipse phase (from date of exposure/infection to an HBV plasma DNA concentration of 1 copy per 20 mL) is not precisely known. Based on limited data from transfusion-transmitted HBV, this period can be inferred to average 15 days (59 days [window period from exposure to detectability] minus 43.6 days [infectious window period relative to Auszyme HBsAg assay calculated from the doubling time model]). However, chimpanzee inoculation studies suggest a variable duration of the eclipse phase which is inversely related to viral inoculum dose (Yoshizawa,

# CAUSE DI **FALLIMENTO** DEGLI SCREENING ANTICORPALI

**DONATORI IN IN PERIODO FINESTRA**

**DONATORI IMMUNOSILENTI**

**DONATORI INFETTI CON MUTANTI VIRALI**

ERRORI DI LABORATORIO

# CAUSE DI **FALLIMENTO** DEGLI SCREENING ANTIGENICI

DONATORI IN PERIODO FINESTRA

**DONATORI INFETTI CON MUTANTI VIRALI:**
ESCAPE

DONATORI CON INFEZIONE CRONICA CON HBsAg NEGATIVO: **EPATITE B OCCULTA**

# PARAMETRI CHE INFLUENZANO I RISULTATI DELLO SCREENING NAT

VELOCITA' DI RADDOPPIO DELLA CARICA VIRALE

**SENSIBILITA'** NAT

**USO** IN SINGOLO O POOL

**QUANTITA' DI PLASMA** UTILIZZATO

**ERRORE DI LABORATORIO**

# VANTAGGI E LIMITI DELLA NAT

## VANTAGGI:

FASE FINESTRA
INFEZIONI Ab SILENTI
VARIANTI VIRALI
INCIDENZA SUI DONATORI
CONSIGLIO AL DONATORE

## LIMITI:

SOGGETTI IN FASE ACUTA E CRONICA
Ab + NAT -

**RISCHIO RESIDUO**: UNITA' NEG AD UN DETERMINATO SCREENING MA CAPACI DI INFETTARE

R.R. TALMENTE BASSO CHE NON PUO' ESSERE PIU' DETERMINATO CON :
STUDI PROSPETTICI, RETROSPETTIVI, CASO – CONTROLLO MA CON
**MODELLI MATEMATICI**

**R.R.= INCIDENZA X PERIODO FINESTRA**

# R.R. IN USA. NAT POOL:1/2.000.000 X HIV E HCV SINGOLO: 1/3-4.000.000

TABLE 3. HIV-1 and HCV residual risks and ID-NAT yield projections per $10^6$ donations derived with repeat donation history data versus MP-NAT and S/LS-EIA yield data

| Data source | Yield of ID-NAT, as 1 in number of screened donations (95% CI) | Residual risk of transfusion of an infectious unit, as 1 in number of screened donations (95% CI) | |
|---|---|---|---|
| | ID to MP | 1 copy/20 mL to MP-NAT | 1 copy/20 mL to ID-NAT |
| HIV-1 | | | |
| Repeat donation history | 1 in $5.0 \times 10^6$ (1 in $9.3 \times 10^5$-1 in $3.4 \times 10^6$) | 1 in $1.9 \times 10^6$ (1 in $3.5 \times 10^5$-1 in $1.3 \times 10^6$) | 1 in $3.0 \times 10^6$ (1 in $5.7 \times 10^5$-1 in $2.0 \times 10^6$) |
| MP-NAT yield | 1 in $6.0 \times 10^6$ (1 in $20.3 \times 10^5$-1 in $3.6 \times 10^6$) | 1 in $2.3 \times 10^6$ (1 in $7.7 \times 10^5$-1 in $1.3 \times 10^6$) | 1 in $3.7 \times 10^6$ (1 in $12.4 \times 10^5$-1 in $2.2 \times 10^6$) |
| S/LS-EIA yield | 1 in $6.1 \times 10^6$ (1 in $9.1 \times 10^5$-1 in $4.6 \times 10^6$) | 1 in $2.3 \times 10^6$ (1 in $3.4 \times 10^5$-1 in $1.7 \times 10^6$) | 1 in $3.7 \times 10^6$ (1 in $5.5 \times 10^5$-1 in $2.8 \times 10^6$) |
| HCV | | | |
| Repeat donation history | 1 in $5.2 \times 10^6$ (1 in $7.4 \times 10^5$-1 in $4.1 \times 10^6$) | 1 in $1.8 \times 10^6$ (1 in $2.5 \times 10^5$-1 in $1.4 \times 10^6$) | 1 in $2.6 \times 10^6$ (1 in $3.8 \times 10^5$-1 in $2.0 \times 10^6$) |
| MP-NAT yield | 1 in $5.4 \times 10^6$ (1 in $7.3 \times 10^5$-1 in $4.3 \times 10^6$) | 1 in $1.8 \times 10^6$ (1 in $2.5 \times 10^5$-1 in $1.4 \times 10^6$) | 1 in $2.7 \times 10^6$ (1 in $3.7 \times 10^5$-1 in $2.2 \times 10^6$) |

# PROBLEMATICHE LEGATE ALLA NAT PER

# HBV

Table 1
Preliminary data of confirmed HBV yield cases detected with TMA (Gen-Probe/Chiron) applied in ID or MP (pools of 8) test format in July 2005 as observed in countries of intermediate prevalence of hepatitis B.

| Pooling | Pre-HBsAg window-phase donations confirmed in follow-up and alternative NAT | Anti-HBc positive occult or latent HBV infections identified by discriminatory test or alternative NAT | Number of donations tested[a] |
|---|---|---|---|
| ID-NAT | 4 [+3][b] | 45 [+9][c] | 437,000[d] |
| Yield rate | 1:109,000 | 1:9700 | |
| MP-NAT (1:8) | 0 | 5 [+2][c] | 189,000[e] |
| Yield rate | | 1:38,000 | |
| Total | 4 [+3] | 50 [+11][c] | 626,000 |

[a] Additional potential yield cases that were not yet confirmed by follow-up or alternative NAT are shown in brackets.

[b] 3 confirmed window-phase donations were identified in Spain and one in Poland. There were 3 additional HBV-NAT reactive donors in Poland (between brackets) who at that time had not yet been confirmed (Gronowska et al., 2005).

[c] In total 50 donations were confirmed by either discriminatory HBV TMA and/or PCR assays and 11 additional donations (between brackets) were TMA reactive in duplicate, TMA reactive some of the time, but negative in discriminatory test, or not confirmed because of lack of sample. The difference in yield rate of occult HBV infection detected by ID-NAT and MP-NAT (pools of 8) was highly significant ($p < 0.005$).

[d] Donations screened by ID-NAT were from Italy (215,000), Spain (66,000), Poland (125,000), Lithuania (25,000) and New Zealand (6000).

[e] Donations screened by MP-NAT were from Italy (87,000) and Spain (102,000).

