Safe Donors for Safe Blood

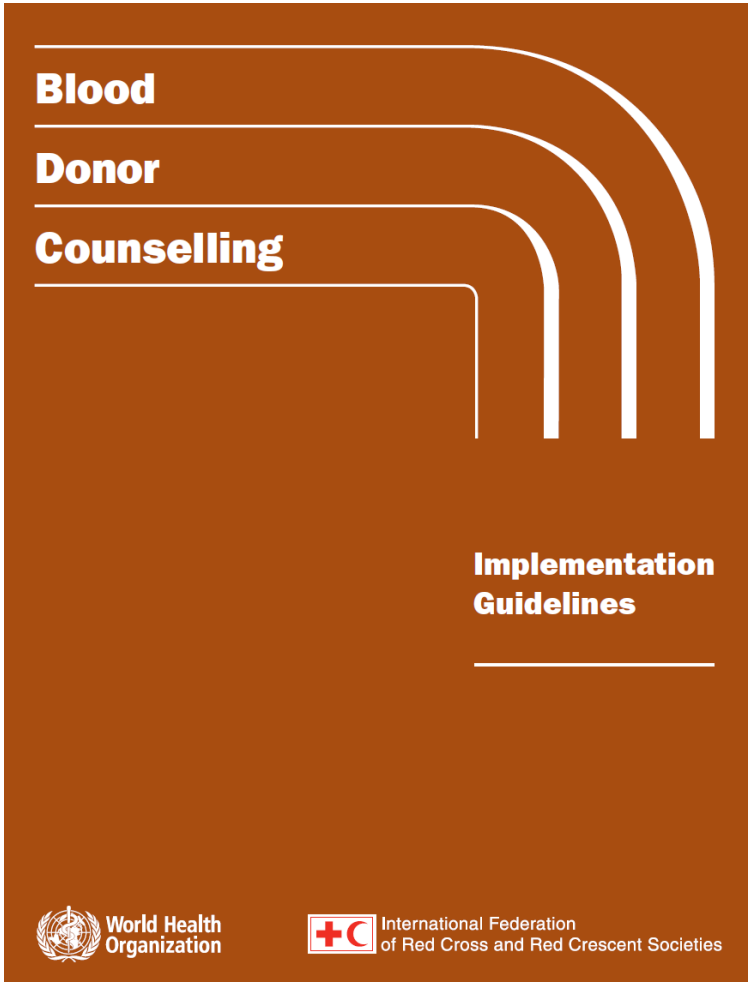
Erhard Seifried, M.D., Ph.D.

Medical Director & CEO
Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Qualification of New Donors Before Donation: Pros & Cons
Workshop Rome, Italy February 3rd, 2014

From the WHO / IFRC Implementation Guidelines for Blood Donor Counselling 2013

- Pre-donation information and counselling are linked to the process of donor selection in which each individual's suitability to donate is carefully assessed against a set of criteria related to their medical history and risk for TTI. This is followed by a basic health check to:
  - Ascertain that they are healthy, suitable to give blood and **will not be harmed by blood donation**; and
  - Avoid collecting blood from individuals who may be **unsuitable due to the risk of TTI or other health factors that may harm patients**.



Blood Donations Worldwide

- **„It is estimated that more than 85 million blood donations are given every year. About 35% of these are donated in developing and transitional countries where nearly 75% of the world's population lives. The average blood donation rate is more than 16 times higher in developed countries than in developing countries."**

World Health Organization (WHO), 2009

Family, Replacement and Paid Donors

- „Family or replacement donors and paid donors still remain a significant source of blood for transfusion in many developing and transitional countries.
- Adequate stocks of safe blood can only be assured by regular donation by voluntary unpaid blood donors, because the prevalence of bloodborne infections is lowest among these donors.
- […] But in 42 countries, less than 25% of blood supplies come from voluntary unpaid donors.“

World Health Organization (WHO), 2009

The Donor Environment … Determines the Individual Risk

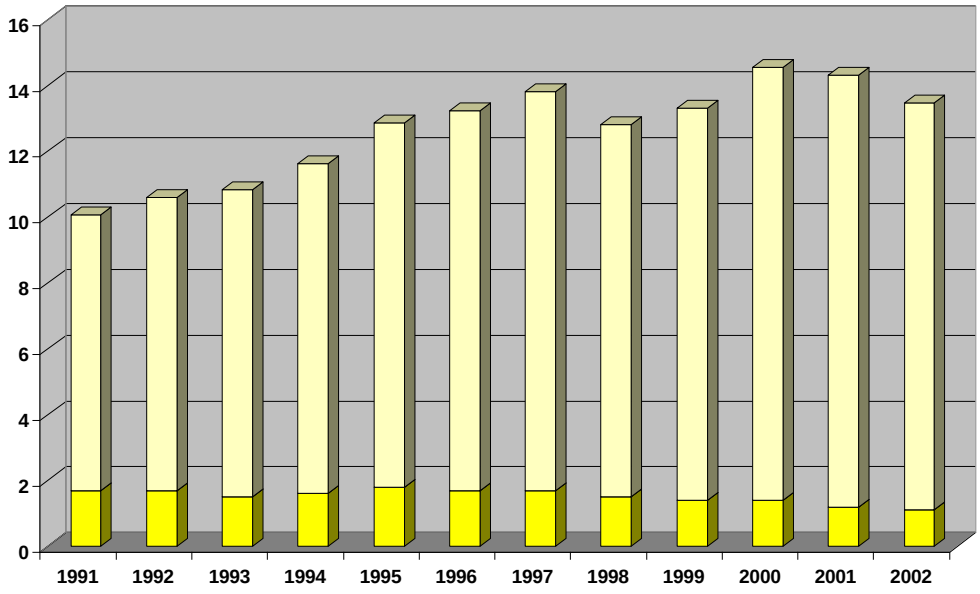
- A: smoker vs. non-smoker
- B: travelling: regional vs. world wide
- B: vegan vs. “carnivore“
- B: native vs. immigrant
- B: healthy vs. not healthy
- B: male vs. female
- B: old vs. young
- B: voluntary unpaid vs. remunerated
- C: urban vs. rural environment
- C: single vs. in stable relationship
- C: promiscuous vs. stable relationship
- C: surgical procedures vs. medical drugs
- C: (chronic) infection vs. no infection
- C: social background: rich vs. poor
- C: higher education vs. lower education
- C: civilian vs. soldier
- C: history of pregnancy vs. hormonal contraception
- C: modern (piercing, tattoo, etc.) vs. old-fashioned
- C: Eastern (Germany) vs. Western (Germany)

Photo: Korean Red Cross Blood Services

Institute for Transfusion Medicine and Immunohematology
University Clinics Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Blood Donor Selection

- Social and political climate
- Selective donor attraction
- Donor information
- Targeted motivation
- No remuneration
- No donations from donors in affected areas
- No donations from donors under health risks
- Multiple donors preferred
- Stuctured history
- Medical interview
- Medical examination
- Self exclusion of donors

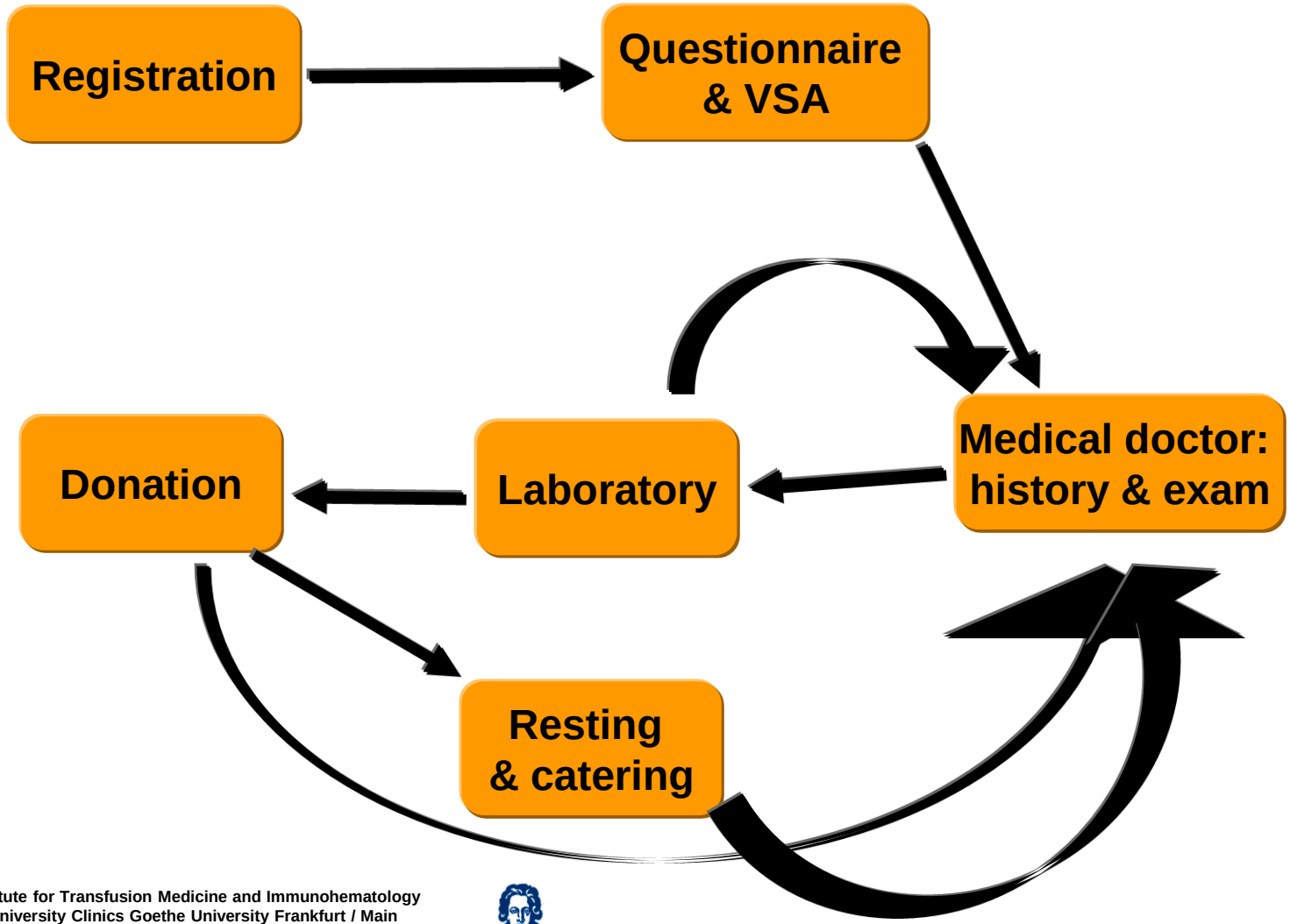


= Donor exclusion by history & exam

= Donor exclusion by lab testing

Institute for Transfusion Medicine and Immunohematology
University Clinics Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Donation Procedure: Following the Donor



The Blood Donor Questionnaire

German Red Cross
Blood Transfusion Service Baden-Württemberg – Hessen gGmbH

Blood Donor Questionnaire

Mr./Ms./Mrs. First Name _____ Surname _____ Title ____

Street/House number _____

Postal code _____ City _____

Date of birth _____ Maiden name _____

Phone _____ E-mail _____

Family doctor/GP _____

First-time donor ☐ male ☐ female ☐ Address Check _____

Change of Adress ☐ Donor ID-card lost ☐ Donor ID-card forgotten ☐

Declaration of consent: I hereby consent to give blood and to my blood being used for medical, scientific and pharmaceutical purposes. I have read, understood and taken note of the information "What blood donors need to know before giving blood" and in the confidential self-exclusion form. I confirm that I do not have any of the risk factors and that I am not a member of any of the risk groups. As viruses can be transmitted by blood, I agree to my blood being tested accordingly, in particular for AIDS and hepatitis, and I will be informed of any results therefrom or from scientific examinations that may be relevant to my health. The results may also be sent to a doctor of my choice. I have answered all questions on the reverse as truthfully as possible. I have been informed of the risks and side effects of giving blood, such as bruising, inflammation of the needle insertion site, circulatory problems, iron deficiency and, very rarely, thrombosis or nerve damage through the venepuncture procedure. Permanent damage to health in rare instances cannot be ruled out. I was able to discuss all issues satisfactorily with a doctor. I am aware that I may not operate a vehicle for at least 30 minutes after giving blood and that I must observe certain restrictions at work (e. g. driving a vehicle with passengers) and in my free time (e. g. sporting activities).

Data protection: I have been informed that giving blood means that my personal details (e. g. name, address, telephone number, e-mail-address, medical test results) will be recorded, processed and used according to blood transfusion rules. I am aware that if I am suspected of carrying a particular infection, this will have to be reported to the appropriate health authorities in accordance with the Infektionsschutzgesetz (Infection Protection Act).

I would like to receive information about future blood donation dates by mail, e-mail or phone ☐ yes ☐ no

I agree to my contact details and donation frequency data being used for a donor recognition programme ☐ yes ☐ no

I have been fully informed regarding my blood donation and do not have any further questions.

