

# Needle and Sharps Injuries Prevention

## Building the wall:

Implementing the Directive  
2010/32/EU in Italy



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Sharps Safety in the European Union Group

**EPSU-HOSPEEM**

**2nd Regional Seminar Rome, 7 March 2013**

# Awareness Raising

# HBV Vaccination

| Western European country | People living with HIV/AIDS 2009 | Adult prevalence % 2009 | with HIV/AIDS 2009 |
|--------------------------|----------------------------------|-------------------------|--------------------|
| Belgium                  | 14,000                           | 0.2                     | 4,400              |
| Denmark                  | 5,300                            | 0.2                     | 1,400              |
| Finland                  | 2,600                            | 0.1                     | <1,000             |
| <b>France</b>            | <b>150,000</b>                   | <b>0.4</b>              | <b>48,000</b>      |
| Germany                  | 67,000                           | 0.1                     | 12,000             |
| Greece                   | 8,800                            | 0.1                     | 2,700              |
| Ireland                  | 6,900                            | 0.2                     | 2,000              |
| <b>Italy</b>             | <b>140,000</b>                   | <b>0.4</b>              | <b>48,000</b>      |
| Netherlands              | 22,000                           | 0.2                     | 6,900              |
| Portugal                 | 42,000                           | 0.6                     | 13,000             |
| <b>Spain</b>             | <b>85,000</b>                    | <b>0.2</b>              | <b>20,000</b>      |
| Sweden                   |                                  |                         |                    |
| United Kingdom           | 85,000                           | 0.2                     | 20,000             |

**HIV**

**+4000-9000 cases/y**

Figure 6. Estimated number of HBsAg-positive individuals by country, based on general population prevalence estimates

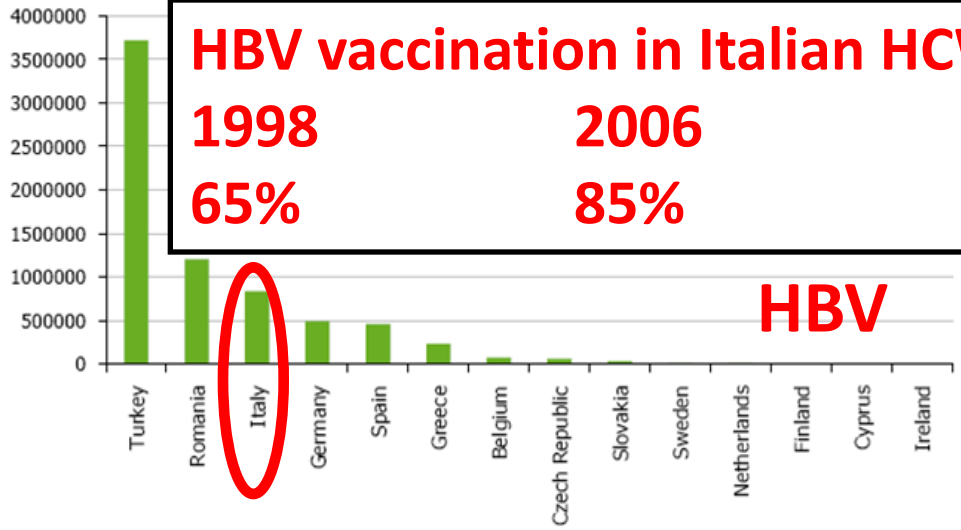
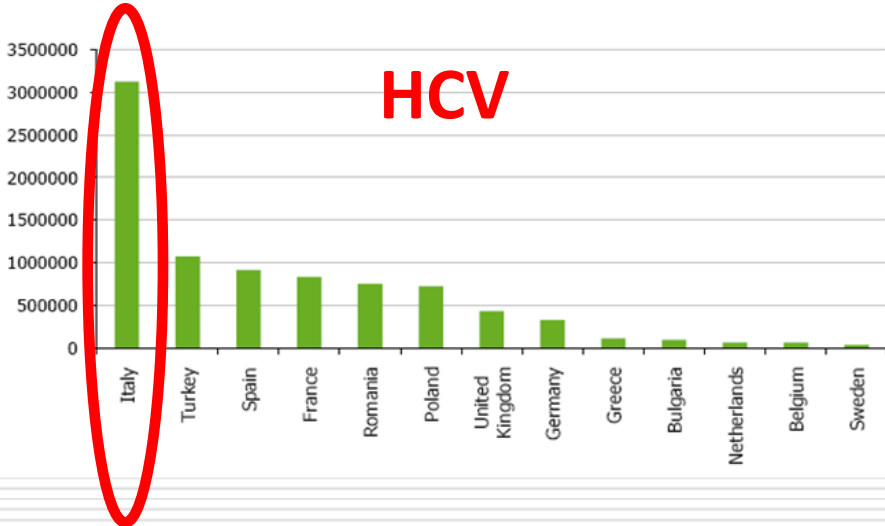


Figure 7. Estimated number of anti-HCV-positive individuals by country, based on general population prevalence estimates



**HCV-RNA + 1,560,810**  
**50-65 yrs 23,6%**  
**>65 yrs 65,8%**  
**Increasing need for health assistance in the next 20 yrs**

## Occupazionale HIV (SIROH)

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- ❑ **1986-1993:** incidence of occupational HIV infection following an occupational exposure to an HIV-infected source (29 hospitals)
  - ❑ **1992-1993:** incidence of anti-HCV seroconversion following an occupational exposure to an anti-HCV Ab+ source (29 hospitals)
  - ❑ **1994-ongoing:** study of the characteristics and mechanism of occupational exposures, regardless of the infectivity of the source (>150 hospitals, 125 currently involved)
  - ❑ **1990-ongoing:** Italian Registry of Antiretroviral Post-exposure Prophylaxis (nationwide, >90 Infect Dis centres)
-

# Reporting & Recording


Golden Ring +

inmi.it https://siroh.inmi.it/client/index.cfm

IT ?

I.N.M.I.  
"L.Spallanzani"  
I.R.C.C.S.

I.N.M.I. "L.Spallanzani" Venerdì 11 Novembre - 10:00:22 Buongiorno, Operatore Spallanzani

 **SIROH: registro infortuni**  
STUDIO ITALIANO RISCHIO OCCUPAZIONALE DA HIV

Bozza

Esci PDF Salva

Operatore Incidente Procedura e Dispositivo **Rischio Biologico 1** Rischio Biologico 2 Prevenzione Descrizione dell'incidente Fonte Esposto

**Descrizione della fase in cui si è verificato l'incidente**

17. Fase di utilizzo del presidio durante la quale l'incidente si è verificato \*

Prima dell'uso

Prima di usare il dispositivo su un paziente o campione biologico

**Presidio di sicurezza**

18a. Il presidio era di sicurezza? \*

No  Non applicabile/non noto  Sì

18b. Modello commerciale (descrivere) \*

ND

18c. Tipo di dispositivo \*

Passivo

Attivo

Passivo

Altro

18d. Fase di utilizzo del dispositivo durante la quale si è verificato l'incidente \*

Scegli la fase di utilizzo

18e. Il sistema di sicurezza risultava attivato? \*

No  Sì  ND

18f. L'operatore aveva ricevuto formazione specifica sull'uso del dispositivo? \*

No  Sì  Non si applica (non ne era l'originario utilizzatore)  ND

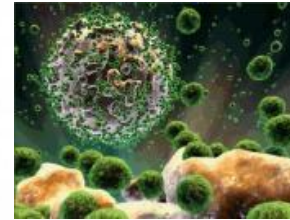
19. Il contenitore resistente alle punture, al momento dell'incidente, era a portata di mano? \*