Table 1 HBV NAT yield of HBsAg-negative donations from chronic carriers and window donors

| Number of donations tested | Pool NAT positive | Missed by pool NAT |
|---|---|---|
| 12·8 million | 21 | 6 (22·2%) |
| Window | | |
| 15 | 13 | 2 (13%) |
| Chronic | | |
| 12 | 8 | 4 (33%) |

Table 2 HBsAg-negative chronic low-titre HBV carriers

| Donor | Mini-pool PCR | ID-PCR | Enr. – PCR | Anti HBs | Anti-HBc |
|---|---|---|---|---|---|
| 1 | – | – | + + + + | 93·7 | + |
| 2 | – | – | + + + – – | 213·1 | + |
| 3 | – | – | + + + – | > 1000 | + |
| 4 | – | – | + + + | – | + |
| 5 | – | – | + + + | > 1000 | + |
| 6 | – | – | + + + | 26 | + |
| 7 | – | – | + + + | 11 | + |
| 8 | – | – | + + + | 1000 | + |
| 9 | – | – | + + + | 102 | + |
| 10 | – | – | + + + | 7·3 | + |
| 11 | – | – | + + + | 3·3 | + |
| 12 | – | – | + + + | 26·7 | + |
| 13 | – | – | + + + | 41 | + |
| 14 | – | + | + + + | – | + |

1144 anti-HBc positive first-time donors were tested by mini-pool PCR, individual donation (ID)-PCR and 9·6 ml enrichment PCR (Enr.-PCR).

JRC: CAMPIONI DI OGNI DONAZ. STOCCATI DAL 1996-2004

# DONATORI CON **CONVERSIONE HBV**:

HBV NAT POOL DA 50(S 22-60 C/ML,P 1100-3000 C/ML),
HBSAG, ANTI HBC, <ANTIS

RICERCATO **CAMPIONE PRECEDENE**: NAT IN SINGOLO:
su 15.721 CAMPIONI DI UNITA' GIA' TRASFUSE

**158 CAPIONI DI UNITA' SOLO NAT IN SIGOLO+**: 1%
60% CON ANTI HBC 40% AB NEG IN FINESTRA
**95% < 100 C/ML** **26% > 100 C/ML (101-860 )**

181 possibili trasmissioni di HBV PT
63 casi studiati con assetto Ab del pz. noto
12 infezioni accertate: **19%**
11/22 da componenti di donatore in finestra
1/33 da componenti di donatore con HBV occulta
nessun componente con anti-HBs ha infettato

# **HBV**: RIDUZIONE DEL R.R.

| PREVALENZA | ALGORITMO | SENSIBILITA' |
|---|---|---|
| | HBSAG | |
| ALTA >8% | ANTI HBC | PRISM 1600 COPIE/ML |
| MEDIA 2-7% | ANTI HBS | AUSZYME 6800 C/ML |
| | USATE U. > 200 MU | |
| BASSA <2% | NAT POOL | NAT SING.20-60 COP. |
| X HBSAG | GIAPP. GERM. | |
| **VACCINAZ.** | CRONICI | NAT POOL 20-60XN° |
| | | 20X20 = 400 C/ML |
| **ESCAPE** | NAT SINGOLO | |
| | PAESI ALTA PREVALENZA | |
| | FINESTRE | |

# EPIDEMIOLOGIA IN ITALIA

# DELLE PRINCIPALI INFEZIONI

# TRASMISSIBILI CON IL SANGUE

# ISS. ULTIMI DATI DISPONIBILI: 3 DONAT.(6.1%) HCV RNA + AB-

Tabella 2 - Incidenza su donazioni da donatori periodici (anno 2004)

| Marcatore | Incidenza per 100.000 donazioni da donatore periodico |
|---|---|
| HIV | 2,1 |
| HBsAg | 2,1 |
| HCV | 2,3 |
| lue | 6,0 |

# DIFF. S.S. PER **LUE** 2004 VS 2003

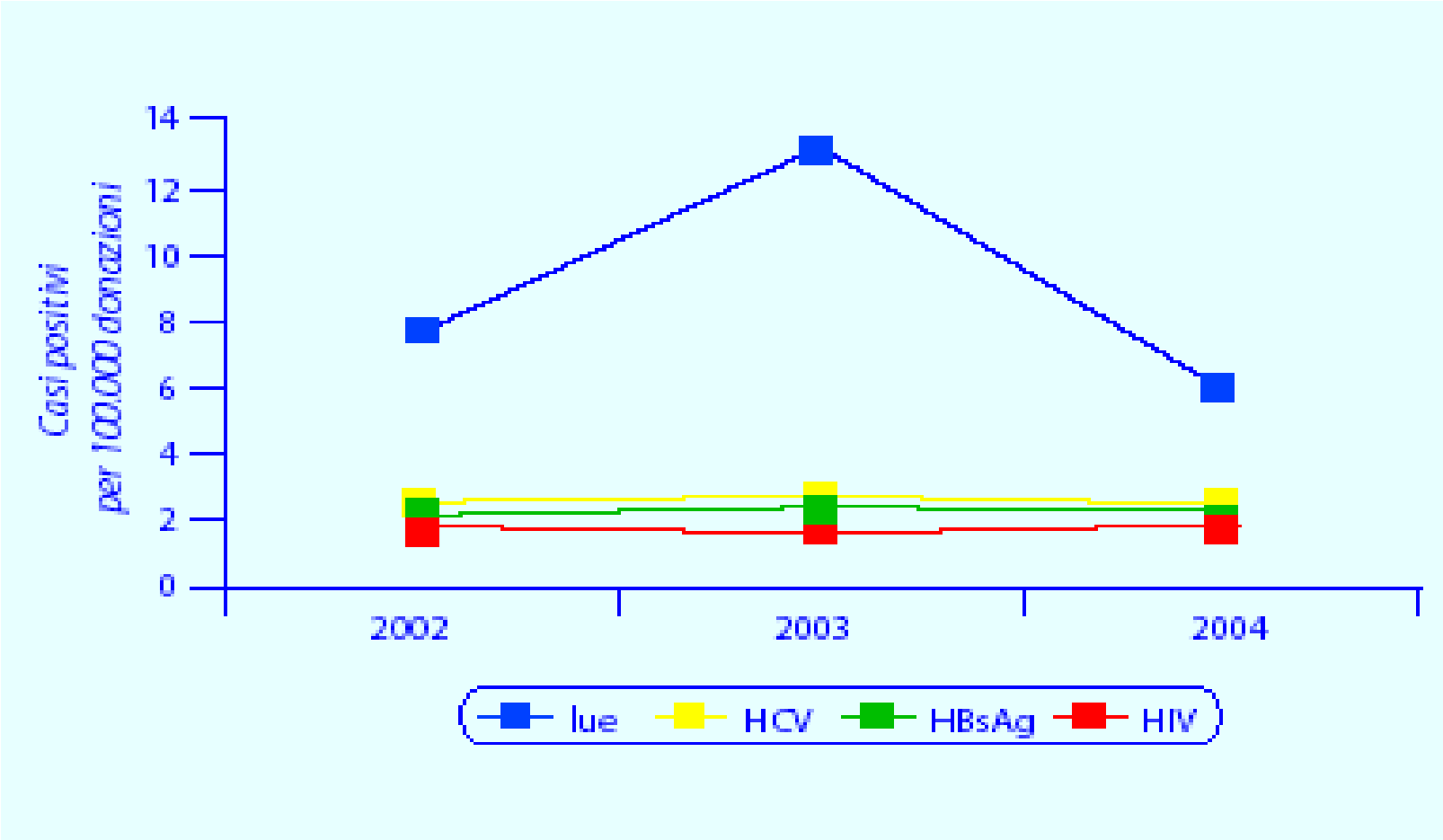



Figura 2 - Incidenze in Italia negli anni 2002-2004 (per 100.000 donazioni)