Place, date _____ Donor's signature with first name and surname _____

Medical data – to be filled in by the examining doctor

Identitätskontrolle ☐ ja Temp. |_|_|,|_| ° C

RR |_|_|_|/|_|_|_| mmHg Puls |_|_|_| min⁻¹

Herz/ggf. Lunge _____ Gew. |_|_|_| kg

Spendefähig ☐ ja ☐ nein

Ausschluss ☐ ja, wegen _____

Rückstellung ☐ ja, bis _____

Attest angefordert ☐ ja

Laboruntersuchung ☐ ja Eisenpräparat ausgegeben ☐ ja

Brief an HA ausgegeben ☐ ja Spenderaufklärung mündlich ☐ ja

Unterschrift Arzt / Ärztin

Herstellungs-Hinweis

Diagnostik-Hinweis

Vom Spender hier einkleben: Verwendungshinweis

Apply barcode sticker here: (Declaration of usability)

Labor	Entnahme	Abnahme
Identitätskontrolle ☐ ja	Identitätskontrolle ☐ ja	Laufzeit in Minuten
Hämoglobin |_|_|,|_| g/dl	Kontrolle Entnahmesystem ☐ ja	Spende ordnungsgemäß ☐ ja
	Kontrolle Röhrchen ☐ ja	Spenderzwischenfall ☐ ja
Unterschrift	Desinfektion und Punktion ordnungsgemäß ☐ ja	
	Unterschrift	Unterschrift

06.13/113078 E WZ

German Red Cross Blood Transfusion Service Baden-Württemberg – Hessen gGmbH

Please read carefully and mark the appropriate answer (version 12 as at 02/13)

1. Do you feel ill or are you currently excused from work by your doctor? ☐ Yes ☐ No
2. Have you ever been temporarily deferred from donating blood or have you ever suffered any complications while giving blood? ☐ Yes ☐ No
3. Have you given **blood, plasma or blood cells** in the last **8 weeks**? ☐ Yes ☐ No
4. Do you weigh more than **50 kg**? ☐ Yes ☐ No
5. Do you plan to pursue an **activity involving increased risk** in the next 12 hours (e.g. driving a vehicle with passengers, working where there is a risk of falling)? ☐ Yes ☐ No
6. Have you had a simple **infection** or undergone **dental treatment** in the last week? ☐ Yes ☐ No
7. In the last four weeks, have you suffered from **diarrhoea**, any type of **inflammation**, an **infection with fever** or have you come into **contact with persons with infectious diseases** (e.g. measles, mumps)? ☐ Yes ☐ No
8. Have you had an **operation** (including outpatient procedures), an **endoscopy** (e.g. gastroscopy, colonoscopy), a **biopsy, acupuncture** or **treatment involving a catheter** in the last four months? ☐ Yes ☐ No
9. Have you ever had a **blood transfusion** or have you received **plasma derivatives** or **immunoglobulins** such as Tetagam or Beriglobin in the last four months? ☐ Yes ☐ No
10. Have you had any **tattoos** or **body piercings**, or **injured yourself with any instrument** contaminated with blood (e.g. a needle) in the last four months, or have you had any **mucous membrane contact** with blood (e.g. in the eye)? ☐ Yes ☐ No
11. Have you come into **contact** with people infected with **hepatitis, HTLV** or **HIV** in the last four months or do you belong to a risk group (see confidential self-exclusion form)? ☐ Yes ☐ No
12. Have you taken any **medication** in the last four weeks or have you ever used the acne treatments Tigason or Neotigason? For women: Do you take the mini-pill? ☐ Yes ☐ No
    If so, what ? _____ When did you last take it? _____
13. Have you been **vaccinated** in the last four weeks or have you had an **anti-rabies vaccine** or animal **sera** in the last 12 months? ☐ Yes ☐ No
    If so, which vaccine? _____ When? _____
14. Are you or have you ever been addicted to **alcohol, drugs** or **medication**, or do you **abuse medication**? ☐ Yes ☐ No
15. Have you been to any **country outside Europe** in the last six months or have you ever had any unexplained **fevers** during or following a trip abroad? ☐ Yes ☐ No
    If so, when? _____ Where? _____
16. Have you ever had **malaria** or were you born or have you ever lived in a **malarial area**? ☐ Yes ☐ No
17. Do you have or have you ever had infectious jaundice (hepatitis)? ☐ Yes ☐ No
    If so, when? _____ What type? _____
18. Have you had or do you have any of the following **diseases**: osteomyelitis, tuberculosis, toxoplasmosis, typhoid/paratyphoid, rickettsial disease (Q fever, epidemic typhus), relapsing fever, babesiosis, brucellosis, leprosy, tularaemia, melioidosis, leishmaniasis, trypanosomiasis (Chagas' disease), HTLV, HIV, HBV or HCV infection, syphilis? ☐ Yes ☐ No
19. Do you or any of your blood relatives suffer from a contagious spongiform **encephalopathy** such as **Creutzfeld-Jakob Disease (CJD)** or its **Variant (vCJD)**, or has there ever been any suspicion that this is the case? ☐ Yes ☐ No
20. Have you ever received **hypophysis hormones** (e.g. growth hormones) or a **cornea, dura mater** (brain covering) or any other kind of human or animal **transplant or tissue**? ☐ Yes ☐ No
21. Did you live for a total of more than six months in the United Kingdom **(Great Britain and Northern Ireland)** between 1980 and 1996? Have you had an operation in the United Kingdom since 1 January 1980, or have you ever received **blood** or **blood components** there? ☐ Yes ☐ No
22. Do you suffer from, or have you ever suffered from, **heart, vascular** or **circulatory** diseases (e.g. high blood pressure) or **illnesses** involving the blood and lymph system, lungs (e.g. asthma), liver, kidneys, stomach/intestines, nervous system or skin, or epilepsy, rheumatic fever, diabetes or tumors (e.g. cancer)? Do you suffer from, an autoimmune disease or a sexually transmitted disease? ☐ Yes ☐ No
23. **For women only:** Are you **pregnant**, have you ever been **pregnant** or are you **breast-feeding**? ☐ Yes ☐ No
    If so, when last? _____

Thank you!

06.13/113078 E WZ

The Blood Donor Questionnaire

German Red Cross Blood Transfusion Service Baden-Württemberg – Hessen gGmbH

Please read carefully and mark the appropriate answer (version 12 as at 02/13)

1. Do you feel ill or are you currently excused from work by your doctor?	☐ Yes ☐ No
2. Have you ever been temporarily deferred from donating blood or have you ever suffered any complications while giving blood?	☐ Yes ☐ No
3. Have you given **blood, plasma or blood cells** in the last **8 weeks**?	☐ Yes ☐ No
4. Do you weigh more than **50 kg**?	☐ Yes ☐ No
5. Do you plan to pursue an **activity involving increased risk** in the next 12 hours (e.g. driving a vehicle with passengers, working where there is a risk of falling)?	☐ Yes ☐ No
6. Have you had a simple **infection** or undergone **dental treatment** in the last week?	☐ Yes ☐ No
7. In the last four weeks, have you suffered from **diarrhoea**, any type of **inflammation**, an **infection with fever** or have you come into **contact with persons with infectious diseases** (e.g. measles, mumps)?	☐ Yes ☐ No
8. Have you had an **operation** (including outpatient procedures), an **endoscopy** (e.g. gastroscopy, colonoscopy), a **biopsy, acupuncture** or **treatment involving a catheter** in the last four months?	☐ Yes ☐ No
9. Have you ever had a **blood transfusion** or have you received **plasma derivatives** or **immunoglobulins** such as Tetagam or Beriglobin in the last four months?	☐ Yes ☐ No
10. Have you had any **tattoos** or **body piercings**, or **injured yourself with any instrument** contaminated with blood (e.g. a needle) in the last four months, or have you had any **mucous membrane contact** with blood (e.g. in the eye)?	☐ Yes ☐ No
11. Have you come into **contact** with people infected with **hepatitis, HTLV** or **HIV** in the last four months or do you belong to a risk group (see confidential self-exclusion form)?	☐ Yes ☐ No
12. Have you taken any **medication** in the last four weeks or have you ever used the acne treatments Tigason or Neotigason? For women: Do you take the mini-pill? If so, what ? _____ When did you last take it? _____	☐ Yes ☐ No

The Blood Donor Questionnaire

13. Have you been **vaccinated** in the last four weeks or have you had an **anti-rabies vaccine** or animal **sera** in the last 12 months? ☐ Yes ☐ No
If so, which vaccine? _____ When? _____

14. Are you or have you ever been addicted to **alcohol, drugs** or **medication**, or do you **abuse medication**? ☐ Yes ☐ No

15. Have you been to any **country outside Europe** in the last six months or have you ever had any unexplained **fevers** during or following a trip abroad? ☐ Yes ☐ No
If so, when? _____ Where? _____

16. Have you ever had **malaria** or were you born or have you ever lived in a **malarial area**? ☐ Yes ☐ No

17. Do you have or have you ever had infectious jaundice (hepatitis)? ☐ Yes ☐ No
If so, when? _____ What type? _____

18. Have you had or do you have any of the following **diseases**: osteomyelitis, tuberculosis, toxoplasmosis, typhoid/paratyphoid, rickettsial disease (Q fever, epidemic typhus), relapsing fever, babesiosis, brucellosis, leprosy, tularaemia, melioidosis, leishmaniasis, trypanosomiasis (Chagas' disease), HTLV, HIV, HBV or HCV infection, syphilis? ☐ Yes ☐ No

19. Do you or any of your blood relatives suffer from a contagious spongiform **encephalopathy** such as **Creutzfeld-Jakob Disease (CJD)** or its **Variant (vCJD)**, or has there ever been any suspicion that this is the case? ☐ Yes ☐ No

20. Have you ever received **hypophysis hormones** (e.g. growth hormones) or a **cornea, dura mater** (brain covering) or any other kind of human or animal **transplant or tissue**? ☐ Yes ☐ No

21. Did you live for a total of more than six months in the United Kingdom **(Great Britain and Northern Ireland)** between 1980 and 1996? Have you had an operation in the United Kingdom since 1 January 1980, or have you ever received **blood** or **blood components** there? ☐ Yes ☐ No

22. Do you suffer from, or have you ever suffered from, **heart, vascular** or **circulatory** diseases (e.g. high blood pressure) or **illnesses** involving the blood and lymph system, lungs (e.g. asthma), liver, kidneys, stomach/intestines, nervous system or skin, or epilepsy, rheumatic fever, diabetes or tumors (e.g. cancer)? Do you suffer from, an autoimmune disease or a sexually transmitted disease? ☐ Yes ☐ No

23. **For women only:** Are you **pregnant**, have you ever been **pregnant** or are you **breast-feeding**? ☐ Yes ☐ No
If so, when last? _____

Thank you!

06.13/113078 E WZ

Confidential Self-Exclusion

The German Red Cross Blood Transfusion Service Baden-Württemberg - Hessen

Why do you have to decide if we can use your blood?

The German Red Cross Blood Transfusion Service Baden-Württemberg - Hessen tests all blood donations for AIDS (HIV) and Hepatitis (HBV, HCV). But because several weeks may elapse between the time a person becomes infected and is already contagious and when this can be detected by the tests, **it is highly important that blood from persons at risk of infection not be given to patients.**

If you elect to donate blood, in spite of belonging to any of the above risk groups, use the confidential self-exclusion form to make sure your blood will not be administered to a patient.

What do you have to do?

- Be sure you have this information sheet, the blood donor questionnaire and the blood donor information brochure before giving blood.
- Read the information carefully and decide if you belong to any of the risk groups listed on the back of this sheet.
- Follow the instructions on the reverse of this form to tell us if we can use your blood. To do so, please place the appropriate barcode sticker in the confidential area of the questionnaire.
- If you have any doubts about the safety of your blood after you have made your decision (e.g. after you have given blood), please talk to one of our physicians for a confidential consultation.
- The details you have provided about yourself are protected by doctor-patient confidentiality and will be handled anonymously.

Institute for Transfusion Medicine and Immunohematology
University Clinics Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Confidential self-exclusion

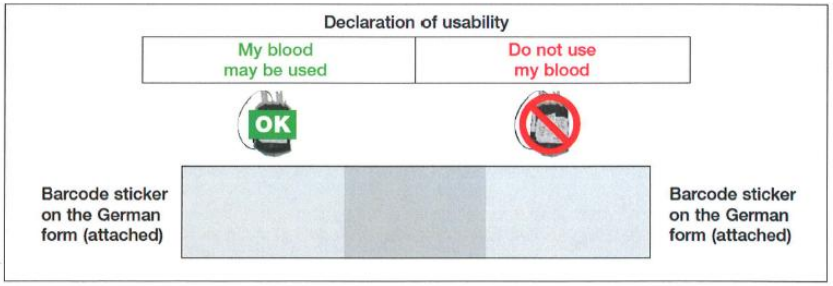
Special preventative measures are needed to avoid the spread of diseases like AIDS and hepatitis by blood transfusions. Help us to prevent the spread of these diseases.