No  Sì  Non disponibile presso il servizio  Non si applica  ND

Tesi S.p.A., © 2001-2011

Start Golden Ring - Mozilla ... Surveillance Nov 2011

11:14



# HIV Sero Conversion (SC) Rates

By type of exposure, to blood or at-risk body fluids

SIROH, 1986-2011

1986-1996  
(pre-HAART)

| Type of exposure             | SC/exposures | % rate | 95% CI      |
|------------------------------|--------------|--------|-------------|
| <i>Percutaneous</i>          | 3/2066       | 0.14   | 0.03 - 0.42 |
| <i>Mucous contamination</i>  | 2/486        | 0.41   | 0.05 - 1.48 |
| <i>Non-intact skin cont.</i> | 0/547        | 0      | 0 - 0.67    |

**Tot=3099**

1997-2011  
(post-HAART)

| Type of exposure             | SC/exposures | % rate | 95% CI       |
|------------------------------|--------------|--------|--------------|
| <i>Percutaneous</i>          | 1/1162       | 0.09   | 0.002 - 0.48 |
| <i>Mucous contamination</i>  | 0/835        | 0      | 0 - 0.44     |
| <i>Non-intact skin cont.</i> | 0/245        | 0      | 0 - 1.49     |

**Tot=2242**



# HCV and HBV SC Rates



SIROH, 1992-2011

|     | Type of exposure                                     | SC/exp         | % Rate      | 95% CI           |
|-----|--|----------------|-------------|------------------|
| HCV | Percutaneous exposure                                | 30/11476       | 0.26        | 0.18-0.37        |
|     | <i>Hollow-bore, blood -filled needle</i>             | <i>26/3320</i> | <i>0.78</i> | <i>0.51-1.15</i> |
|     | <i>Hollow-bore, non- filled needle</i>               | <i>0/2527</i>  | -           | -                |
|     | <i>Solid sharp/needle</i>                            | <i>4/5629</i>  | <i>0.07</i> | <i>0.02-0.18</i> |
|     | Mucous contamination                                 | 2/6524         | 0.03        | 0.003-0.11       |
|     | <i>Conjunctival exp to blood</i>                     | <i>2/2181</i>  | <i>0.09</i> | <i>0.01-0.33</i> |
|     | <i>to other biological materials</i>                 | <i>0/650</i>   | -           | -                |
|     | <i>Other membranes to blood</i>                      | <i>0/186</i>   | -           | -                |
|     | <i>to other biological materials</i>                 | <i>0/53</i>    | -           | -                |
|     | Non intact skin cont, with blood                     | 0/1447         | -           | -                |
| HBV | Percutaneous exposure                                | 1/219          | 0.46        | 0.01-2.52        |
|     | Susceptible subjects (118 vaccinated after exposure) |                |             |                  |





A CASE-CONTROL STUDY OF HIV SEROCONVERSION IN HEALTH CARE  
WORKERS AFTER PERCUTANEOUS EXPOSURE

DENSE M. CARDO, M.D., DAVID H. CULVER, PH.D., CAROL A. CIESIELSKI, M.D., PAME  
RUTHANNE MARCUS, M.P.H., DOMINIQUE ABTEBOUL, M.D., JULIA HEPTONSTA  
GIUSEPPE IPPOLITO, M.D., FLORENCE LOT, M.D., PENNY S. MCKIBBEN, DAVID  
AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION NEEDLESTICK SURV

ABSTRACT

**Background** The average risk of human immunodeficiency virus (HIV) infection after percutaneous exposure to HIV-infected blood is 0.3 percent, but the factors that influence this risk are not well understood.

**Methods** We conducted a case-control study of health care workers with occupational, percutaneous exposure to HIV-infected blood. The case patients were those who became seropositive after exposure to HIV, as reported by national surveillance systems in France, Italy, the United Kingdom, and the United States. The controls were health care workers in a prospective surveillance project who were exposed to HIV but did not seroconvert.

**Results** Logistic-regression analysis based on 33 case patients and 665 controls showed that significant risk factors for seroconversion were deep injury (odds ratio = 15; 95 percent confidence interval, 6.0 to 41), injury with a device that was visibly contaminated with the source patient's blood (odds ratio = 6.2; 95 percent confidence interval, 2.2 to 21), a procedure involving a needle placed in the source patient's artery or vein (odds ratio = 4.3; 95 percent confidence interval, 1.7 to 12), and exposure to a source patient who died of the acquired immunodeficiency syndrome within two months afterward (odds ratio = 5.6; 95 percent confidence interval, 2.0 to 16). The case patients were significantly less likely than the controls to have taken zidovudine after the exposure (odds ratio = 0.19; 95 percent confidence interval, 0.06 to 0.52).

**Conclusions** The risk of HIV infection after percutaneous exposure increases with a larger volume of blood and, probably, a higher titer of HIV in the source patient's blood. Postexposure prophylaxis with zidovudine appears to be protective. (N Engl J Med 1997;337:1485-90.)

©1997, Massachusetts Medical Society.

**T**HE average risk immunodeficiency care worker after HIV-infected b 0.3 percent.<sup>1-4</sup> However, this risk have not been d of postexposure prophyla has not been clinically prophylaxis is effective, new strategy for preven nonoccupational setting preferred strategy of pre occupational exposure t tant opportunity to eval laxis, because the source, the exposure are known, placebo-controlled trial ( dine after percutaneous health care workers was health care workers enr many thousands would tion of a 0.3 percent ris theless, occupational exp continue to occur, and t health need for data on t prophylaxis.

We conducted a case

From the Hospital Infectious Pr Diseases (D.M.C., D.H.C., E.U.S.), of HIV/AIDS, National Center (C.A.C.), Centers for Disease Cont National de Recherche et de Scur d'Exposition au Sang, Paris (D.A.); Communicable Disease Surveillance; Riferimento AIDS-Coordinatione out Occupazionale di HIV, Rome

Characterization of risks

MAJOR ARTICLE

## Risk Factors for Hepatitis C Virus Transmission to Health Care Workers after Occupational Exposure: A European Case-Control Study

Y. Yazdanbakhsh,<sup>1,2,3,4</sup> G. De Carli,<sup>11</sup> B. Miguéras,<sup>4</sup> F. Lot,<sup>1</sup> M. Campino,<sup>2</sup> G. Colombo,<sup>2</sup> T. Thomas,<sup>12</sup> S. Desfleux-Burban,<sup>2</sup> M. H. Provat,<sup>13</sup> M. Demant,<sup>12</sup> A. Terraccini,<sup>1</sup> D. Abilleau,<sup>12</sup> P. Dany,<sup>12</sup> S. Pol,<sup>7</sup> J. C. Desseaux,<sup>4</sup> V. Puro,<sup>14</sup> and E. Bouvard<sup>1,2</sup>