# 6 DONAT. (1.4%) HCV RNA + AB-

Tabella 3 - Prevalenze su donazioni da donatori nuovi (anno 2004)

| Marcatore | Prevalenze per 100.000 donazioni da donatore nuovo |
|---|---|
| HIV | 16,6 |
| HBsAg | 214,2 |
| HCV | 205,7 |
| lue | 89,9 |

# DECREMENTO S.S. PER **HBV**

# INCREMENTO S.S. PER **HIV** 2004 VS 2003

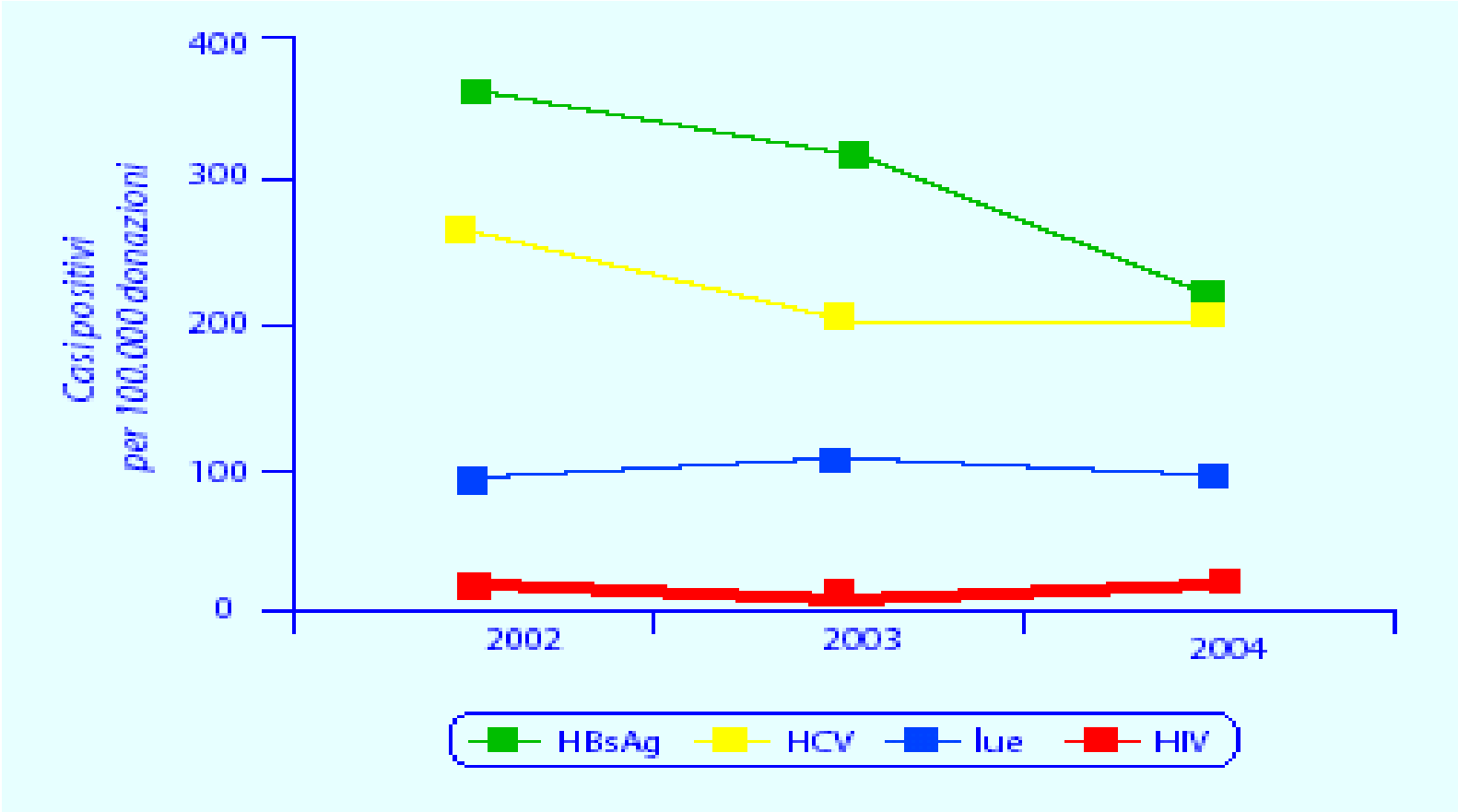



**Figura 3** - Prevalenze in Italia negli anni 2002-2004 (per 100.000 donazioni)

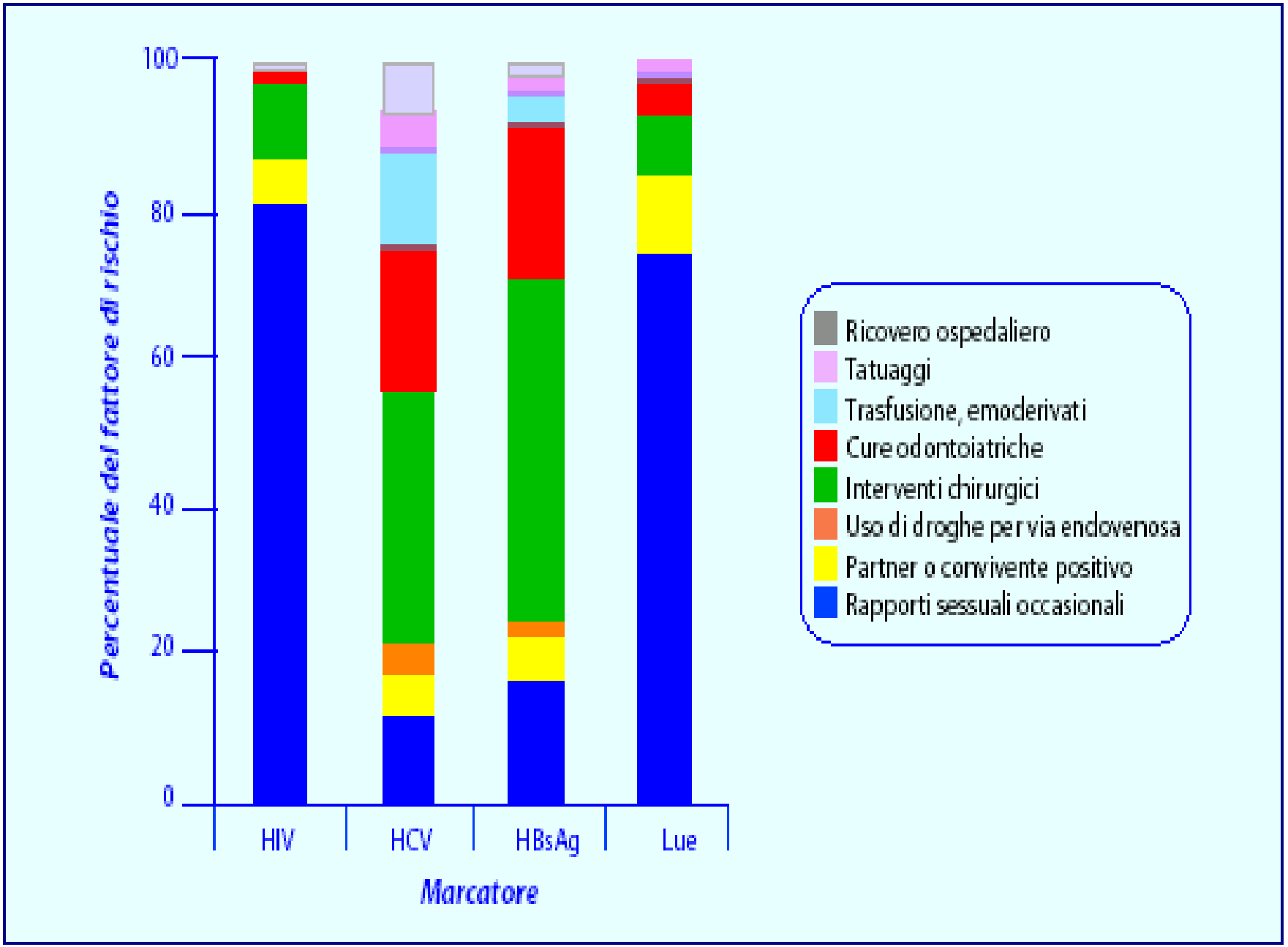



Figura 5 – Distribuzione dei possibili fattori di rischio noti per ogni marcatore