People in any of the following risk groups may not donate blood or at least not allow their blood donation to be used for transfusion:

- anybody who has ever tested positive for **AIDS (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or HTLV** or who is suffering from any of these diseases,
- persons who have returned within the last four months from a region with comparatively high prevalence of these viruses and who spent more than 6 months there, e.g. **sub-saharan Africa, the Caribbean, Southeast Asia, South and Central America,**
- **men who have had sex with men,**
- male or female **prostitutes,**
- **anyone who has ever engaged in sex tourism or frequently changes sexual partners,**
- anyone who injects illicit **drugs**,
- **anyone with a bleeding disorder** (hemophilia),
- **former prison inmates** discharged within the last 4 months
- anyone who within the last 4 months has engaged in sexual activities with an individual from any of the above groups,
- anyone living in a domestic partnership with a hepatitis-infected individual and for 4 months thereafter,
- individuals who within the last 4 months have engaged in casual sexual encounters with partners of either gender, including so-called **"one-night stands".**

What do you have to do?

1. If you do not belong to any of the above groups with an increased risk for blood-borne viral diseases, choose the barcode sticker **"Mein Blut kann verwendet werden"** (my blood may be used) on the German form (attached).
   If you belong to one of the above groups or for some other reason believe, that your blood should not be used, choose the barcode sticker **"Mein Blut nicht verwenden"** (do not use my blood) on the German form (attached).



2. Remove the applicable barcode sticker and place it into the appropriate field ("Verwendungshinweis", declaration of usability) on the blood donor questionnaire.
3. Then, discreetly discard the German information sheet with the remaining sticker.

Thank you for acting responsibly!

PLEASE TURN OVER!

Confidential Self-Exclusion

Confidential self-exclusion

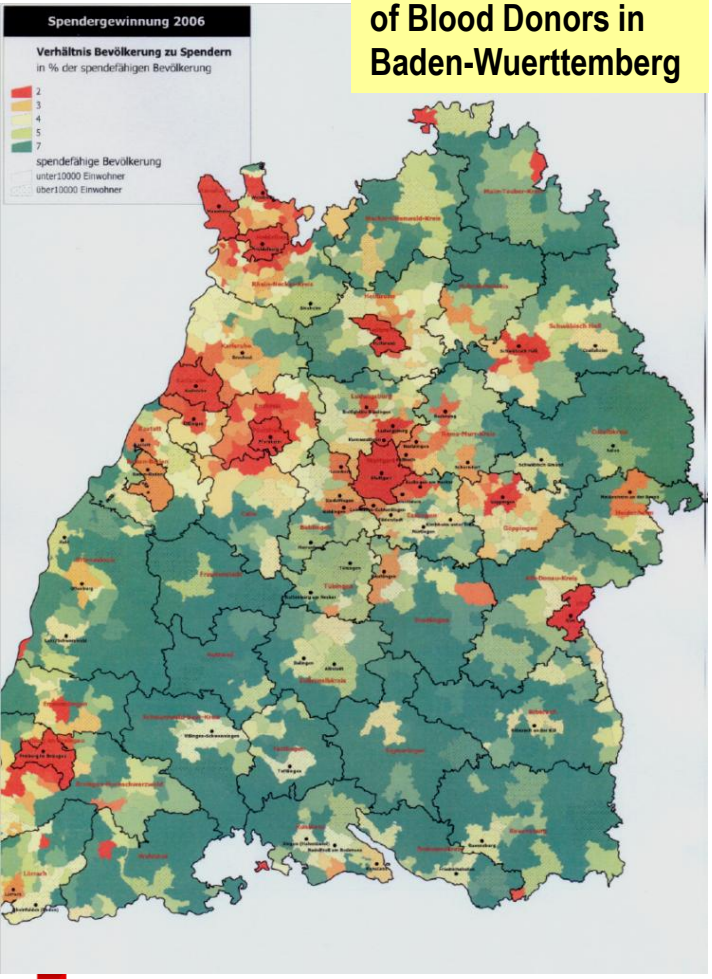
Special preventative measures are needed to avoid the spread of diseases like AIDS and hepatitis by blood transfusions. Help us to prevent the spread of these diseases.

People in any of the following risk groups may not donate blood or at least not allow their blood donation to be used for transfusion:

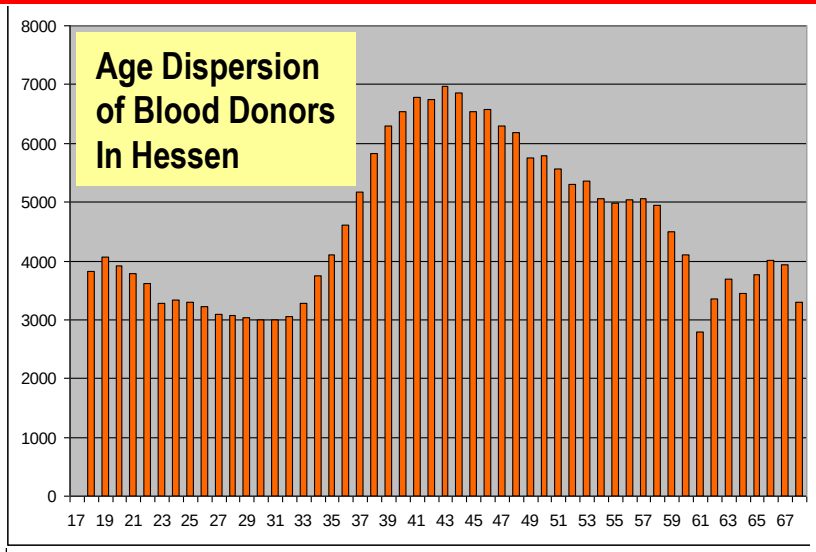
- anybody who has ever tested positive for **AIDS (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or HTLV** or who is suffering from any of these diseases,
- persons who have returned within the last four months from a region with comparatively high prevalence of these viruses and who spent more than 6 months there, e.g. **sub-saharan Africa, the Caribbean, Southeast Asia, South and Central America,**
- **men who have had sex with men,**
- male or female **prostitutes,**
- **anyone who has ever engaged in sex tourism or frequently changes sexual partners,**
- anyone who injects illicit **drugs**,
- **anyone with a bleeding disorder** (hemophilia),
- **former prison inmates** discharged within the last 4 months
- anyone who within the last 4 months has engaged in sexual activities with an individual from any of the above groups,
- anyone living in a domestic partnership with a hepatitis-infected individual and for 4 months thereafter,
- individuals who within the last 4 months have engaged in casual sexual encounters with partners of either gender, including so-called **"one-night stands".**

Blood Donors: Age and Regional Dispersion in Baden-Wuerttemberg & Hessen 2006 & 2007

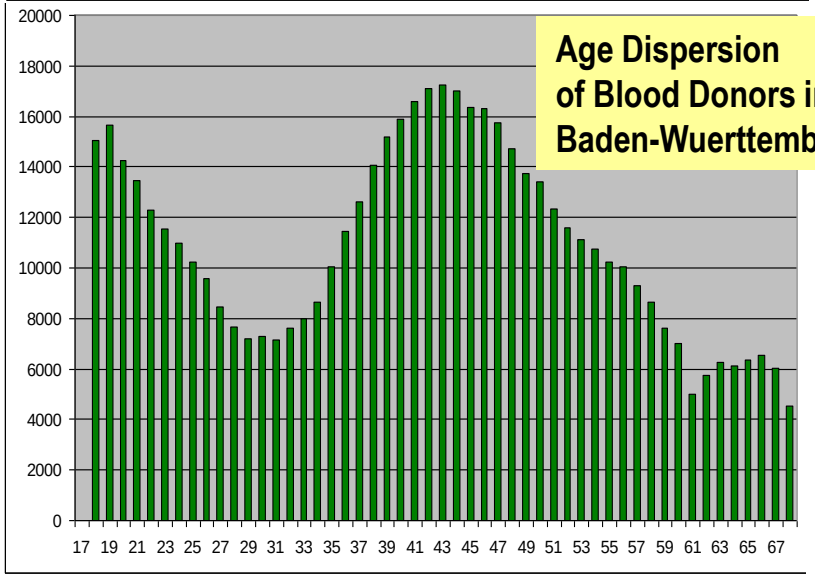
Regional Dispersion of Blood Donors in Baden-Wuerttemberg



Age Dispersion of Blood Donors In Hessen

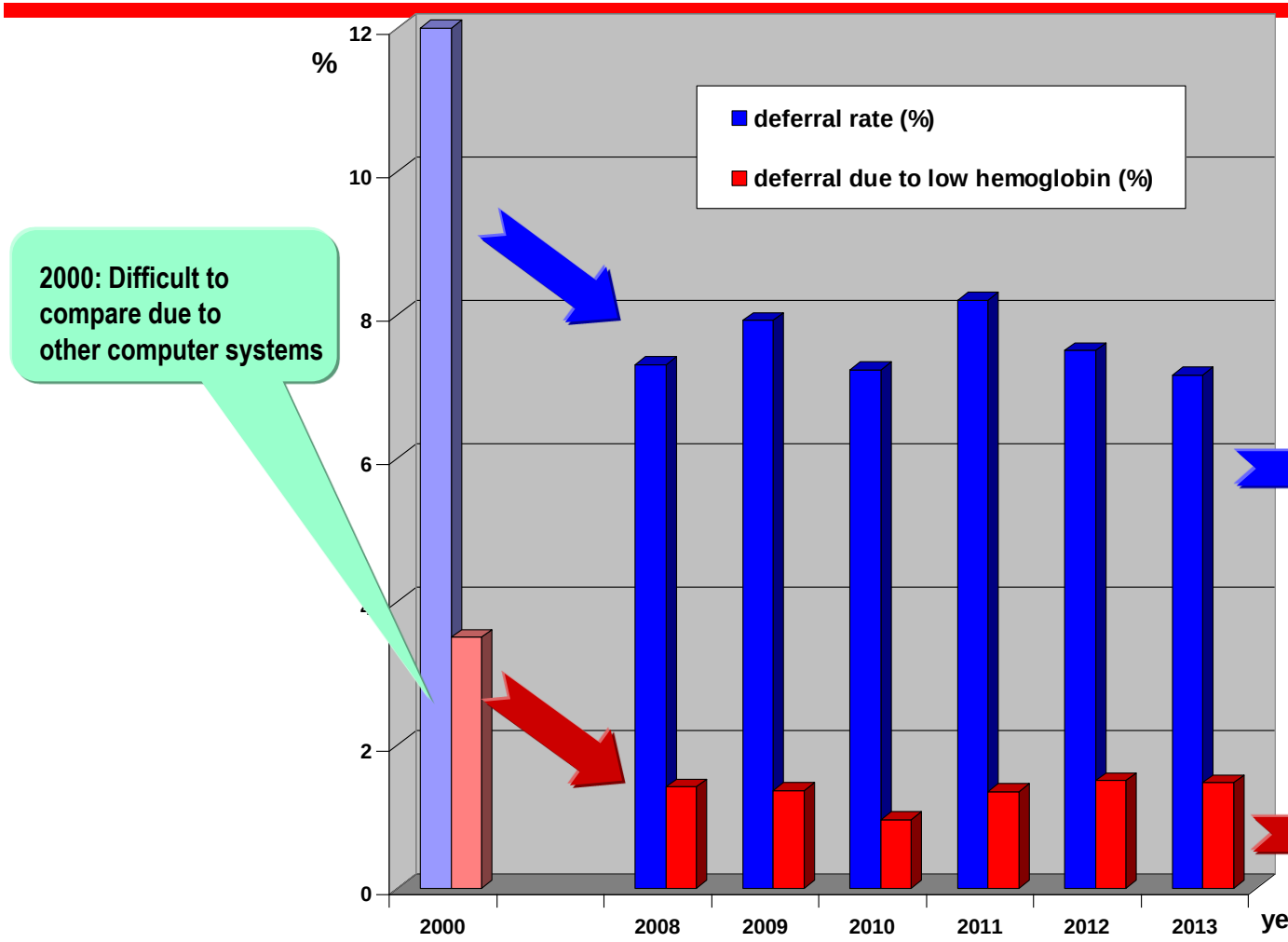


Age Dispersion of Blood Donors in Baden-Wuerttemberg



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Donor Deferral Rates: Overall Percentage and due to Low Hemoglobin Level



2000: Difficult to compare due to other computer systems

Consistent overall deferral rates over time and region (institutes): about 7.5%

Consitent deferral rates for low hemo-globin level: about 1.5%

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

The Global Problem of Donor Recruitment

Study Shows U.S. Blood Donor Pool Smaller Than Originally Estimated

The pool of eligible blood donors in the United States is substantially smaller than originally estimated, according to a study in the July issue of *TRANSFUSION*. The conventional method, based on age, estimates that 60.2 percent of the 294 million people in the U.S. are eligible to donate. However, the study suggests that the conventional method overestimates the national donor pool because it does not take into account the prevalence of other factors within the population that exclude people from donating. The exclusion-adjusted model developed in the study estimates that only 37.8 percent of the population is eligible to donate. According to the study, when using this model, voluntary blood donor rates are nearly 59 percent higher than present data suggests. In 1999, voluntary blood donation rates were reported as 80.8 units of blood per 1,000 eligible donors. By using the exclusion-adjusted model, the rate would be 128.8 units per 1,000 eligible donors.