<sup>1</sup>Service des Maladies Infectieuses et du Voyageur, Centre Hospitalier de Toulouse; <sup>2</sup>Equipe d'accueil 2604, Faculté de Médecine de Lille, and <sup>3</sup>Laboratoire de Recherches Économiques et Sociales, Centre National de la Recherche Scientifique URA 352, Lille; <sup>4</sup>Groupe d'Étude sur le Risque d'Exposition au Sang; <sup>5</sup>Service de Médecine du Travail, and <sup>6</sup>Service des Maladies Infectieuses et Tropicales, Hôpital Bichat, and <sup>7</sup>Unité d'Hépatologie et Institut National de la Santé et de la Recherche Médicale U-370, Hôpital Necker, Paris; <sup>8</sup>Institut de Veille Sanitaire, Saint-Maurice; <sup>9</sup>Service de Médecine du Travail, Hôpital Raymond Poincaré, Garches; and <sup>10</sup>Laboratoire de Bactériologie-Virologie, Hôpital Aulnay, Bobigny, France; <sup>11</sup>Istituto Nazionale per lo Studio delle "L. Spallanzani," Rome, Italy; <sup>12</sup>Servicio de Medicina Preventiva y Epidemiología, Hospital Vall d'Hebron, Barcelona, Spain; <sup>13</sup>Referenzlabor für blutübertragbare Infektionen im Gesundheitsbereich, Division of Infectious Disease and Hospital Epidemiology, University Hospital, Zurich, Switzerland; and <sup>14</sup>IV and STI Division Communicable Disease Surveillance Centre, London, United Kingdom

**Background.** Additional studies are required to identify risk factors for hepatitis C virus (HCV) transmission to health care workers after occupational exposure to HCV.

**Methods.** We conducted a matched case-control study in 5 European countries from 1 January 1991 through 31 December 2002. Case patients were health care workers who experienced seroconversion after percutaneous or mucocutaneous exposure to HCV. Control subjects were HCV-exposed health care workers who did not experience seroconversion and were matched with case patients for center and period of exposure.

**Results.** Sixty case patients and 204 control subjects were included in the study. All case patients were exposed to HCV-infected fluids through percutaneous injuries. The 37 case patients for whom information was available were exposed to viremic source patients. As risk factors for HCV infection, multivariate analysis identified needle placement in a source patient's vein or artery (odds ratio [OR], 100.1; 95% confidence interval [CI], 7.3-1365.7), deep injury (OR, 135.2; 95% CI, 7.1-3417.2), and sex of the health care worker (OR for male vs. female, 3.1; 95% CI, 1.0-10.0). Source patient HCV load was not introduced in the multivariate model. In unmatched univariate analysis, the risk of HCV transmission increased 11-fold for health care workers exposed to source patients with a viral load >6 log<sub>10</sub> copies/mL (95% CI, 1.1-114.1), compared with exposures to source patients with a viral load ≤4 log<sub>10</sub> copies/mL.

**Conclusion.** In this study, HCV occupational transmission was found to occur after percutaneous exposures. The risk of HCV transmission after percutaneous exposure increased with deep injuries and procedures involving hollow-bore needle placement in the source patient's vein or artery. These results highlight the need for widespread adoption of needlestick-prevention devices in health care settings, together with other preventive measures.

## Risk factors for acquiring an occupational infection following a percutaneous exposure

| Risk factor                          | Added risk of acquiring HIV (adj. OR, CI 95%) <sup>1</sup> | Added risk of acquiring HCV (adj. OR, CI 95%) <sup>2</sup> |
|--------------------------------------|--|--|
| Deep injury                          | 15,34 (6,01-41,05)   | 155,2 (7,1-3417,2)   |
| Visible blood on the device          | 6,18 (2,15-20,74)  |  |
| Device posed in vein or artery       | 4,33 (1,71-11,89)  | 100,1 (7,3-1365,7)   |
| Source patient with terminal illness | 5,60 (1,99-16,06)  |  |
| Viremia > 6 log <sub>10</sub> cp/mL  |  | 11,0 (1,1-114,1)   |
| Zidovudine PEP                       | 0,19 (0.06-0,52)   |  |
| Male healthcare worker               |  | 3,1 (1,0-10,0)   |

<sup>1</sup> Cardo DM , Culver DH, Ciesielski CA et al. N Engl J Med 1997;337:1485-90

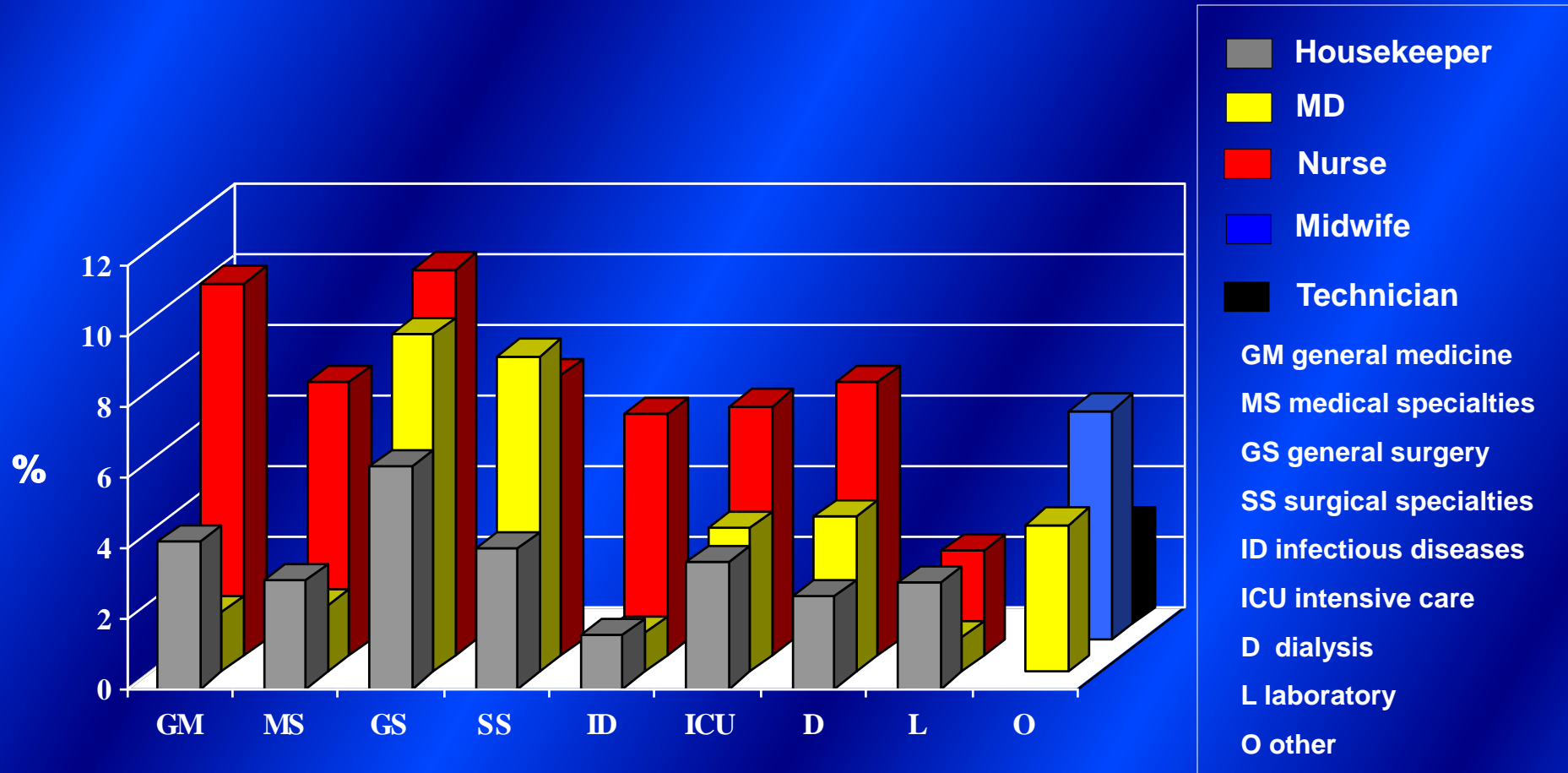
<sup>2</sup> Yazdanpanah Y , De Carli G, Miguere B et al. CI Infect Dis 2005; 41:1423-30.