# EPOCA PRE NAT

ANTI-HIV: 1/ 526.310

ANTI-HCV: 1/ 59.737

HBV : 1/ 14.459

RR DEGLI SCREENING AB AG CON MODELLO MATEMATICO

TABLE 2. Estimated incidence and residual risk of TTI for repeat blood donors: Italy, 1999 through 2001

| Marker | Number of seroconversions | Incidence per 100,000 person-years (95% CI) | Residual risk per 1 million donations | Probable range |
|---|---|---|---|---|
| HIV | 77 | 3.17 (3.15-3.19) | 1.91 | 0.52-3.32 |
| HCV | 225 | 9.26 (9.20-9.32) | 16.74 | 9.57-24.01 |
| HBsAg | 260 | 11.03 (10.95-11.11) | | |
| HBV | | 44.12 (43.81-44.43) | 69.16 | 43.12-102.70 |

# RR DEGLI SCREENING AB HC CON MODELLOMATEMATICO:EPOCA PRE NAT

HIV 1/ 408.163, HCV 1/ 229.885, HBV 1/62.271

**Table II.** Length of window period and residual risk of viral infection per 1 million blood units; Italy 1994–1999.

| Markers | Length of window period (d) | | Residual risk per 1 million units (probable range) |
|---|---|---|---|
| | Estimate | Range | |
| HIV | 22 | 6–38 | 2·45 (0·13–12·33) |
| HCV | 66 | 38–94 | 4·35 (0·30–22·39) |
| HBV | | | |
| HBsAg | 59 | 37–87 | 4·36 (0·32–23·27) |
| Total HBV | – | – | 15·78 (1·16–84·23) |

HIV, human immunodeficiency virus; HCV, hepatitis C virus; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen.

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# RR CON MOD. MAT. CON EVENTUALE INTRODUZIONE DI NAT

Table III. Hypothetical reduction in the residual risk of infection following the introduction of nucleic acid amplification testing (NAT) testing in donor screening.

| | Estimated window period (d)* | Estimated residual risk per 1 million donations tested by NAT | Reduction in the estimated residual risk† |
|---|---|---|---|
| HIV | 11 | 1-22 | −50% |
| HCV | 12 | 0-79 | −82% |
| HBV | 35 | 9-36 | −41% |

*Busch (2000).

†Compared to third generation enzyme-linked immunosorbent assay.

# INTRODUZIONE DELLA NAT.

## UNITA' HCV RNA + Ab - ITALIA

## GUADAGNO SU ELISA CON NAT

| PERIODO | N° | POS | pari a |
|---|---|---|---|
| 2001-O2 | 1.906.659 | 6 | 1/317.776 |
| 2003 | 1.988.235 | 6 | 1/331.372 |
| 2004 | 2.227.999 | 5 | 1/445.599 |
| 2005 | 2.174.890 | 5 | 1/434.987 |
| 2006 | 2.478.505 | 5 | 1/495.701 |
| **TOTALE** | **10.776.288** | **27** | **1/399.195** |

14 TRANS. NORMALI

# INTRODUZIONE VOLONTARIA DELLA NAT: UNITA' HIV RNA + Ab - ITALIA.

## GUADAGNO SU ELISACON NAT

| PERIODO | N° | POS | pari a |
|---|---|---|---|
| 2001-02 | 886.506 | 1 | |
| 2003 | 1.297.962 | 3 | 1/432.654 |
| 2004 | 1.641.262 | 5 | 1/328.251 |
| 2005 | 1.841.691 | 4 | 1/460.422 |
| 2006 | 2.262.579 | 1 | |
| **TOTALE** | 7.932.000 | 14 | **1/566.571** |

# INTRODUZIONE VOLONTARIA DELLA NAT:

## UNITA' HBV RNA+ HBsAg-ITALIA

## GUADAGNO SU ELISACON NAT

| PERIODO | N° | POS | pari a |
|---|---|---|---|
| 2004 | 278.252 | 14 | 1/9.887 |
| 2005 | 1.019.768 | 66 | 1/15.461 |
| 2006 | 2.107.292 | 117 | 1/18.011 |
| **TOTALE** | 3.405.497 | 197 | 1/17.286 |

# CARATTERIZZAZIONE ANTICORPALE DI **111/197** DONATORI HBV NAT+ HBsAg-

| | | | | |
|---|---|---|---|---|
| ANTI Hbc+ | ANTI Hbe- | ANTI Hbs- | 17 | 15% |
| ANTI Hbc+ | ANTI Hbe+ | ANTI Hbs- | 16 | 15% |
| ANTI Hbc+ | ANTI Hbe- | ANTI Hbs+ | 51 | 46% |
| ANTI Hbc+ | ANTI Hbe+ | ANTI Hbs+ | 19 | 17% |
| Ab NEGATIVI ( FINESTRA ) | | | 8 | 7% |