AABB Weekly Report 13.07.2007

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Donor Safety

Incidences of Severe Donation Complications

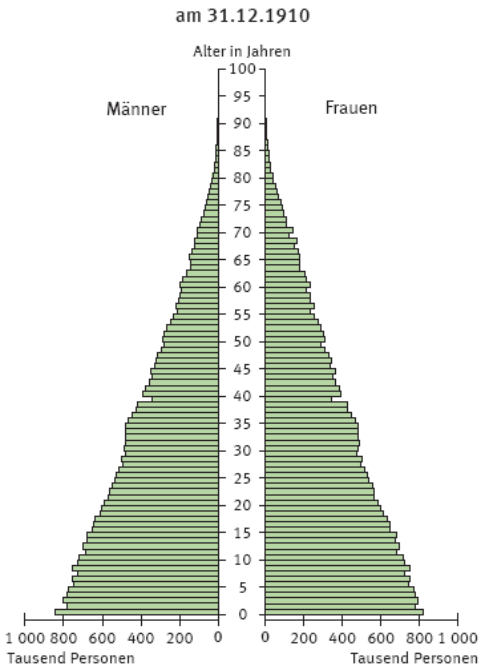
7/2009 - 6/2010, n=693

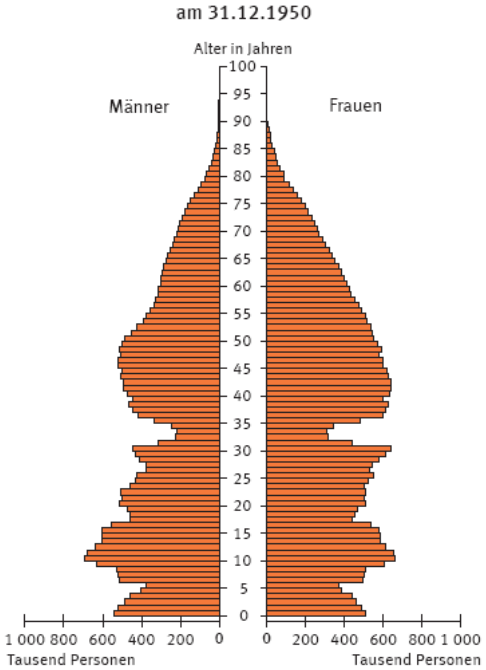
Donor group	Incidences	Donations	Risk
First time donor female	**119**	**33,444**	1 : 281
First time donor male	**78**	**31,000**	1 : 397
Frequent donor female	**281**	**302,486**	1 : 1076
Frequent donor male	**170**	**419,353**	1 : 2467

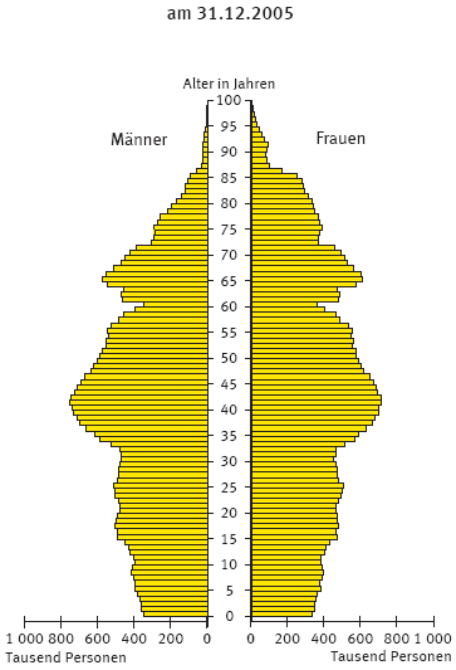
Source: GRC Blood Transfusion Service Baden-Wuerttemberg - Hessen

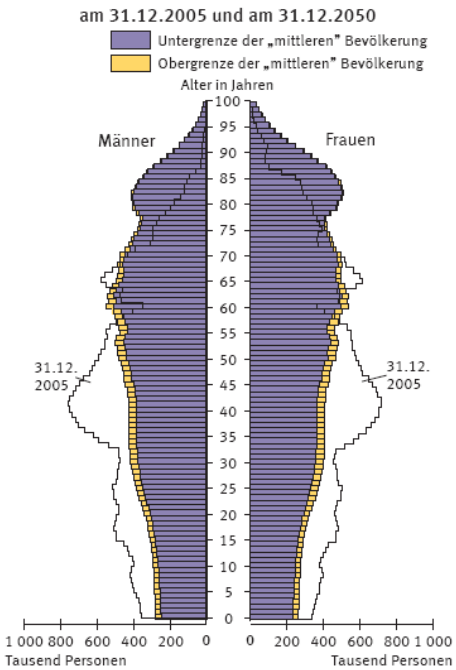
Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Demographics of the German Population
1910 – 2050 (prognosis)









1910 **1950** **2005** **2050**

(prognosis)

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Source: Statistisches Bundesamt, Wiesbaden, 2006

Increasing the donor age – Is this a safe strategy?

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

VoxSanguinis
The International Journal of Transfusion Medicine

ISBT International Society of Blood Transfusion

Vox Sanguinis (2012) **102**, 134–139

ORIGINAL PAPER

DOI: 10.1111/j.1423-0410.2011.01531.x

Safety and frequency of whole blood donations from elderly donors

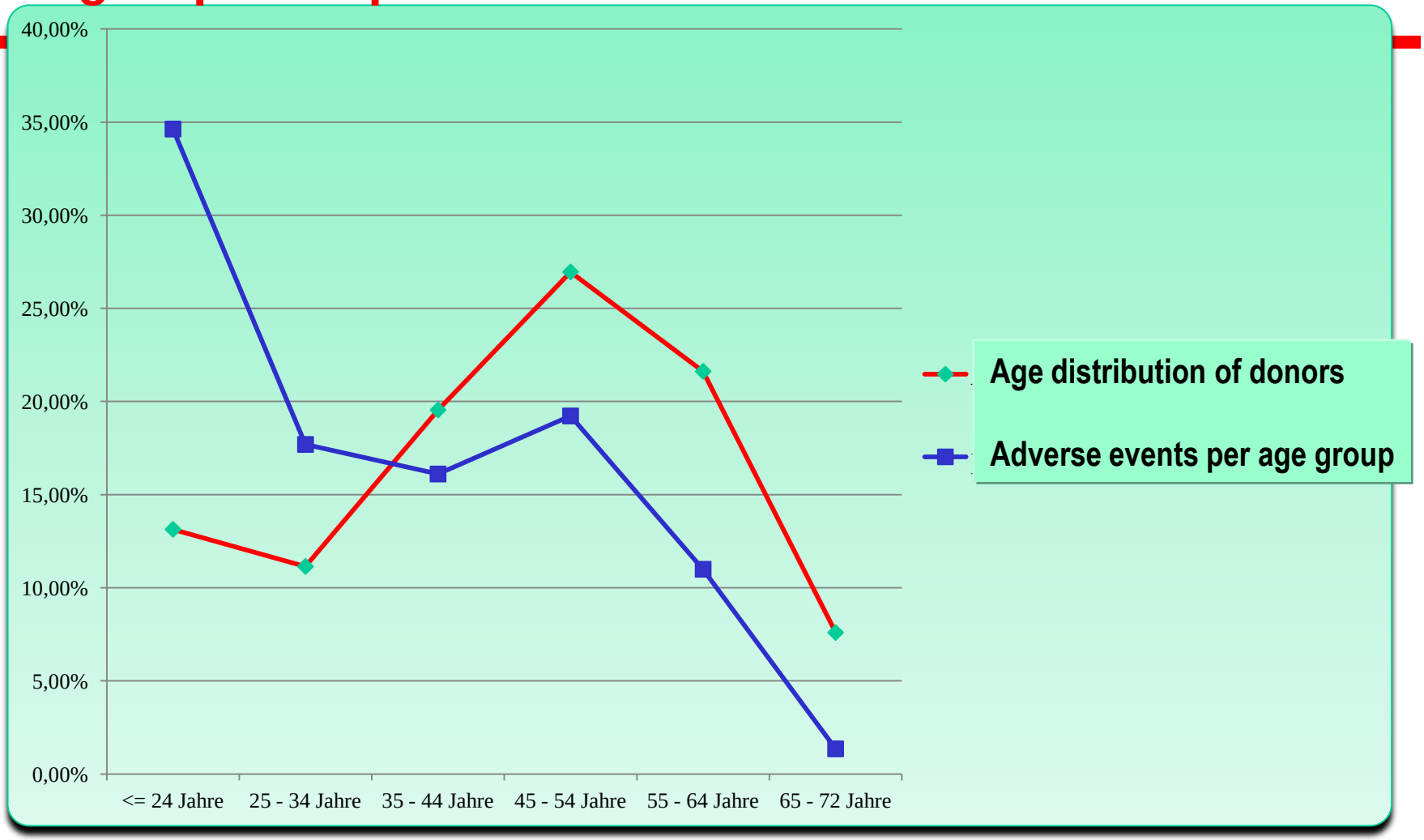
M. Müller-Steinhardt,[1,2] T. Müller-Kuller,[1,3] C. Weiß,[4] D. Menzel,[1,5] M. Wiesneth,[1,6] E. Seifried[1,3] & H. Klüter[1,2]

[1]*German Red Cross Blood Service Baden-Württemberg – Hessen, Mannheim, Germany*
[2]*Institute of Transfusion Medicine and Immunology, Medical Faculty Mannheim, University of Heidelberg, Mannheim, Germany*
[3]*Institute of Transfusion Medicine and Immunohaematology, Medical Faculty Johann Wolfgang Goethe University Frankfurt, Frankfurt, Germany*
[4]*Department of Medical Statistics and Biomathematics, Medical Faculty Mannheim, University of Heidelberg, Mannheim, Germany*
[5]*Institute of Clinical and Experimental Transfusion Medicine, Medical Faculty University of Tübingen, Tübingen, Germany*
[6]*Institute of Clinical Transfusion Medicine and Immunogenetics, Medical Faculty University of Ulm, Ulm, Germany*

Conclusions Elderly donors have very low adverse reaction frequencies and are highly committed to donate blood. Thus, we consider donations from repeat donors aged 69–70 safe and suggest it a powerful short- to midterm strategy to, at least partially, overcome the challenges of the demographic change.

Donor Safety

Adverse Events during Blood Donation in different age groups – experience in the GRC BTS North-East



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Influence of Age on Blood Safety?

- Medical drugs
- Autoimmune diseases
- Coronary heart disease
- Bacteraemia
- (unknown) cancer
- (Chronic) infections
- Cumulative (lifelong) exposure to viral infections

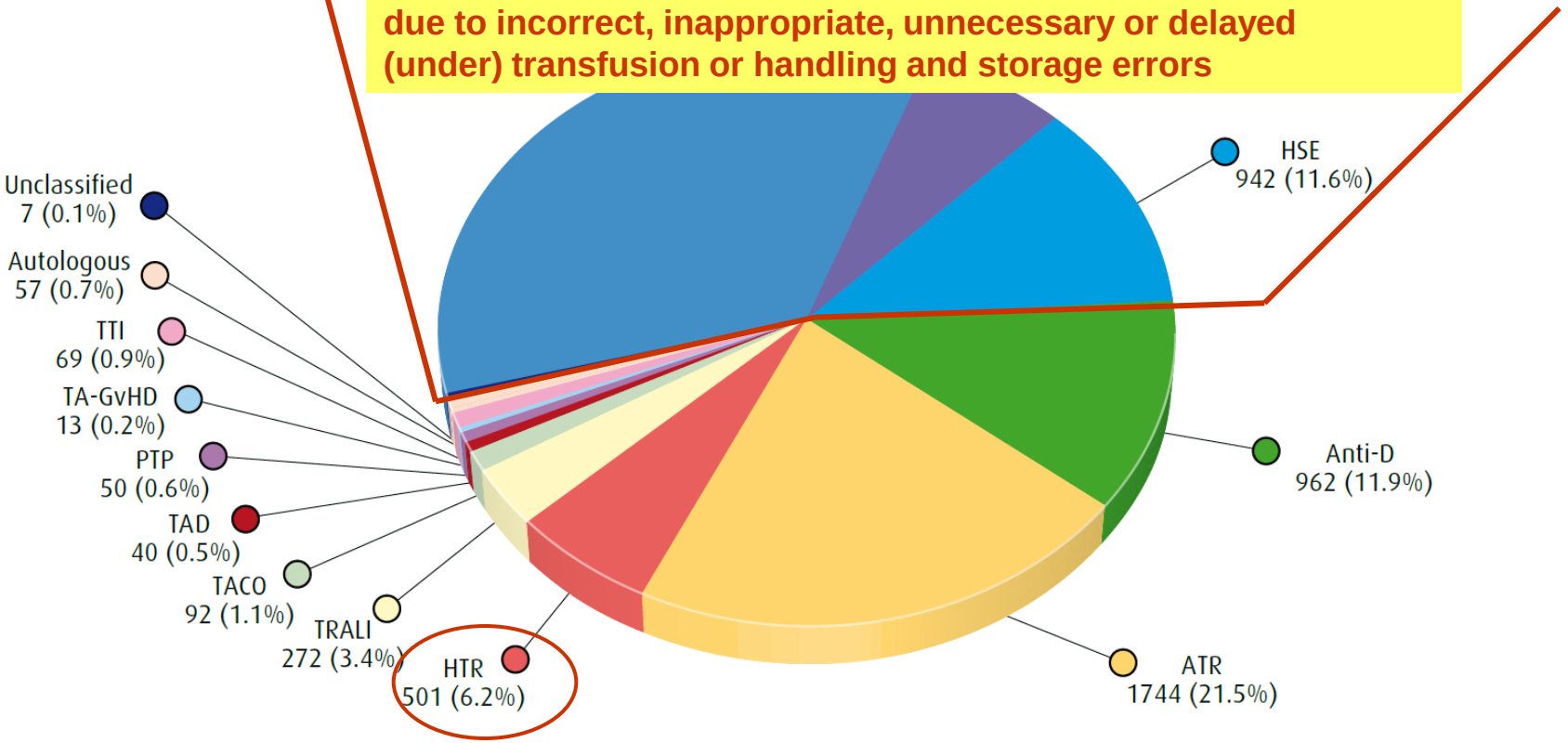
- Different lifestyle in young donors vs. old donors
- Cumulative lifetime risk different in young donors vs. old donors
- Switch in donor risk profiles from young donors to old donors