Puro V, De Carli G, Petrosillo N, Ippolito G and the SIROH Group. Infect Control Hosp Epidemiol 2001; 22:206-10.

# Percutaneous exposures per 100 full-time equivalents, by job category and area

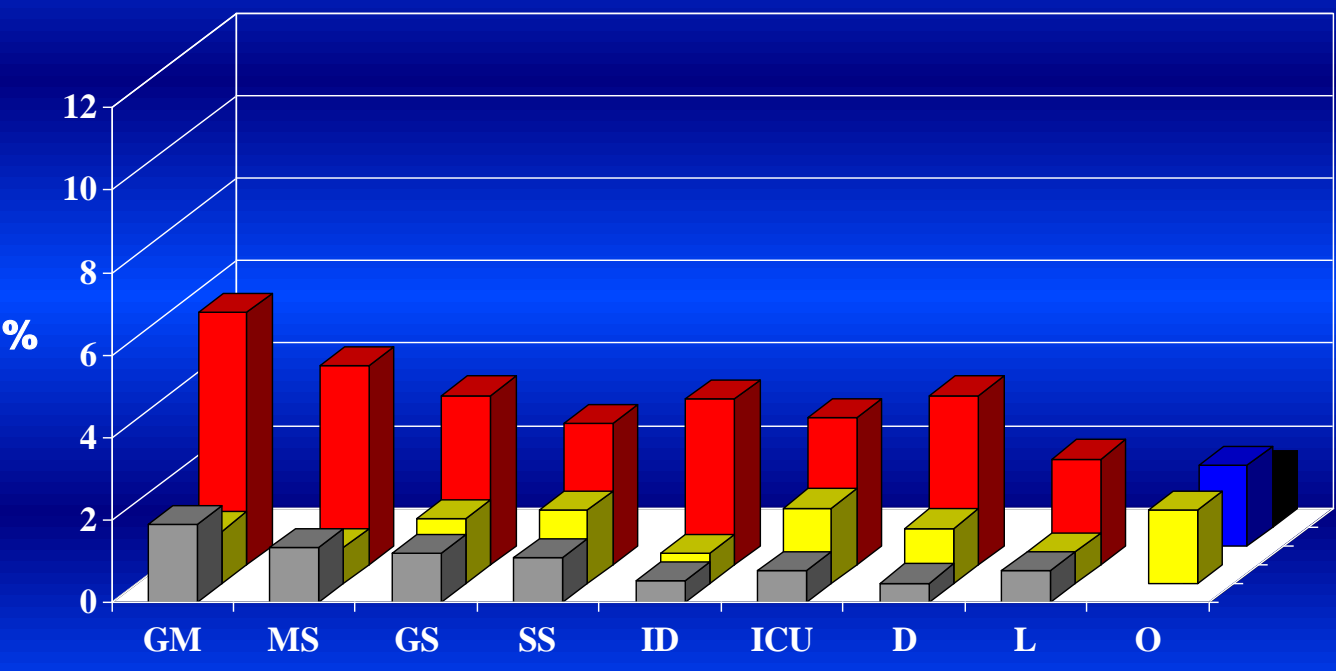
## SIROH, 18 hospitals, 1994-98



Map of risk

Puro V, De Carli G, Petrosillo N, Ippolito G and the SIROH Group. Infect Control Hosp Epidemiol 2001; 22:206-10.

# High-risk percutaneous exposures per 100 FTE, by job category and area SIROH, 18 hospitals, 1994-98



- Housekeeper
- MD
- Nurse
- Midwife
- Technician
- GM general medicine
- MS medical specialties
- GS general surgery
- SS surgical specialties
- ID infectious diseases
- ICU intensive care
- D dialysis

Quantification of

Characterization of

Map of risk

## Risk Assessment

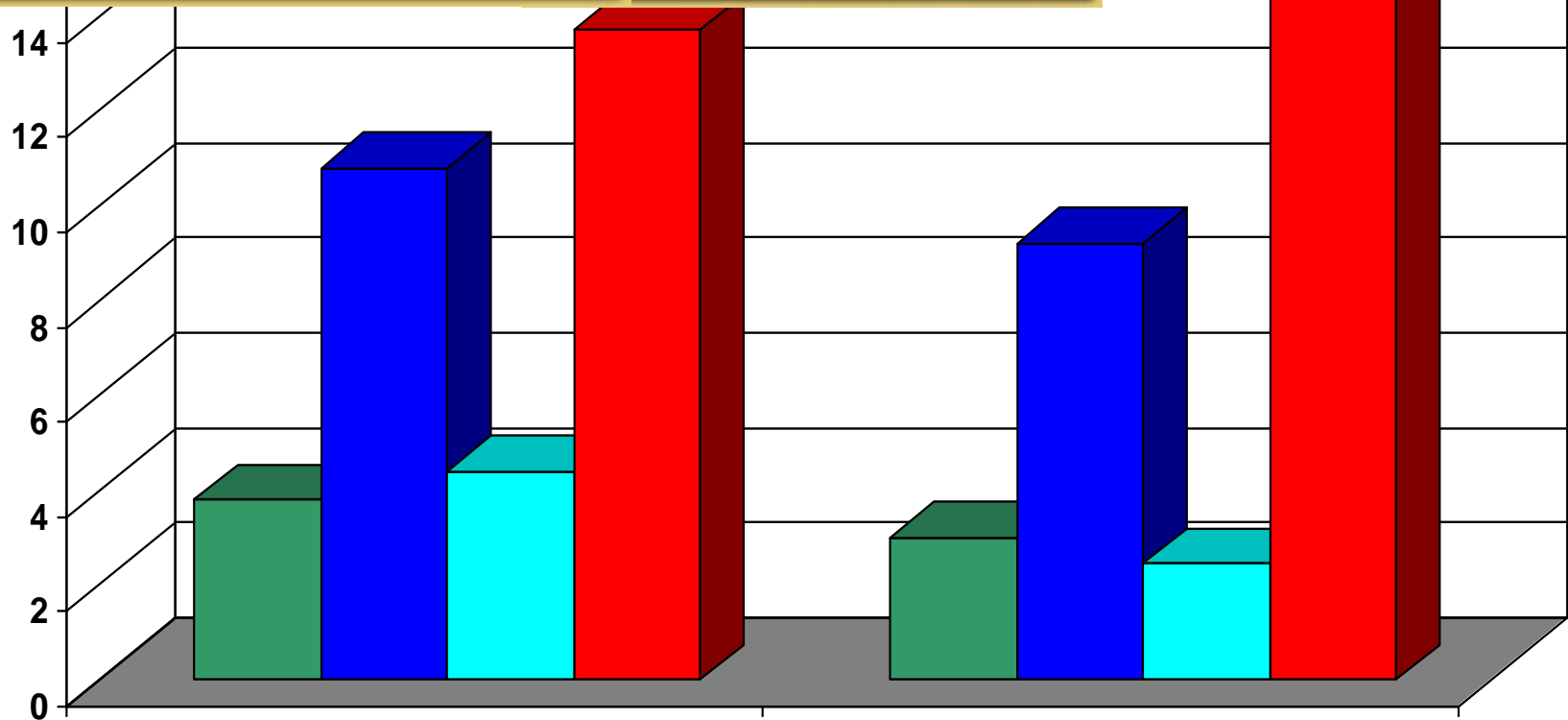
# Device-specific injury rates per 100,000 used devices (19 hospitals - SIROH)