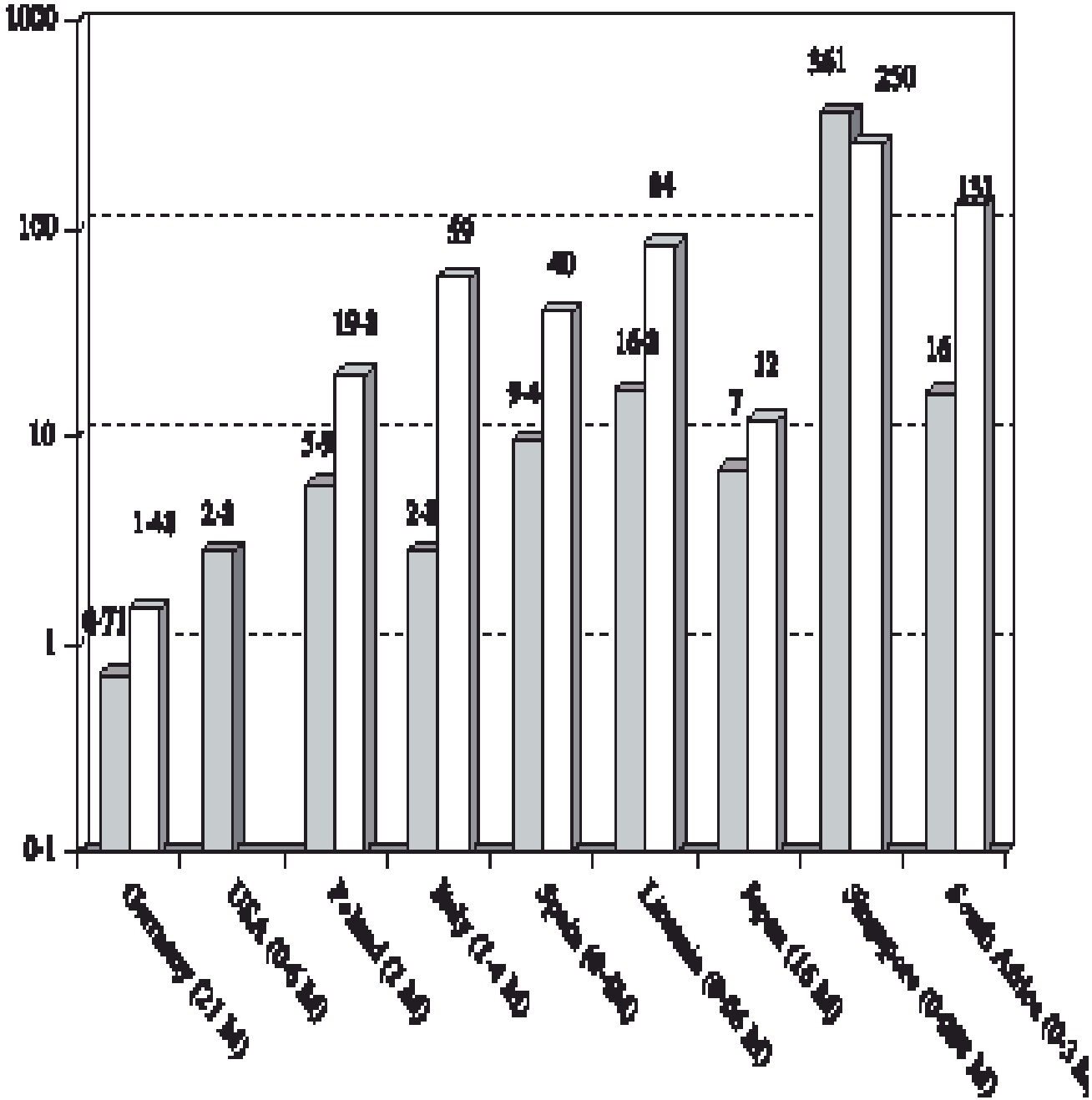



Fig. 3 HBV-NAT yield in the early phase (grey bars) and in the late phase of the HBV infection (white bars) for several countries expressed per million donations (log10 scale). For each country the number of tested donations is in brackets. [25,28,45–50]

# GUADAGNO CON HCV RNA VERSO I TEST ELISA IN EUROPA E ITALIA

EUROPA 2001-03: 54 NAT+AB-/ 58 MILIOMI DONAZ.

GUADAGNO = 0.93 X MILIONE DI UNITA'

ITALIA 2001-06: 27 NAT+AB-/10.778.288 DONAZ.

GUADAGNO = 2.5 X MILIONE DI UNITA'

13 NAT+AB- GPT NORMALI

GUADAGNO = 1.2 X MILIONE DI UNITA'

# ITALIA

# **RISCHIO RESIDUO POST NAT:**

## *(M.M. INC. X P.F.)*

PER HCV: 1 UNITA' / 5.000.000 NAT NEGATIVE IN POOL

PER HIV: 1 UNITA' / 714.285 NAT NEGATIVE IN POOL

PER HBV: GUADAGNO DI **57,85 UNITA' / 1.000.000** R.R. ?

# DOVE SONO LE EPATITI B DA TRASFUSIONE ?

# EPATITI B POST-TRASFUSIONE:

## CI SONO MA NON VENGONO EVIDENZIATE ?

USA 2003: 1/7381

ITALIA 2000-01: 6 ASSOCIATE A TRASF.

4071 EP. ACUTE, **1320 B.** 25 CON CHIR. + TRASF

## SONO EFFETTIVAMENTE POCHE

DONAZ IN FINESTRA: +INFETTIVE MA POCHE

DONAZ IN F. CRONICA: MOLTE MA BASSA CARICA CON ANTI Hbs

UOMO = MARMOTTA?

PZ. DA TRASFONDERE CON ANTI HBc E/O HBs

**LIGURIA 27.5%**

VIRIONI INCOMPLETI NAT+ NON INFETTANTI

PZ: IMMUNOCOMPET. O IMMUNOSOPPRESSO?

# EPIDEMIOLOGIA IN LIGURIA DELLE INFEZIONI TRASMISSIBILI CON IL SANGUE

# METODICHE USATE IN LIGURIA NEL PERIODO 2003-2006

| SIT | *SIEROLOG.* | | *NAT* | |
|---|---|---|---|---|
| | | **HCV** | **HIV** | **HBV** |
| IMP. | ABB | PCR(15) | PCR | PCR |
| P.L. | ABB | PCR(20) | PCR | - |
| SV. | ORT | PCR(20) | PCR | - |
| 3ASL | ABB | TMA(S) | TMA | - |
| SPA | ABB | TMA(S) | TMA | - |
| GAL. | ABB | PCR(20) | PCR | - |
| S.M. | ORT | TMA(S) | TMA | - |
| LAV. | ABB | PCR(20) | PCR | PCR |
| SP | ABB | PCR(20) | PCR | PCR |
| TOT | 305.486 | 305.486 | 171.969 | 67.231 |

# DONAZIONI DA NUOVO DONATORE (ND), DONATORE ABITUALE (DA) E POS Ab e NAT: 2003-2006

| **D. Nuovi** | **D. Abituali** | **TOT** |
|---|---|---|
| POS / TOT | POS / TOT | |
| 87 / 24.913 | 21 / 280.573 | **108* / 305.486** |
| 0,35% | 0,007% | |