SHOT data 1996-2010 n=8117

SERIOUS HAZARDS OF TRANSFUSION SHOT

Cumulative numbers of cases reviewed 1996–2010 *n* = 8117

53% or 4310 out of 8117 serious hazards occurred
due to incorrect, inappropriate, unnecessary or delayed (under) transfusion or handling and storage errors



** IBCT, incorrect blood component transfused; I&U, inappropriate, unnecessary and under/delayed transfusions; HSE, handling and storage errors; ATR, acute transfusion reactions; HTR, haemolytic transfusion reactions; TRALI, transfusion-related acute lung injury; TACO, transfusion-associated circulatory overload; TAD, transfusion-associated dyspneoa; PTP, post-transfusion purpura; TA-GvHD, transfusion-associated graft versus host disease; TTI, transfusion-transmitted infection.*

Risks Associated with Blood Products
Blood Donor Screening (year of introduction)

Serological

- HBsAg (1975)
- TPHA (1984)
- Anti-HIV 1/2 (1985)
- Anti-HCV (1992)
- CMV (1995)
- Anti-HBc (2006)

PCR

- HBV (1997)
- HCV (1997)
- HIV (1997)
- HAV (2000)
- Parvo B19 (2000)
- (WNV?)
- Dengue?)

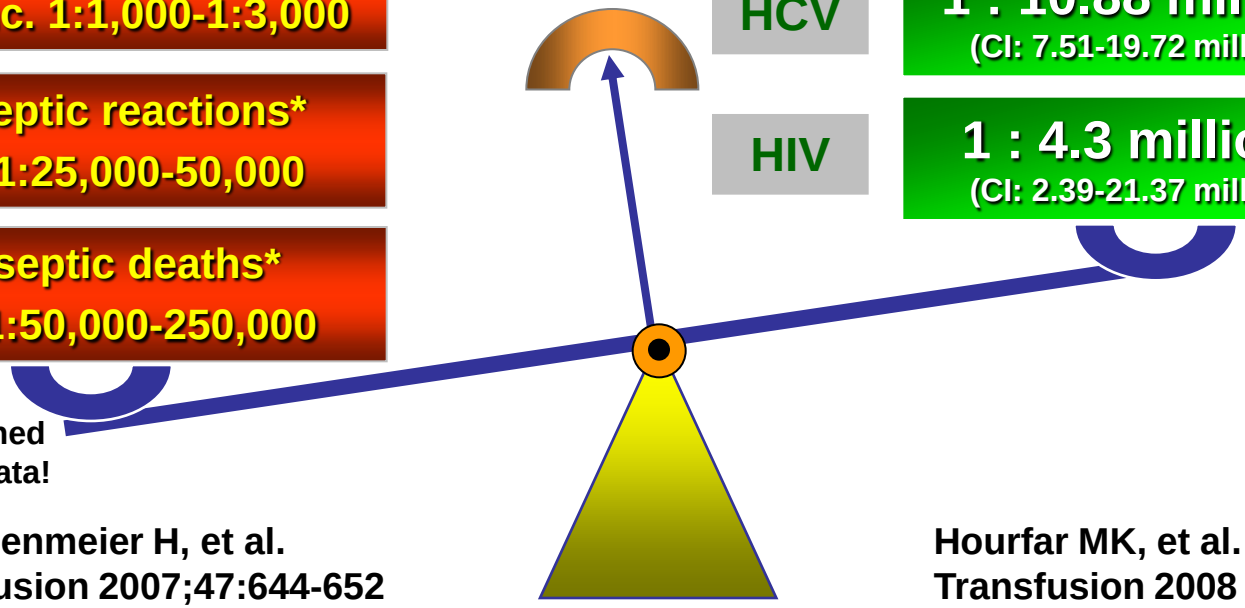
Risks Associated with Blood Products

Observed bacterial risk* (Platelet conc.)

- contaminated platelet conc. 1:1,000-1:3,000
- septic reactions* ~1:25,000-50,000
- septic deaths* ~1:50,000-250,000

Calculated viral transmission risk

HBV	1 : 360,000 (CI: 0.19-3.36 millions)
HCV	1 : 10.88 millions (CI: 7.51-19.72 millions)
HIV	1 : 4.3 millions (CI: 2.39-21.37 millions)



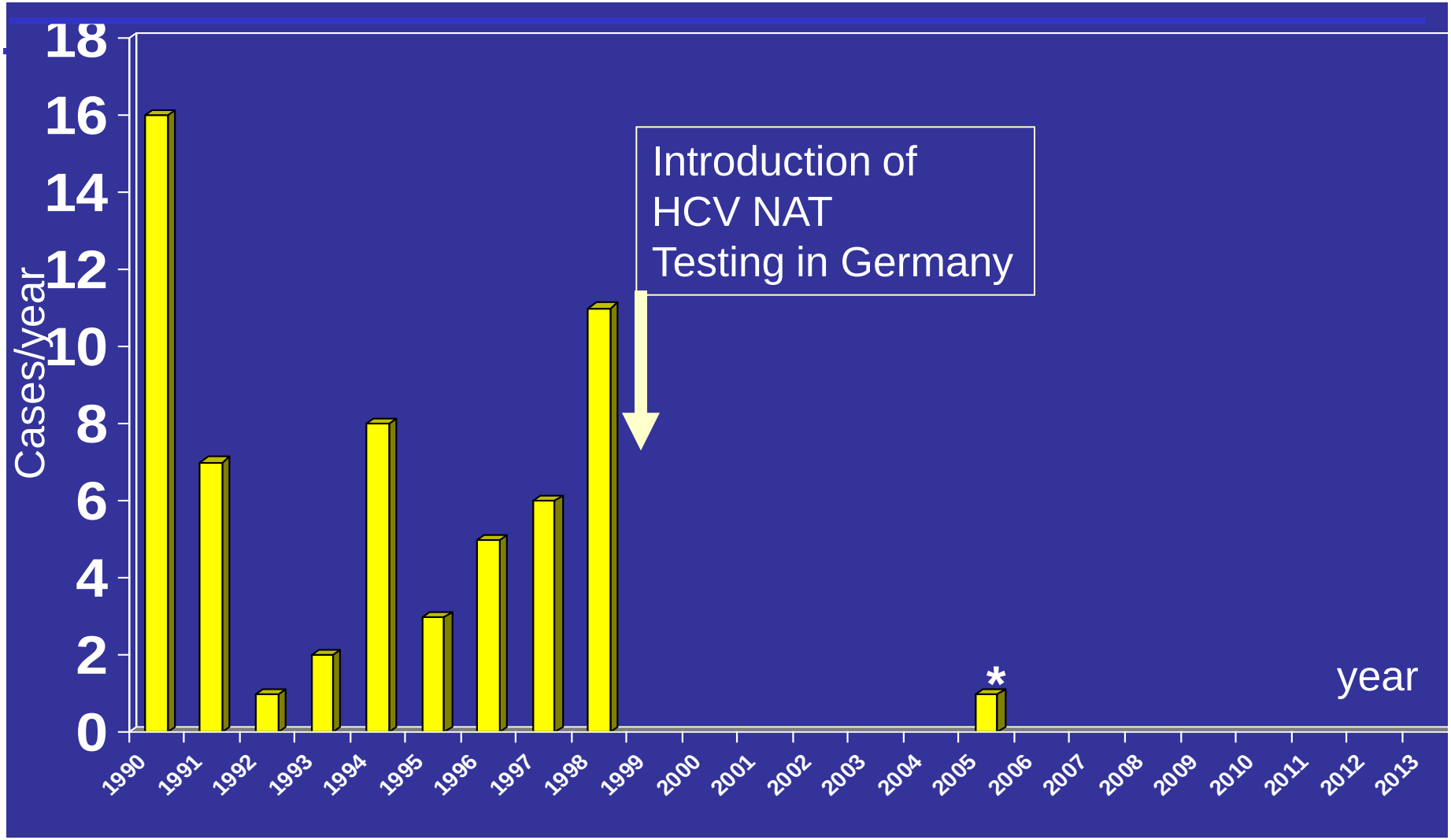
*: study not powered/designed to obtain epidemiological data!

Schrezenmeier H, et al. Transfusion 2007;47:644-652

Hourfar MK, et al. Transfusion 2008

Risks Associated with Blood Products

Transfusion-associated HCV infections reported to PEI



* Case report: Kretzschmar E et al.; Vox Sang 2007;92:297-301

M. Nübling, M. Funk,
B. Keller-Stanislawski, PEI

Institute for Transfusion Medicine and Immunohematology
University Clinics Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Risks Associated with Blood Products
(Re-) Emerging Pathogens

1996	Variant Creutzfeldt-Jakob disease
1997	Avian influenza virus type A (H5N1)
1999	West Nile virus (Flaviviridae) in USA
1999	Nipah virus
2003	SARS (Coronaviridae)
2003	Monkeypox virus
2004	Metapneumovirus
2005	Chikungunya virus in Ile de la Réunion
2006	Chikungunya virus in France
2007	Chikungunya virus in Italy
2008	West Nile virus in Italy and Hungary
2009	"Swine flu" (influenza A H1N1 virus)

?

Müller, Henschler, Seifried
Pathogen Inactivation
(AuBuchon, Ed.) 2010

Vox Sanguinis (2002) **83**, 285–293

REVIEW

Paying for blood donations: still a risk?

C. L. van der Poel,[1] E. Seifried[2] & W. P. Schaasberg[3]

[1]*Sanquin Blood Supply Foundation, Amsterdam, the Netherlands*
[2]*Red Cross Blood Donor Service, Frankfurt, Germany*
[3]*Statistics Netherlands, Voorburg, the Netherlands*

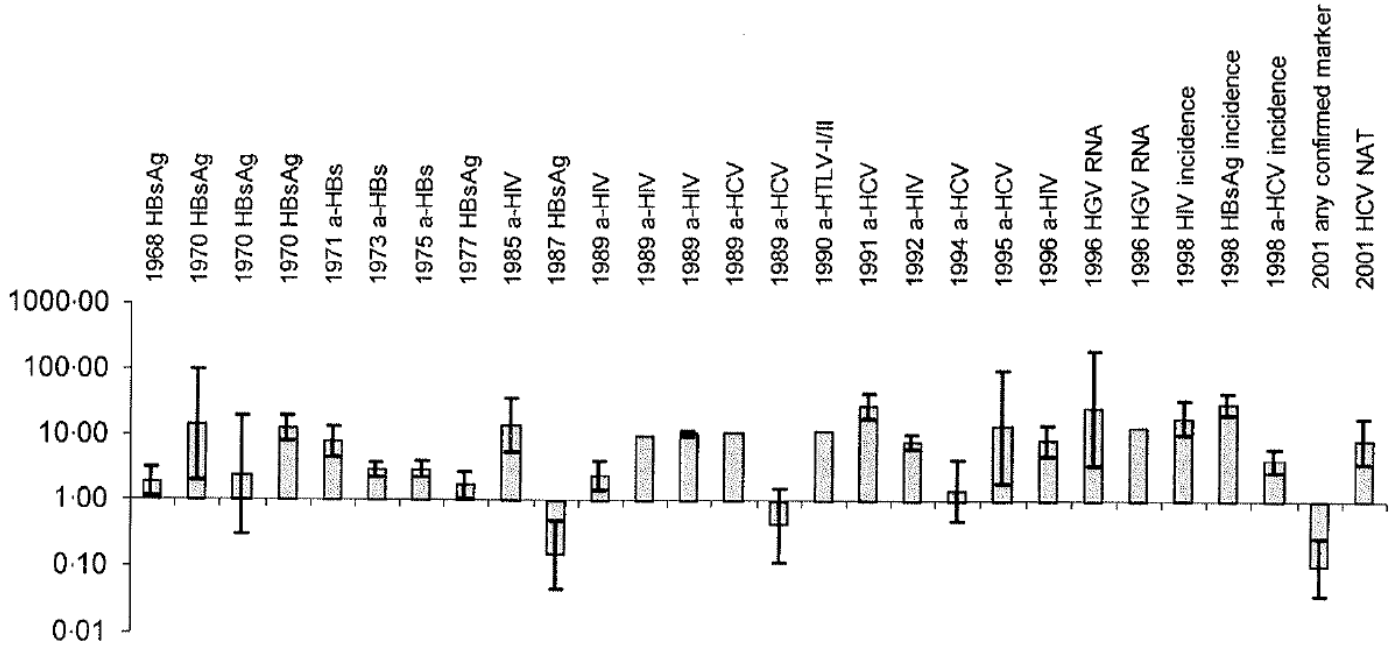


Fig. 1 From 25 studies, comparing the frequency of infectious disease markers (IDM) among paid and unpaid donor populations (definition see text), 28 data sets are included (see Table 1). The relative risks (RR), or risk ratios, were estimated for each data set, in addition to their 95% confidence intervals (95% CI) (GraphPad Instat™). For four data sets, the 95% CI could not be calculated, as only frequencies were given in the original report and data on the population size were lacking. If RR = 1, paid donors had the same frequency as unpaid donors; if RR = 10, paid donors had a 10-fold higher frequency; if RR = 0·1, unpaid donors had a 10 fold higher frequency. a-, anti; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HGV, hepatitis G virus; HIV, human immunodeficiency virus; HTLV-I/II, human T-cell lymphocytotrophic virus I/II; NAT, nucleic acid amplification testing.