Banning to recapping

Personal Protective Equipment

*Sharps containers*

Education & training



■ Disposable syringe      ■ Winged needle  
■ VTPS straight needle      ■ IV catheter

SIROH, internal report, December 2000



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ORIGINAL ARTICLES  
Euroroundup

EUROPEAN RECOMMENDATIONS FOR THE MANAGEMENT OF HEALTHCARE WORKERS OCCUPATIONALLY EXPOSED TO HEPATITIS B VIRUS AND HEPATITIS C VIRUS

V Puro<sup>1</sup>, G De Carli<sup>1</sup>, S Cicalini<sup>1</sup>, F Soldani<sup>1</sup>, U Balslev<sup>2</sup>, J Begovac<sup>3</sup>, L Boaventura<sup>4</sup>, M Campins Martí<sup>5</sup>, MJ Hernández Navarrete<sup>6</sup>, R Kammerlander<sup>7</sup>, C Larsen<sup>8</sup>, F Lot<sup>9</sup>, S Lunding<sup>9</sup>, U Marcus<sup>10</sup>, L Payne<sup>11</sup>, AA Pereira<sup>4</sup>, T Thomas<sup>11</sup>, G Ippolito<sup>1</sup>

Exposure prevention is the primary strategy to reduce the risk of occupational bloodborne pathogen infections in healthcare workers (HCW). HCWs should be made aware of the medicolegal and clinical relevance of reporting an exposure, and have ready access to expert consultants to receive appropriate counselling, treatment and follow-up.

Vaccination against hepatitis B virus (HBV), and demonstration of immunisation before employment are strongly recommended. HCWs with postvaccinal anti-HBs levels, 1-2 months after vaccine completion,

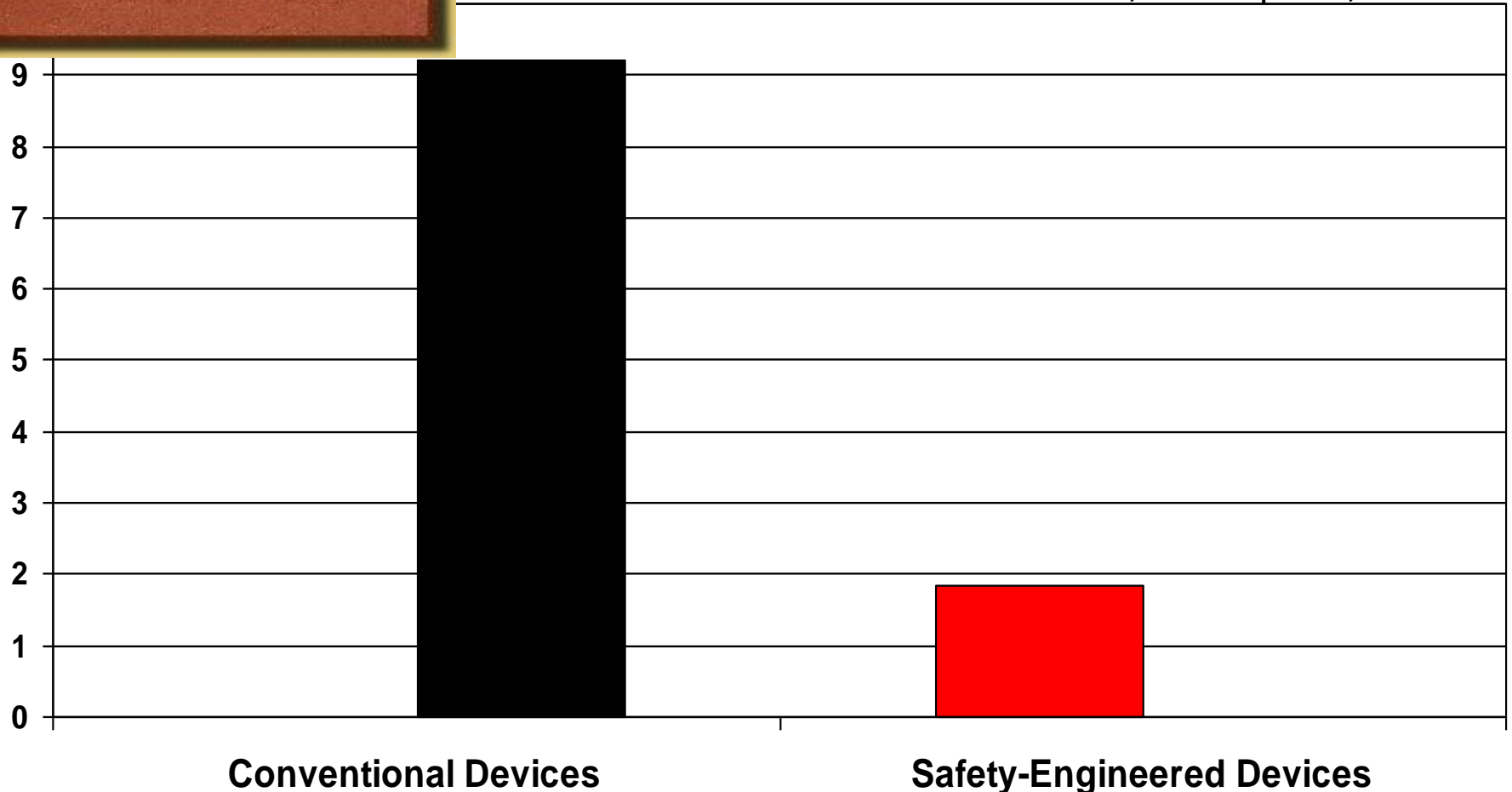
Introduction

Bloodborne pathogens such as hepatitis B (HBV) and C virus (HCV) represent an important hazard for healthcare workers (HCWs) [1]. In the general population, HCV prevalence varies geographically from about 0.5% in northern countries to 2% in Mediterranean countries, with some 5 million chronic carriers estimated in Europe; while HBV prevalence ranges from 0.3% to 3%. The World Health Organization (WHO) estimates that each year in Europe 304 000 HCWs are exposed to at least one percutaneous injury with a sharp



**Injury rates per 100,000 devices used to draw blood:  
Safety-Engineered Devices (n=3,300,000) vs.  
Conventional Devices (n=3,600,000)**  
(IV catheters, blood-collection winged-steel needles,  
arterial blood gas syringes)  
SIROH, 16 hospitals, 2003-2006