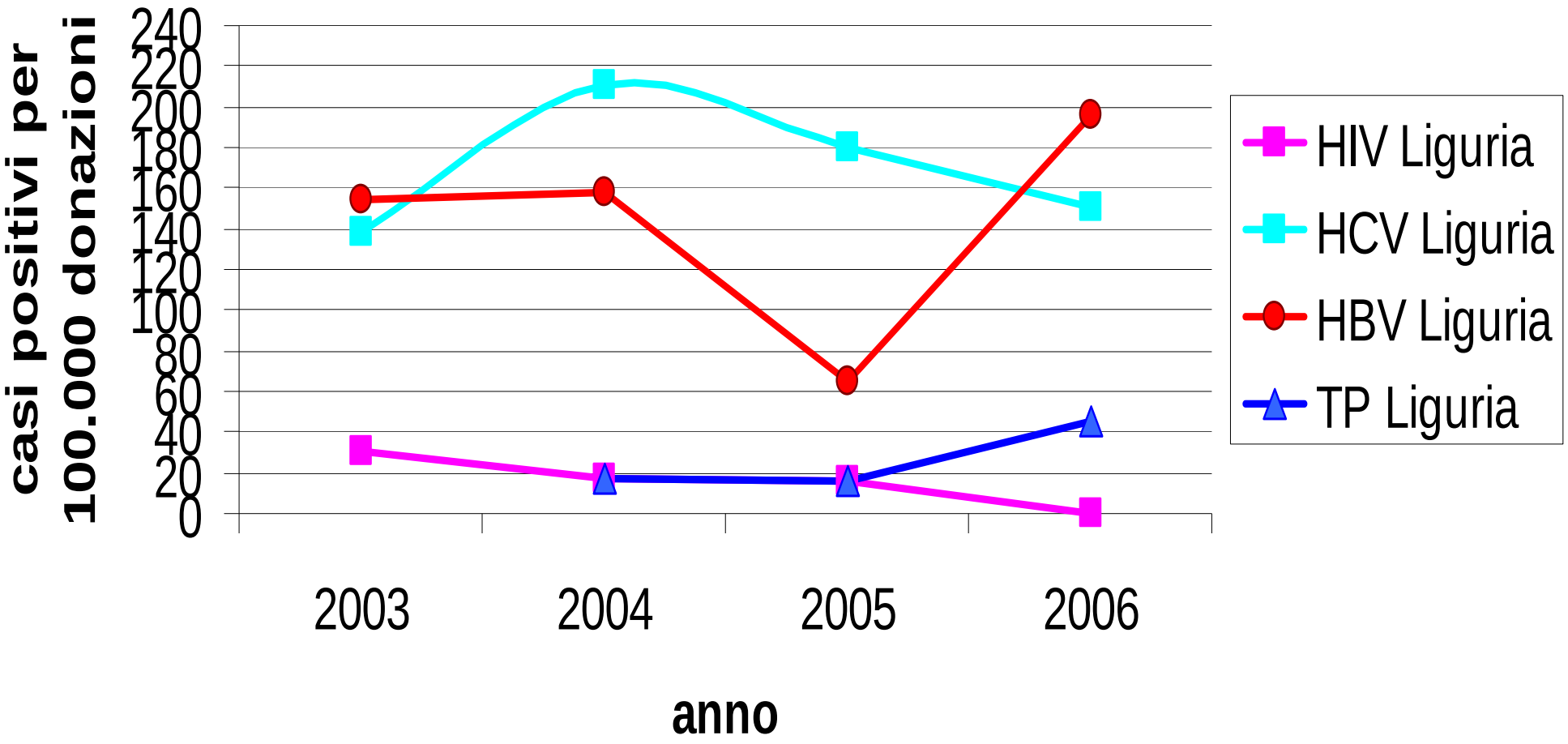
* 2 donazioni Ab- NAT+

# PREVALENZA X 100.000 UNITA' IN LIGURIA E CONFRONTO CON ITALIA

| ***ANNO*** | HIV | | **HCV** | | **HBV** | | anti-T.P. | |
|---|---|---|---|---|---|---|---|---|
| | ITA | LIG | ITA | LIG | ITA | LIG | ITA | LIG |
| *03* | | 30.8 | | **138.9** | | 154.4 | | |
| | | | **P<0.001** | | | | | |
| **04** | 16.6 | 17.5 | 205.2 | **210.5** | 214.2 | 157.9 | 89.9 | 17.5 |
| | | | | | **P<0.01** | | **P<0.001** | |
| | | | | | | **P<0.001** | | |
| 05 | | 16.3 | | 179.7 | | 65.3 | | 16.3 |
| | | **P<0.001** | | | | **P<0.001** | | **P<0.001** |
| 06 | | 0 | | 151.2 | | 196.5 | | 45.7 |

# Andamento della prevalenza per HIV, HBV, HCV, TP in Liguria (2003-2006)

## aumento di HBV e TP s.s.

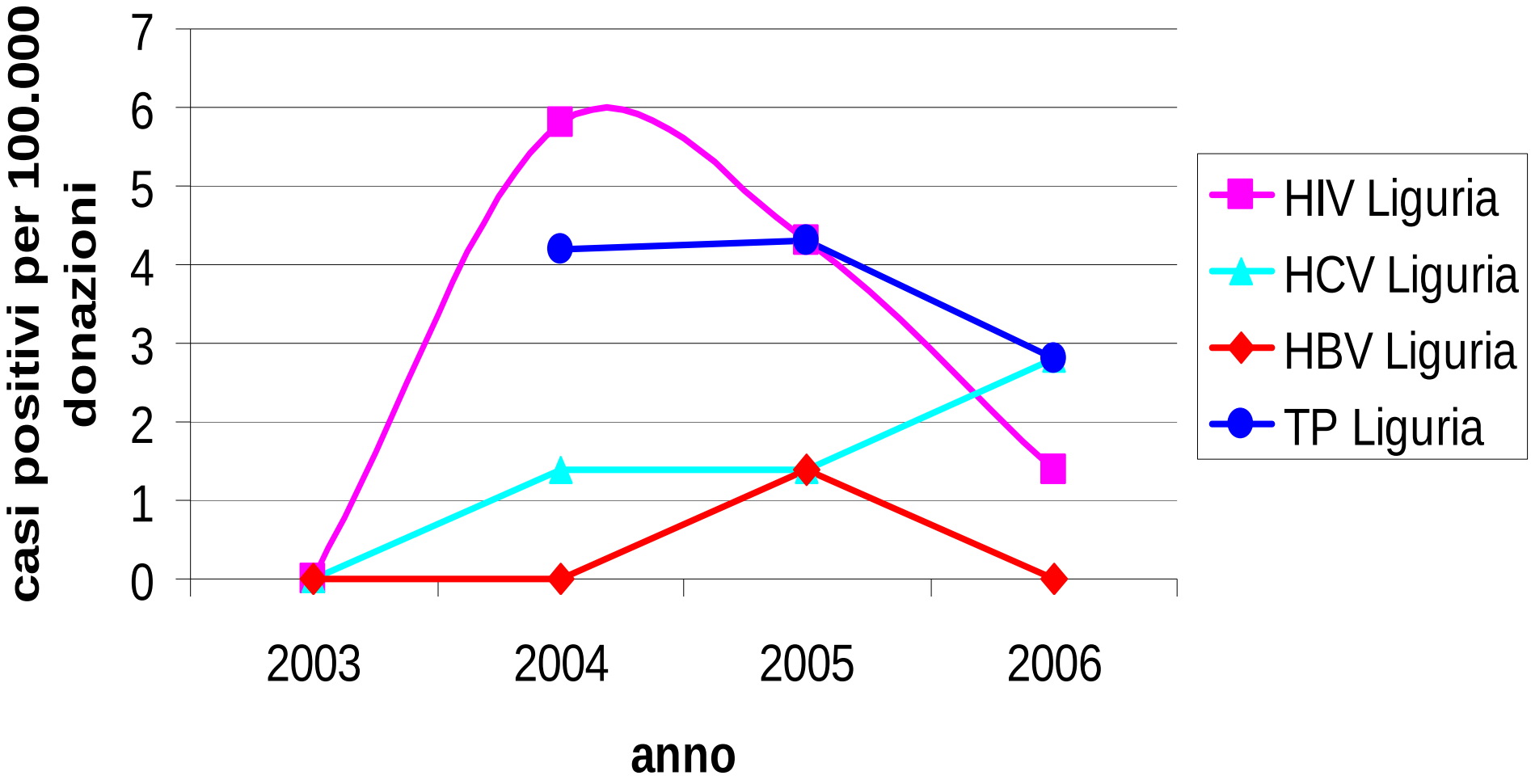


# INCIDENZA X 100.000 UNITA' IN LIGURIA E CONFRONTO CON ITALIA

| ANNO | HIV | | HCV | | HBV | | ANTI T.P. | |
|---|---|---|---|---|---|---|---|---|
| | ITA | LIG | ITA | LIG | ITA | LIG | ITA | LIG |
| ***03*** | | 0 | | 0 | | 0 | | |
| | | **P=0.0521** | | | | | | |
| **04** | 2.1 | 5.8 | 2.3 | 1.4 | 2.1 | 0 | 6 | 4.2 |
| 05 | | 4.3 | | 1.4 | | 1.4 | | 4.3 |
| 06 | | 1.4 | | 2.8 | | 0 | | 2.8 |