HIV Infections in Germany (Source: RKI)

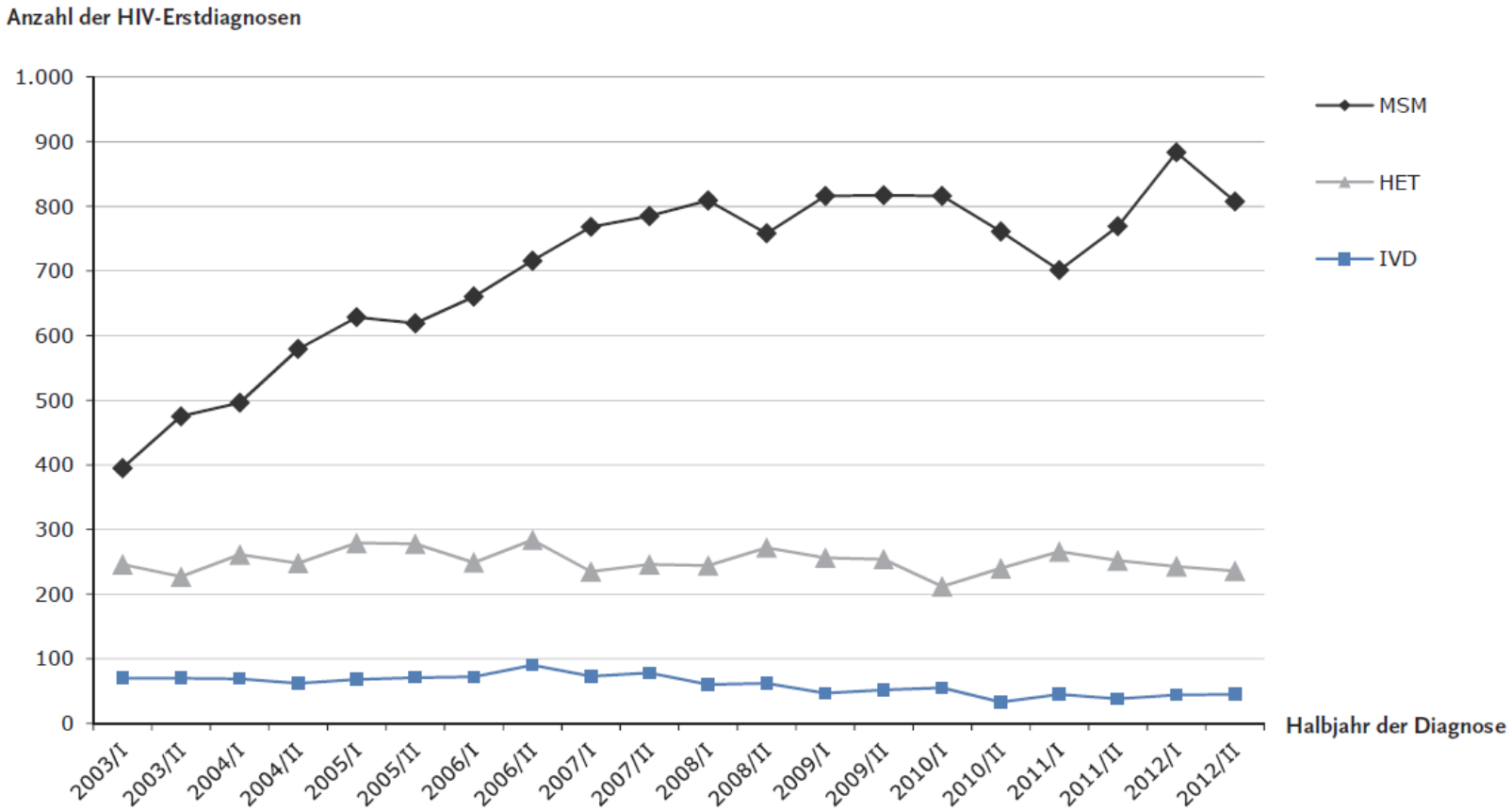


Abbildung 3: HIV in der Bundesrepublik Deutschland
HIV-Erstdiagnosen[3] nach Halbjahr der Diagnose[4] und wahrscheinlichem Infektionsweg[5,6,7]

Stand: 1.3.2013

VoxSanguinis
The International Journal of Transfusion Medicine

ISBT International Society of Blood Transfusion

Vox Sanguinis (2011) **101**, 339–367

DOI: 10.1111/j.1423-0410.2011.01489.x

INTERNATIONAL FORUM

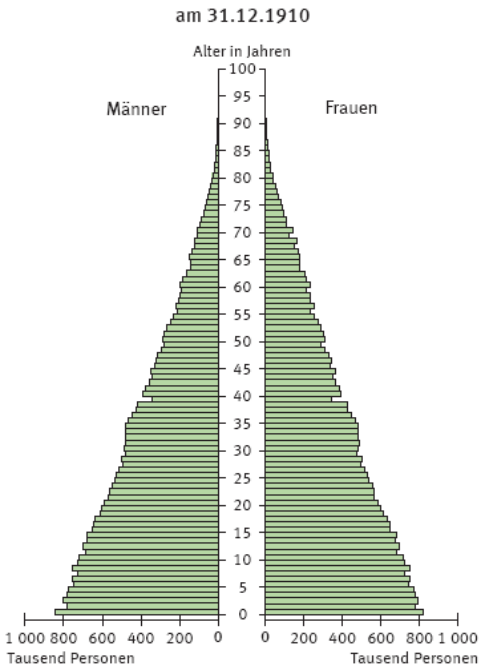
Vox Sanguinis

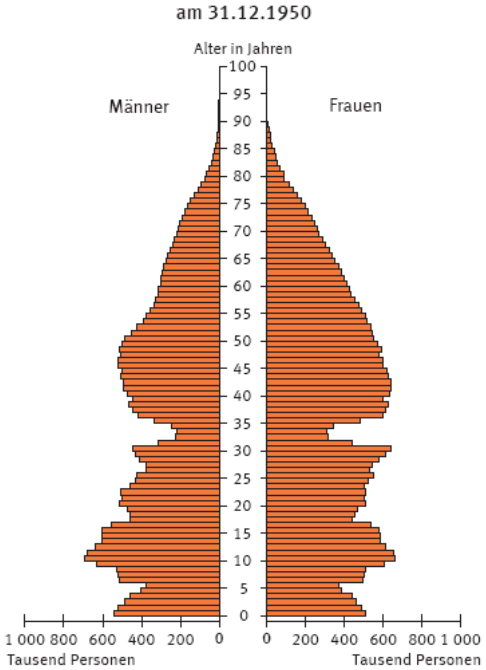
Deferral of males who had sex with other males

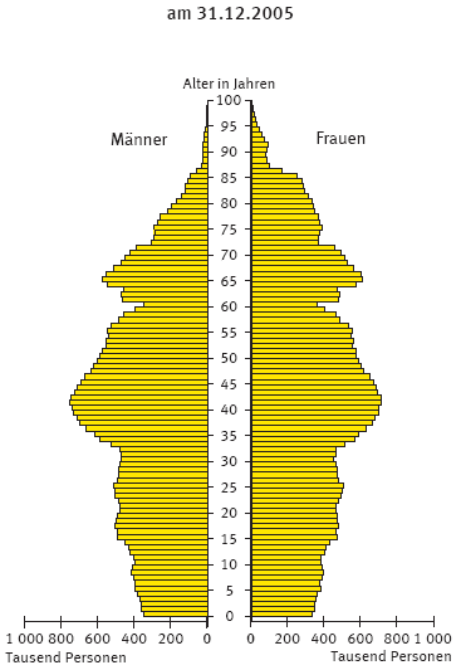
R. J. Benjamin, C. Bianco, M. Goldman, C. R. Seed, H. Yang, J. Lee, A. J. Keller, S. Wendel, S. Biagini, J. Murray, D. V. Devine, Y. Zhu, P. Turek, F. M. Moftah, R. Kullaste, J. Pillonel, B. Danic, F. Bigey, G. Folléa, E. Seifried, M. M. Mueller, C. K. Lin, R. N. Makroo, G. Grazzini, S. Pupella, C. Velati, K. Tadokoro, A. Bravo Lindoro, A. D'Artote González, V. T. Giner, P. Flanagan, R. W. Olaussen, M. Letowska, A. Rosiek, R. Poglod, E. Zhiburt, P. Mali, P. Rozman, S. Gulube, E. Castro Izaguirre, B. Ekermo, S. M. Barnes, L. McLaughlin, A. F. Eder, S. Panzer & H. W. Reesink

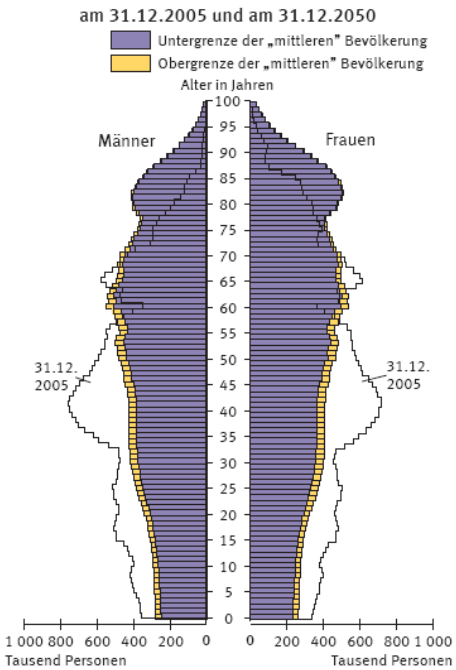
The current major risk factor for HIV infection in the general population is MSM (67% of new HIV infections in Germany in 2009 for which the source of infection is known [1]; incidence for a positive test for HIV about 1 in 29 000 of the whole population). For the donor population, this risk group is deferred. HIV positive test results in regular blood donors are only found in rare situations in

Demographics of the German Population
1910 – 2050 (prognosis)









1910 **1950** **2005** **2050**

(prognosis)