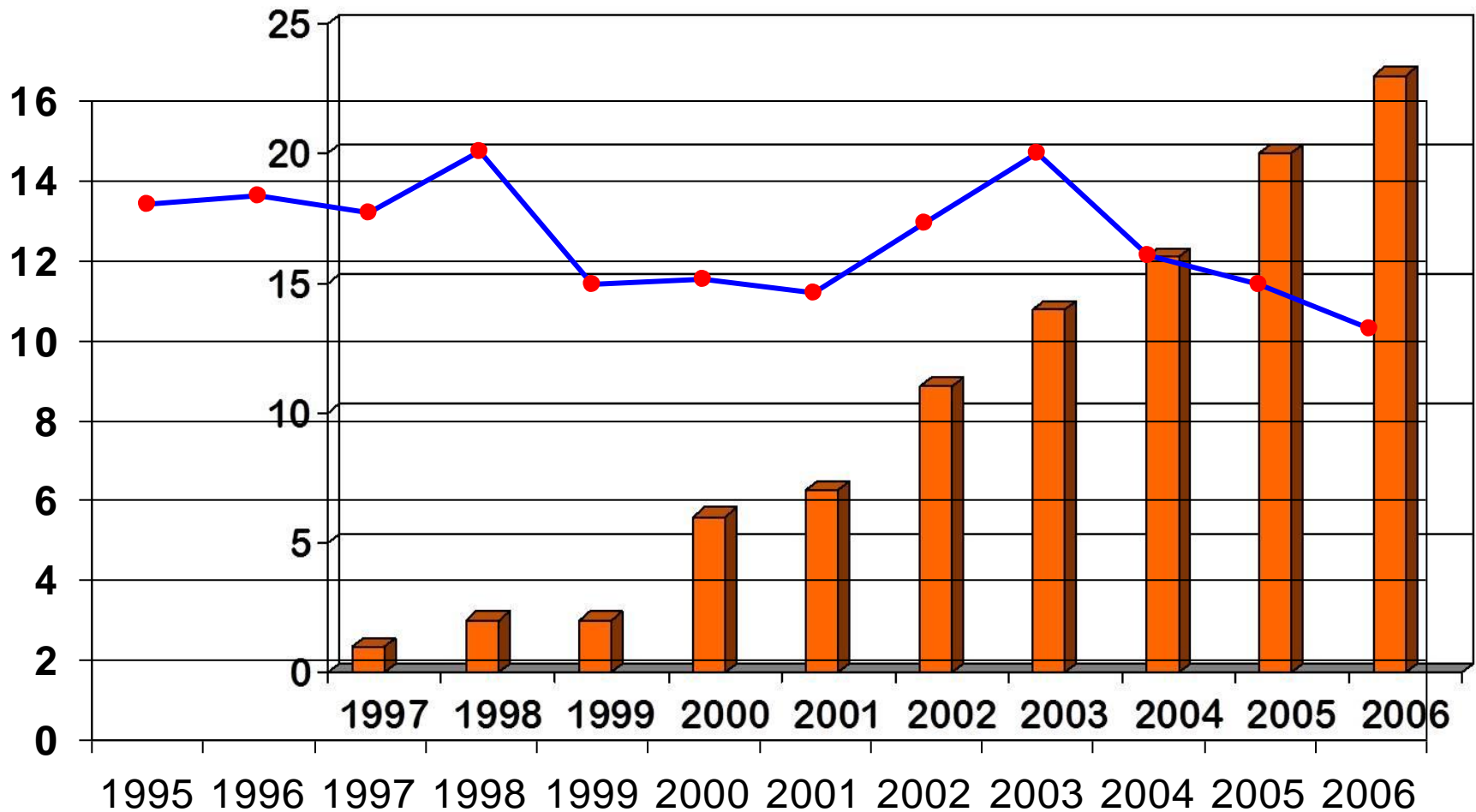
*Safety-engineered devices*



De Carli G, Puro V, Jagger J. Needlestick-prevention devices: we should already be there.  
J Hosp Infect 2009;71:183-4.