# Andamento dell'incidenza per HIV, HBV, HCV, TP in Liguria (2003-2006)

## calo di HIV, HBV e TP; aumento di HCV non s.s.



# NAT IN LIGURIA. POSITIVITA' NEL 2003-06. CONFRONTO CON L' ITALIA

| | HCV RNA POS / TOT | | HIV RNA POS / TOT | | HBV DNA POS / TOT | |
|---|---|---|---|---|---|---|
| **LIGURIA** | | | | | | |
| | 2 | 305.486 | 0 | 171.969 | 0 | 67.231 |
| | 1 | 152.923 | | | | |
| **ITALIA** | | | | | | |
| | 1 | 399.195 | 1 | 566.571 | 1 | 17.286 |
| | | NS | | NS | | **P < 0.05** |

# PREVALENZE NELLA **POPOLAZIONE GENERALE** LIGURE E NEI **NUOVI DONAT.**

ITALIA: 58.462.375 RESIDENTI
3500 NUOVE INFEZ. / ANNO X HIV
110-130.000 SIEROPOSITVI E AIDS
1.000.000 ANTI-HCV +

**LIGURIA**: 1.660.000 RESIDENTI
HIV 150-200 NUOVE INFEZ. / ANNO
4.000-5.000 SIEROPOS. E AIDS (OELMI)
PREVALENZA: **PG 301/ 100.000** ND **30.8/ 100.000**

HBV 1% RESIDENTI E' +: 15.000
PREVALENZA: **PG 903/100.000** ND **196.5/ 100.000**

HCV 1.6% RESIDENTI E'+: 26560
50% RNA+: 13280 (JMV 76 327 2005)
PREVALENZA: **PG 1600/100.000** ND **210.5/ 100.000**

# MARCATORI POS DA ND E DA

| MARCATORE | UNITA' DA ND | UNITA' DA DA |
|---|---|---|
| HIV | 4 / 24.913<br>p< 0.001 | 8 / 280.573<br>ns |
| HCV | 42 / 24.913<br>1 solo NAT<br>ns | 4 / 280.573<br>1 solo NAT<br>ns |
| HBV | 36 / 24.913<br>p<0.001 | 1 / 280.573<br>ns |
| SIFILIDE | 5 / 24.913 | 8 / 280.573 |

# GUADAGNO CON HCV RNA VERSO I TEST ELISA IN EUROPA,ITALIA E LIGURIA

**EUROPA** 2001-03: 54 NAT+AB-/ 58 MILIOMI DONAZ.
GUADAGNO = **0.93** X MILIONE DI UNITA'

ITALIA 2001-06: 27 NAT+AB-/10.778.288 DONAZ.
GUADAGNO = 2.5 X MILIONE DI UNITA'
13 NAT+AB- GPT NORMALI
GUADAGNO = 1.2 X MILIONE DI UNITA'

LIGURIA 2006-06: 2 NAT+AB-/305.486 DONAZ.
GUADAGNO = **0.65 X 100.000** UNITA'

# CARATTERISTICHE DEI DONATORI POSITIVI

| | ND | | | | | DA | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | ETA' | M | F | NASCITA ITA | NASCITA N I | ETA' | M | F | NASCITA ITA | NASCITA N I |
| HIV | 31.2 | 3 | 1 | 3 | 1 | 44.2 | 8 | 0 | 8 | - |
| HCV | 40 | 27 | 15 | 39 | 3 | 44.7 | 2 | 2 | 4 | - |
| HBV | 41 | 25 | 11 | 28 | **8** | 42 | 1 | 0 | 1 | - |
| T.P. | 46 | 3 | 2 | 5 | | 44 | 8 | 0 | 8 | - |
| **TOT** | | **58** | **29** | | **12** | | **19** | **2** | | |