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

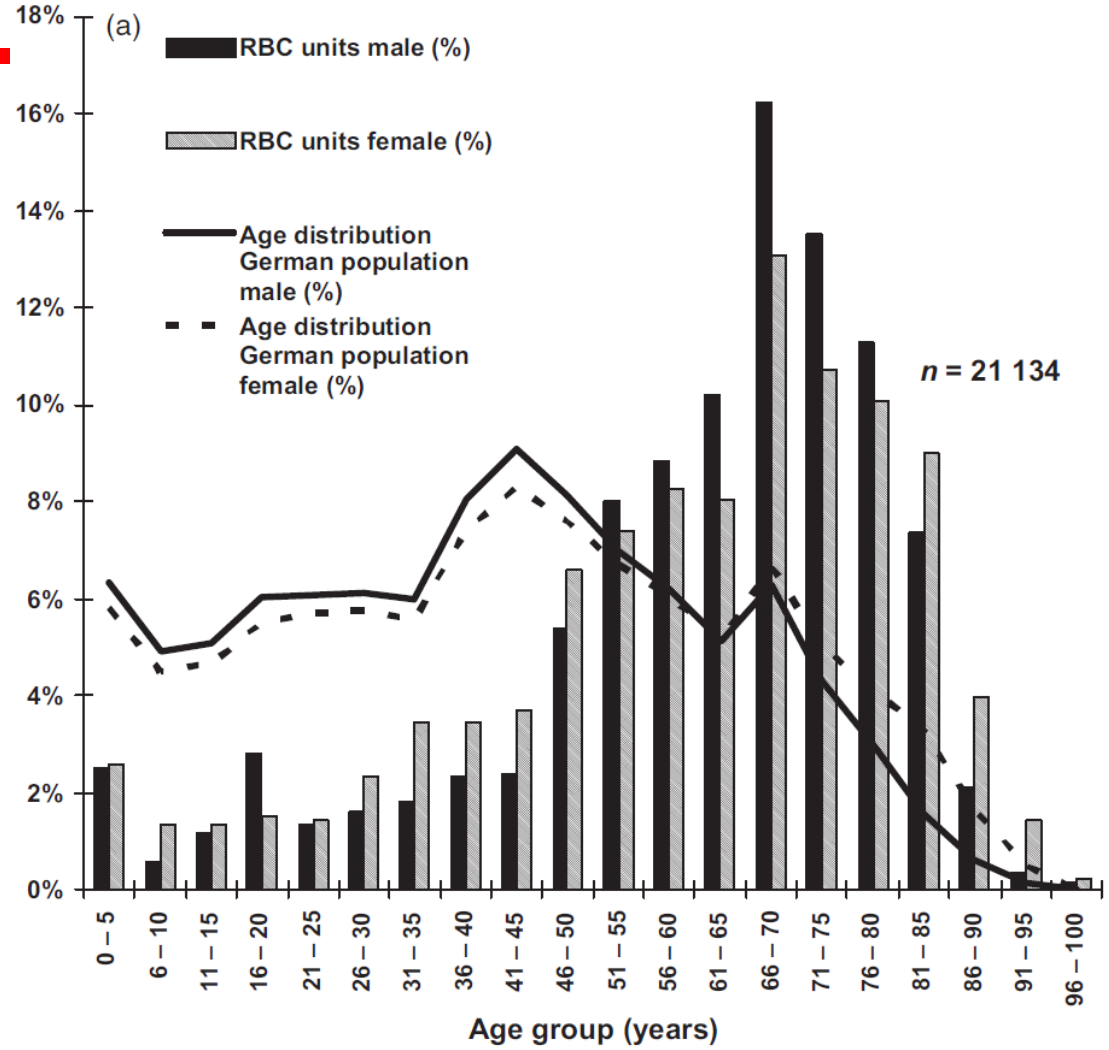
Source: Statistisches Bundesamt, Wiesbaden, 2006

Epidemiology of Blood Transfusion

- Prevalence Survey in USA 1989 to 1992
- No significant change in blood and blood component utilisation during this past timespan analysed in USA
- Incidence of red cell transfusion was 42,88 units per 1000 population per year and varied from 12,08 units in those less than 41 years old to 245,24 units in the group aged more than 65.
- The probability of receiving a RBC transfusion in any year rose 20-fold from the rate in those less than 40 years old to that in those more than 65 years old, who received 53,3 % of the RBCs transfused.

Vamvakas EC, Taswell HF, Transfusion 1994;34:464-470

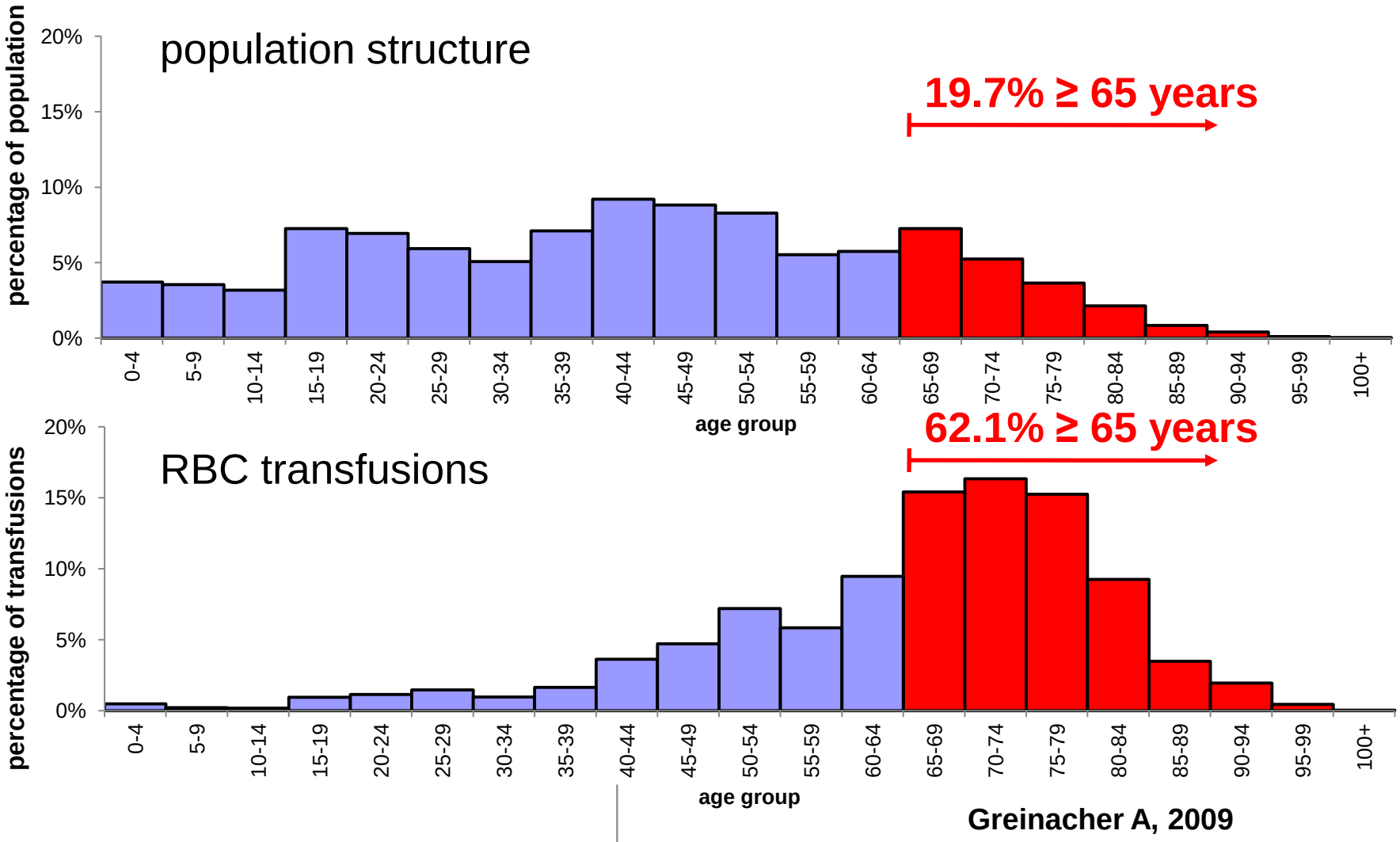
How much blood is needed?
Transfused Red Blood Cell Concentrates



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

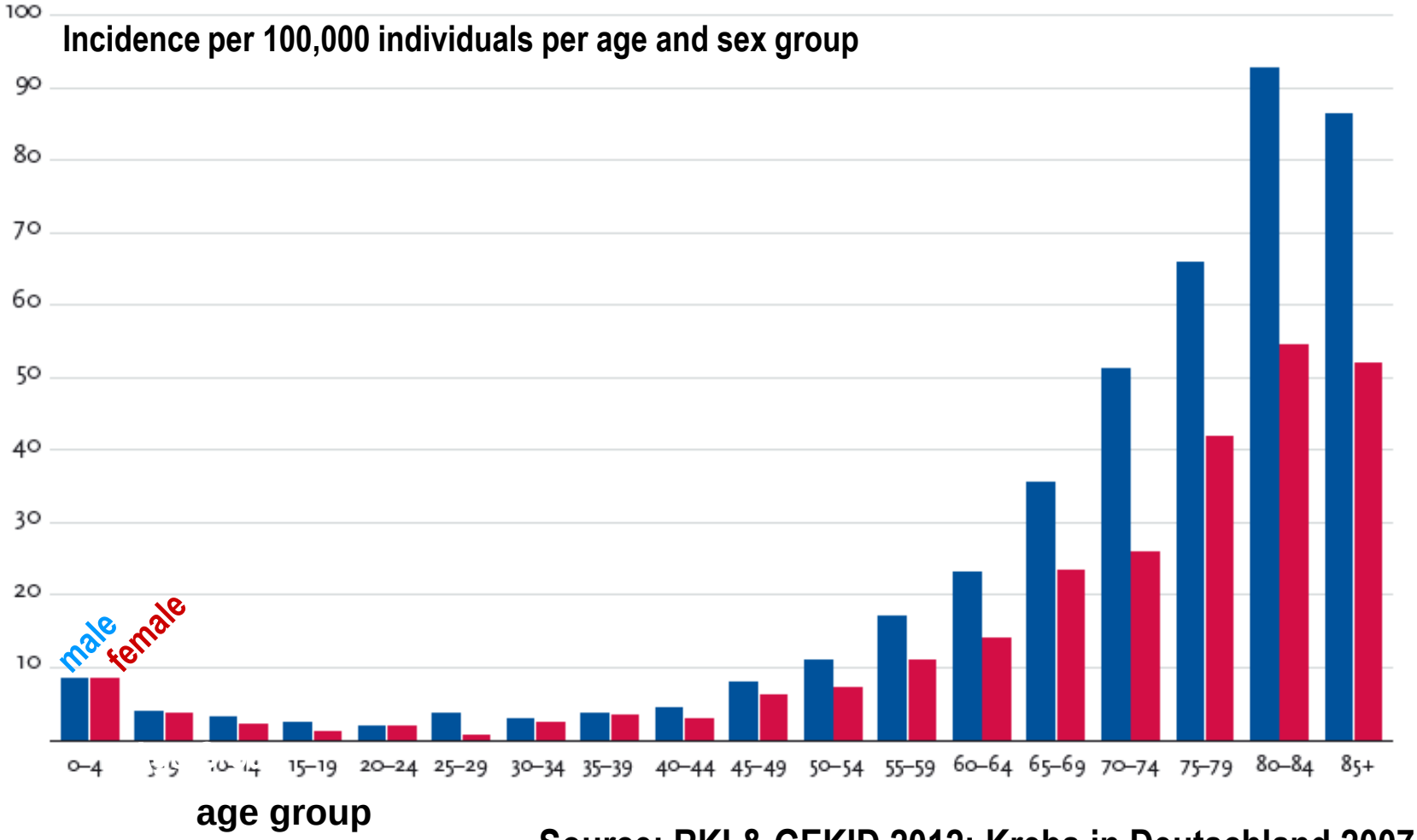
Seifried E et al. Vox Sang. 2011 Jan;100(1):10-21

Population vs. Transfusion



Greinacher A, 2009

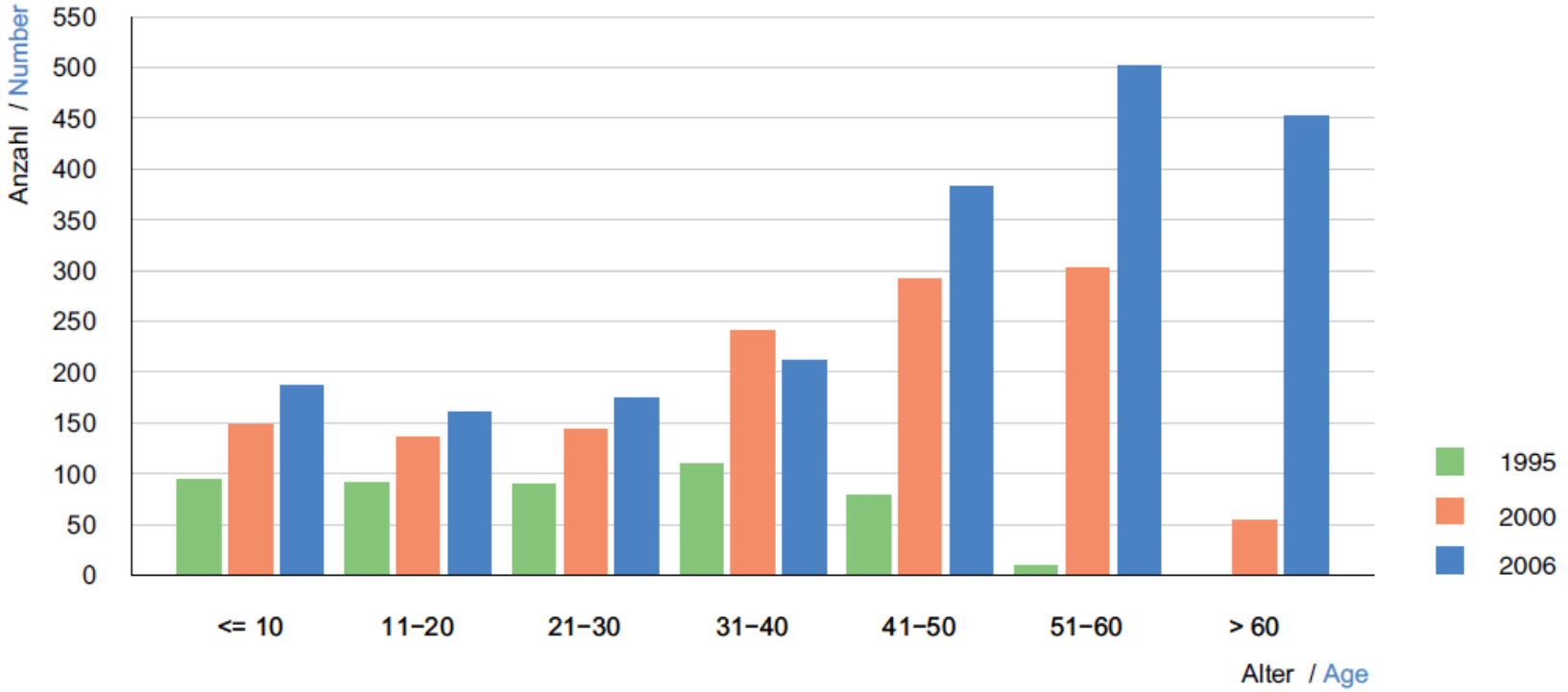
Age-Specific Incidences of Diseases:
Leukaemia Incidences in Germany 2007/2008