# Percutaneous exposures injury rate per 100 occupied beds and hospitals adopting safety-engineered devices- SIROH

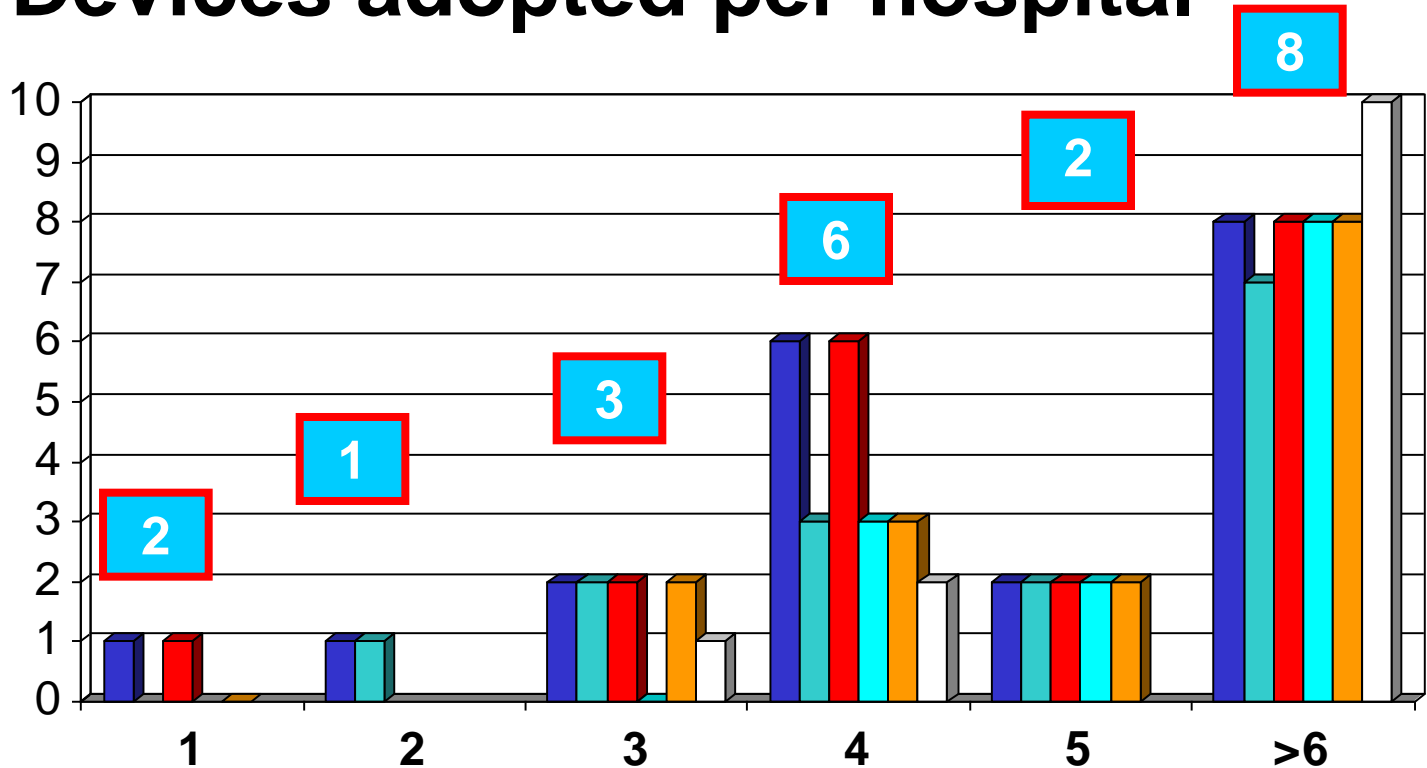
*Safety-engineered devices*



## Number & type of Safety-Engineered Devices adopted per hospital

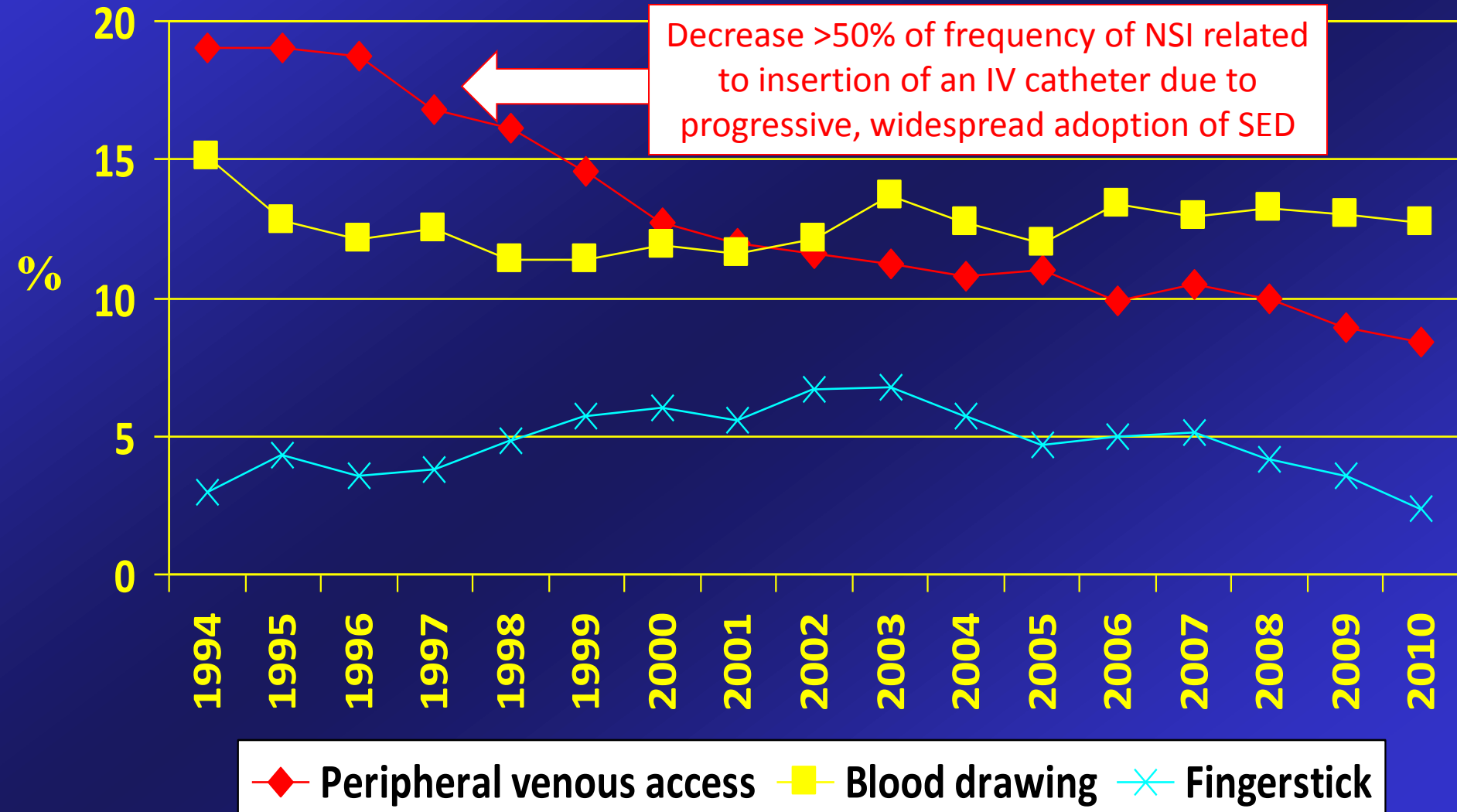


# SED



- VTPS winged needle
- VPTS straight needle
- IV catheter
- ABG syringe
- Lancet
- Other

# Percutaneous exposures - involved procedure in 69,011 injuries – SIROH, 1994-2010





# US – Italy Comparison of Needlestick Rates per 100 Occupied Beds for Five Blood-Drawing Devices 1997-2007 Before and After Passage of the US Needle Safety Law

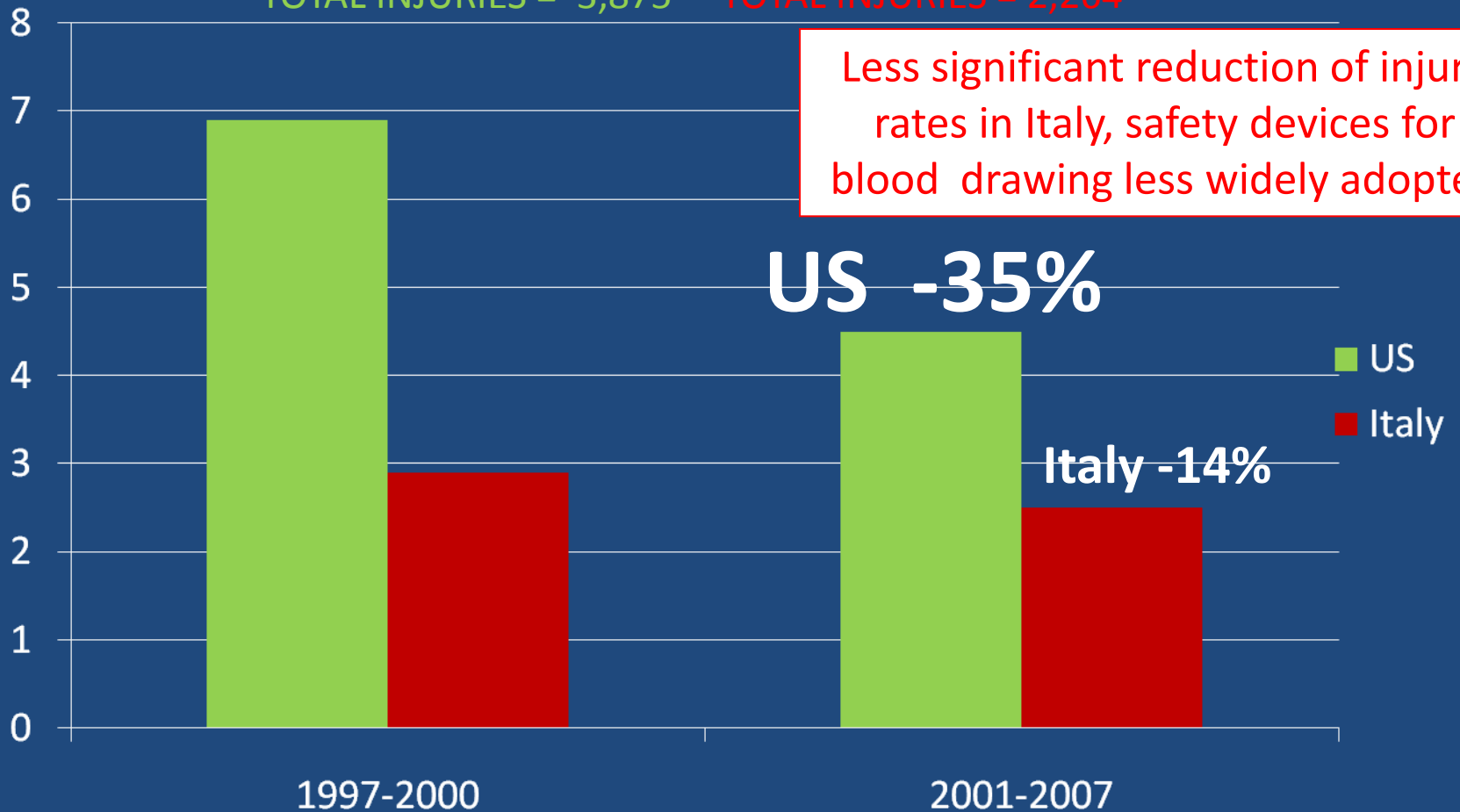
syringes (blood drawing), blood gas syringes, butterfly, phlebotomy needles, lancets

TOTAL BEDS US = 67,573

TOTAL BEDS ITALY = 85,409

TOTAL INJURIES = 3,875

TOTAL INJURIES = 2,264



# Risk Assessment: the integrated approach

Polato R et al. G Ital Med Lav Erg 2010; 32(3): 240-4.