N I = NON ITALIANA

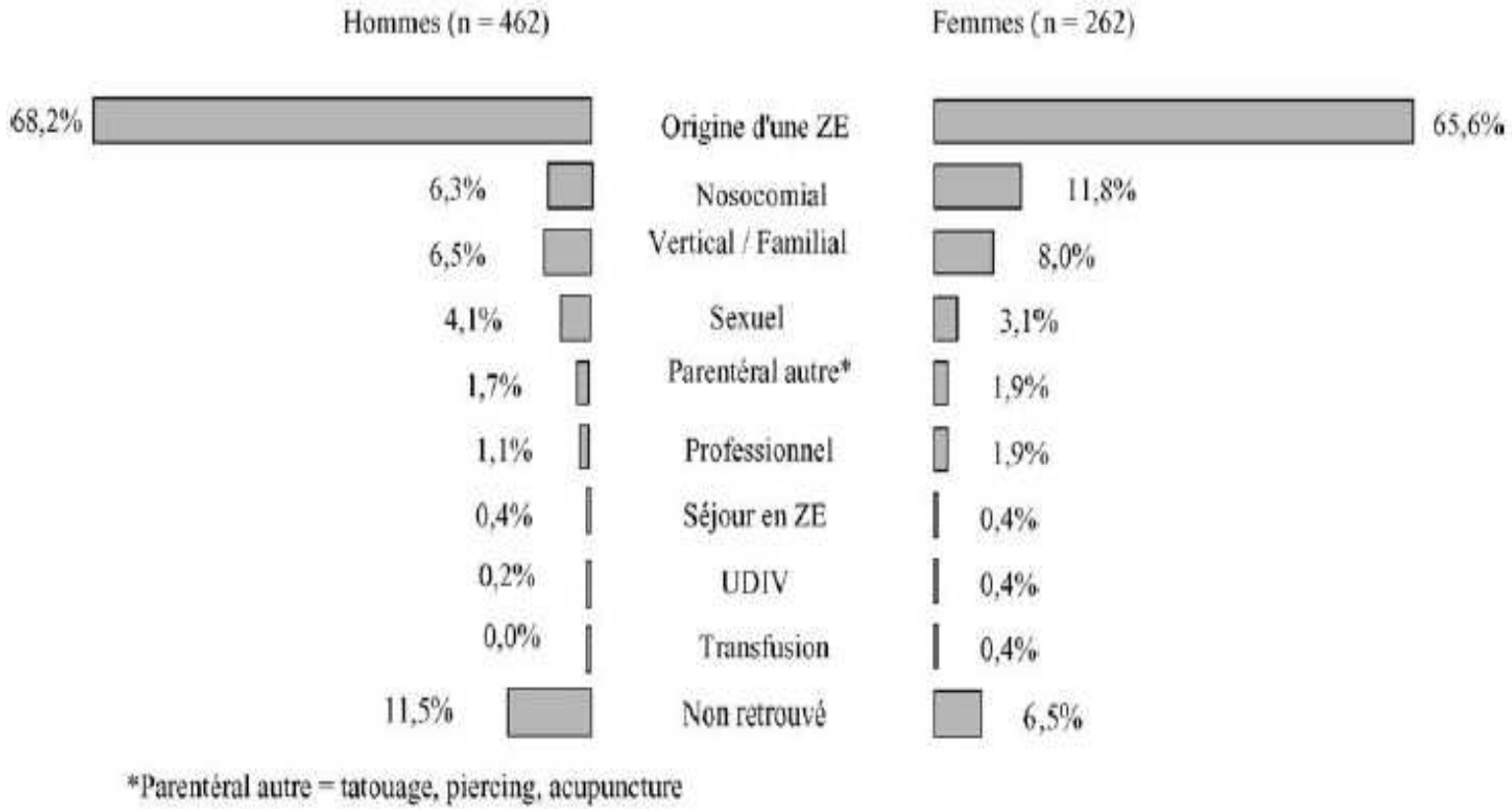
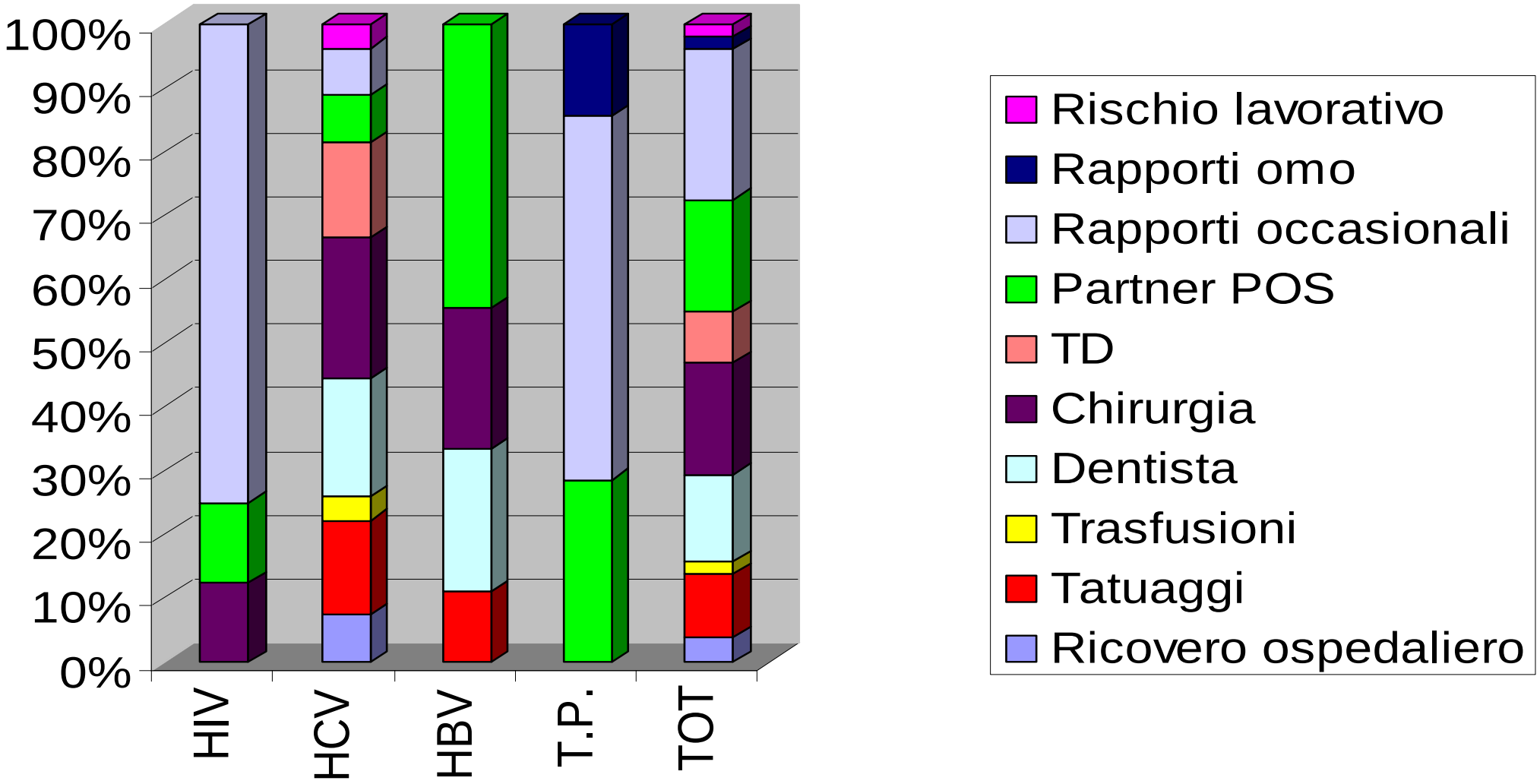



Fig. 8. Facteurs de risque de l'Ag HBs chez les nouveaux donneurs en France métropolitaine selon le sexe, 2001-2003.

# Fattori di rischio per **37**/108

# donatori liguri positivi



# CONCLUSIONI

- LE INCIDENZA SONO **STABILI** NEGLI ANNI E **SIMILI** A QUELLE NAZIONALI. I R.R. POSSONO ESSERE **ASSIMILATI A QUELLI NAZIONALI**

- LE PREVALANZE SONO **SIMILI O <** (HBV E TP) VERSO LE NAZIONALI 04**. HCV E HBV** SONO PIU' DIFFUSE NEI ND COME NELLA POP. GEN. MA IN MODO **NETTAMENTE INFERIORE FRA I DONAT**.: SELEZIONE ED EDUCAZIONE DEL DONATORE

- **SOLO I DATI NAT HBV** SONO STATISTICAMENTE DIVERSI DAI NAZIONALI PERCHE' CON PROBABILITA' LA NAT IN LIGURIA, **TUTTA IN POOL**, PERDE I PORTATORI CRONICI. A CAUSA DEL CAMPIONE RISTRETTO NON SONO EVIDENZIATI I RARI DONATORI IN FINESTRA

# CONCLUSIONI

- LA **NAT PER HCV HA UNA RESA BUONA** CON UN GUADAGNO RISPETTO ALLA SIEROLOGIA DI 0.65 UNITA' / 100.000 TESTATE CON DIFFERENZA PERO' STATISTICAMENTE NON SIGNIFICATIVA RISPETTO AI DATI NAZIONALI

- TRA I NUOVI DONATORI **12** CON MARCATORI POS. ERANO **STRANIERI O NON NATI IN ITALIA**. CIO' RIGUARDA SOPRATTUTTO L' INFEZ. DA **HBV (8)**. TALE DATO PUO' SOLLEVARE IL PROBLEMA DELLA DONAZIONE DA PARTE DI SOGGETTI NON VACCINATI PROVENIENTI DA ZONE ENDEMICHE: SCREENING E VACCINAZIONE PREDONAZIONE?

# CONCLUSIONI

- NESSUNO DEI 33 ND ITALIANI POSITIVI PER HBSAG RICADEVA IN ETA' VACCINALE TRANNE (FORSE) UNO.

- I FATTORI DI RISCHIO EVIDENZIATI ERANO PRINCIPALMENTE **I RAPPORTI OCCASIONALI** PER HIV E SIFILIDE. PER HBV 4 DONAT. AVEVANO IL **PARTNER POSITIVO**: L'ANAMNESI?. PER HCV I POSSIBILI RISCHI SONO MOLTO VARIAMENTE DISTRIBUITI: I PIU' IMPORTANTI SONO LA **CHIRURGIA E LE CURE ODONTOIATRICHE** COME A LIVELLO NAZIONALE.

SI RINGRAZIANO:

- COLLEGHI DEI SERVIZI LIGURI
- PERSONALE DEL CRCC
- DOTT. MARINA SARTINI
- DOTT. CRISTINA FAGIOLI