<http://gimle.fsm.it>

Consensus Group  
2010

Pericolo BASSO es.uffici  
MODERATO es.pulizie  
ALTO es.degenze  
ELEVATO es.lab BSL3/4

Categorie di procedure classificate in relazione al rischio di trasmissione emotrasmesse

Applicazione integrale di PREREQUISITI quali:

- idonee caratteristiche edilizie
- formazione ed informazione
- dispositivi di sicurezza
- procedure IRB, contatti stretti, precauzioni standard e misure di isolamento
- collegamento con CIO – org. di gest. operatori sieropositivi
- prontuario e gestione DPI / DPC
- misure per lavoratrici madri
- procedure rifiuti,
- procedure MOMG
- registro esposti – gestione infortuni ( pre e post VDR)

Non applicazione dei PREREQUISITI

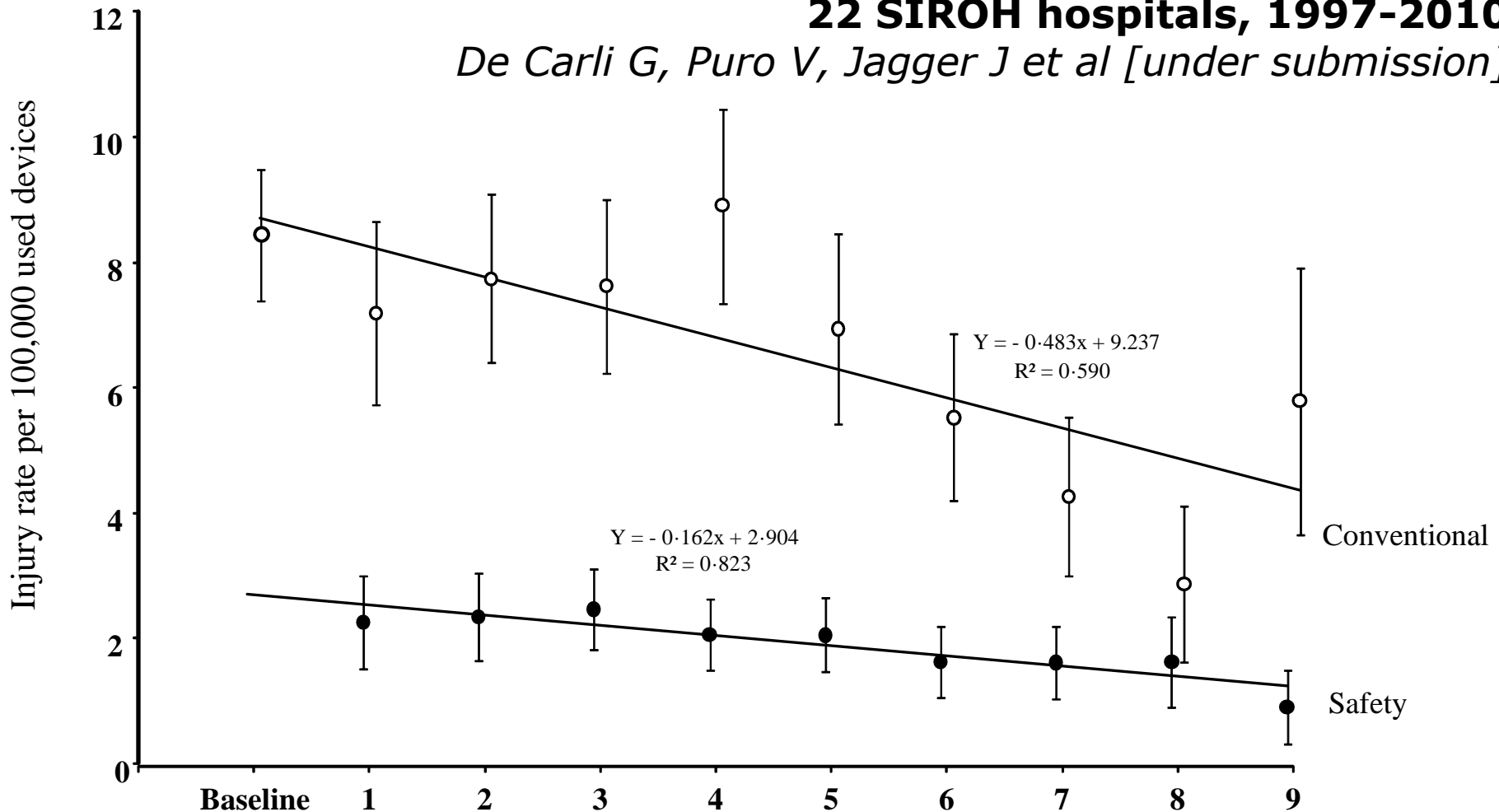
RISCHIO  
BASSO

RISCHIO  
SIGNIFICATIVO

# Risk Assessment: the integrated approach

## Efficacy of safety blood collection devices 22 SIROH hospitals, 1997-2010

*De Carli G, Puro V, Jagger J et al [under submission]*



| Proportion of safety devices use | 56.1% | 52.2% | 60.1% | 64.5% | 66.4% | 62.2% | 64.2% | 63.6% | 67.9% |
|----------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
|----------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|



# Health technology assessment of safety-engineered, needlestick-prevention devices to enhance safety of health care workers

## RICERCA FINALIZZATA 2009

Ministero della Salute – Direzione Generale della Ricerca Scientifica e Tecnologica

RF-2009-1530527

***Nicolotti N\*, De Carli G\*, La Torre G<sup>^</sup>, Saulle R<sup>^</sup>,  
Mannocci A<sup>^</sup>, Boccia A<sup>^</sup>, Ippolito G\*, Puro V\****

\* Department of Epidemiology, L. Spallanzani National Institute of Infectious Diseases

<sup>^</sup> Department of Public Health and Infectious Diseases

**Patients' safety**



# The Sharps Safety in the European Union Group (Rome, 24-26 March 2011)



The SSEU Group was formed to gather expertise and develop practical recommendations and tools to help in the implementation of the Directive

## Clause 9: Reporting

1. This includes the revision of the reporting procedures in place with health and safety representatives and/or appropriate employers/workers representatives. Reporting mechanisms should include local, national and European-wide systems;

# the brick wall of safety

## Sharps Safety

(safest possible working environment)

Safety Devices

Work organization

Personal Protective Equipment

Recording  
Reporting

ion  
& FU

Sharps  
Containers  
Informa

No u



Risk Assessment



**Istituto Nazionale per le Malattie Infettive**

**[www.inmi.it](http://www.inmi.it)**

**SIROH**

**Studio Italiano Rischio Occupazionale da HIV**

**[siroh@inmi.it](mailto:siroh@inmi.it)**

**IRAPEP**

**Italian Registry of Antiretroviral Prophylaxis**

**[irapep@inmi.it](mailto:irapep@inmi.it)**