Source: RKI & GEKID 2012: Krebs in Deutschland 2007-2008

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

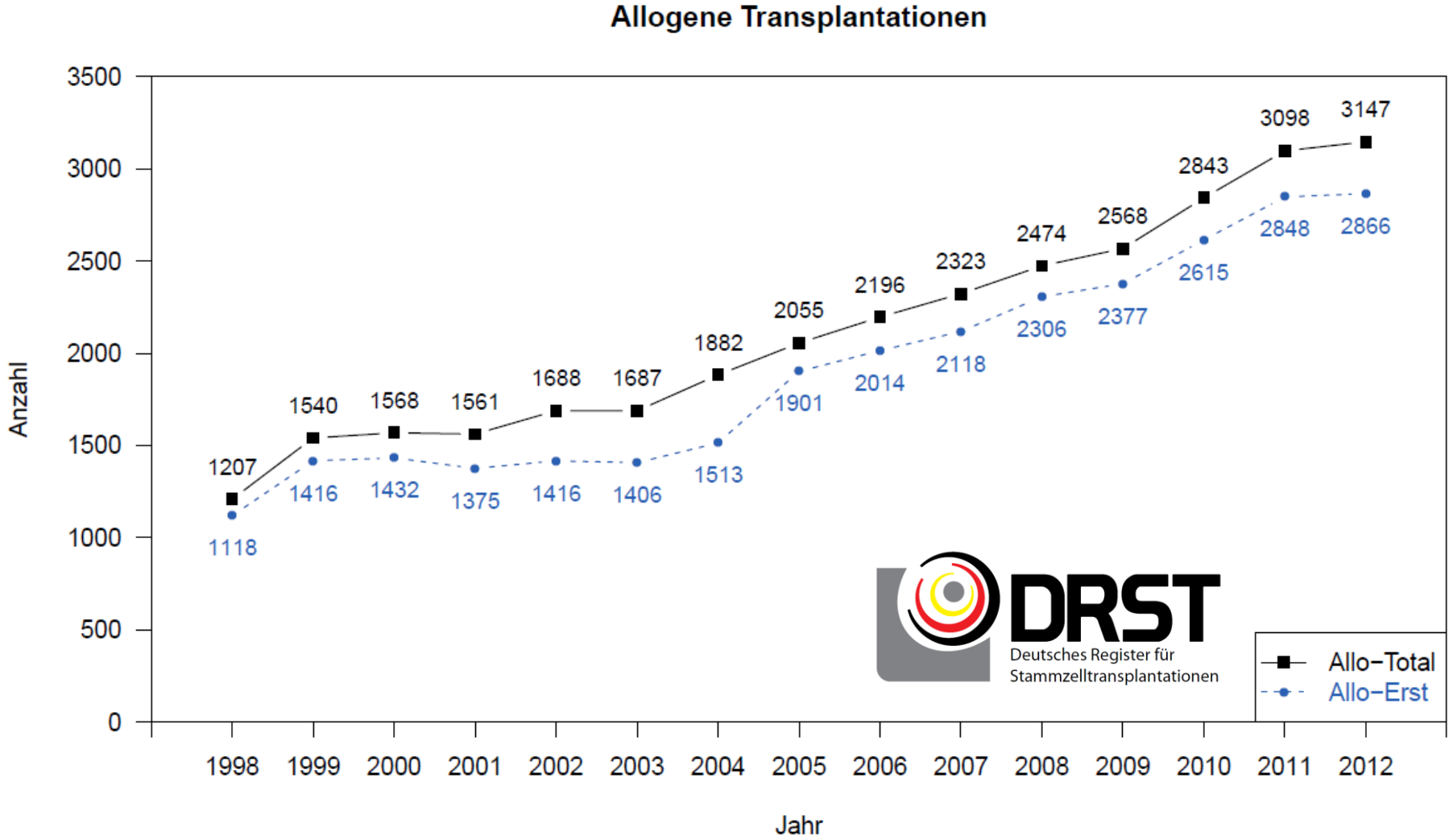
Age Distribution of German Patients, for whom an Allogeneic Stem Cell Transplant Donor was Requested



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Source: ZKRD Annual Report 2004-2006

Increasing Number of Allogeneic Hematopoietic Stem Cell Transplantations in Germany 1998-2012



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

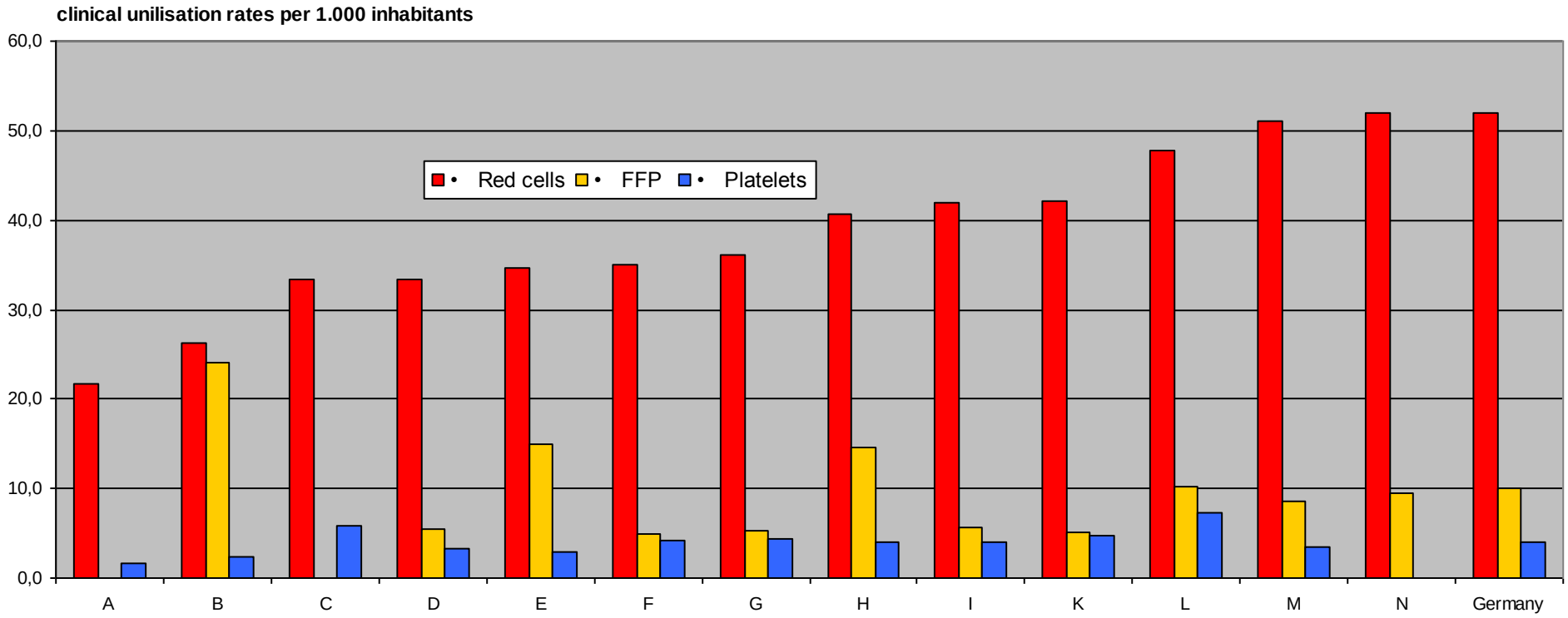
Source: DRST Yearbook 2012

Estimated Change of Incidences in Selected Malignancies (2002 vs. 2012)

Non-Hodgkin Lymphoma	
➢ male	+20%
➢ female	+13%
Multiple myeloma	
➢ male	+30%
➢ female	+16%
Chronic lymphocytic leukemia	
➢ male	+26%
➢ female	+18%
Colon Cancer	
➢ male	+47%
➢ female	+27%

Greinacher A, 2009

Clinical Utilisation Rate of Blood Components 2008 in Different European Countries (per 1,000 inhabitants)

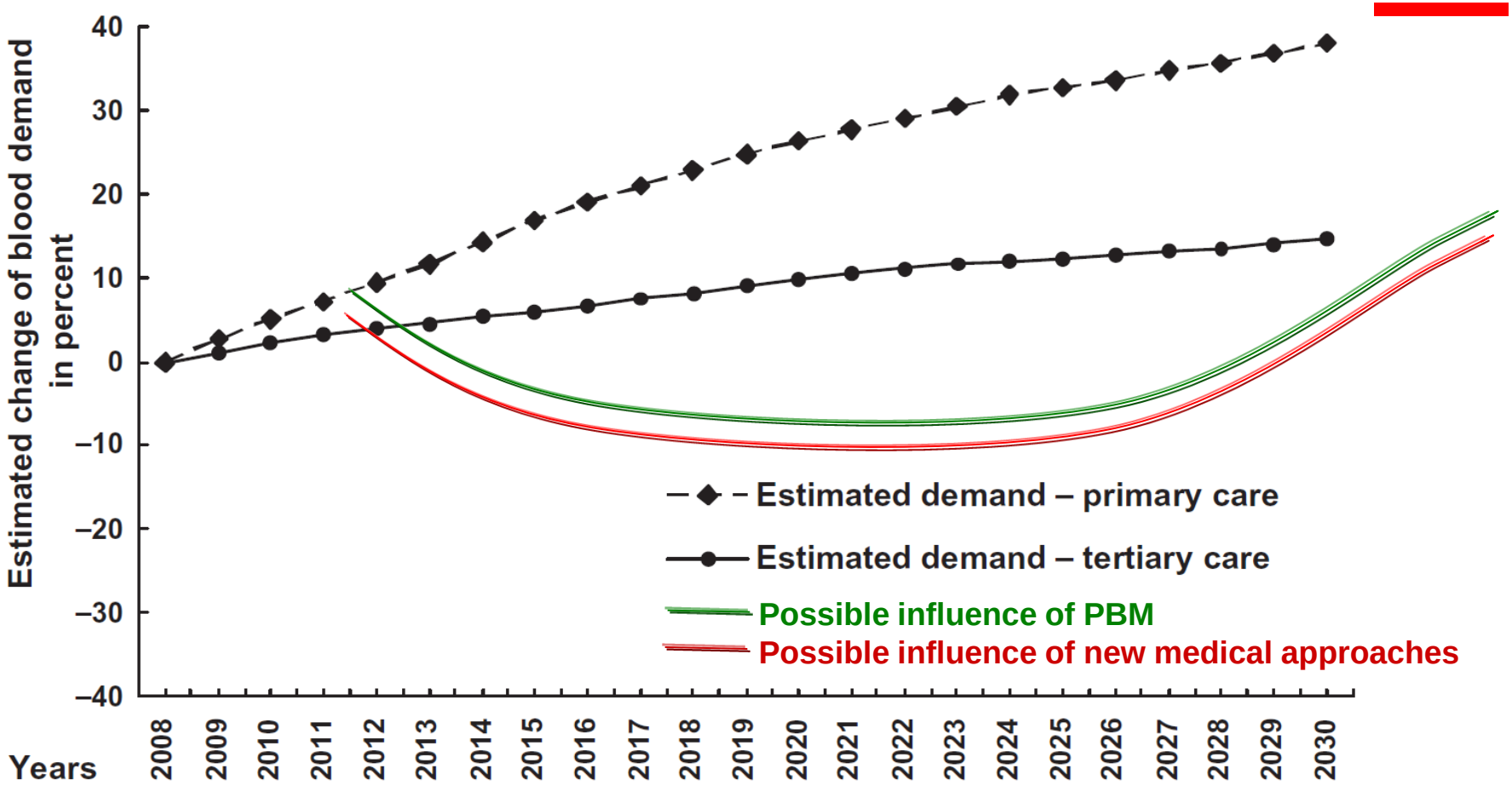


Source: EBA 2009

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

How much blood is needed?

Estimated development in blood demand



Modified from:
Seifried E et al. Vox Sang. 2011 Jan;100(1):10-21

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Optimal Blood USE EU

- Equal
- Eubis
- Domaine
- EUOBUP
- PaBloE (PBM)

PATIENTENBLUT-MANAGEMENT

Kluger Umgang mit einem wertvollen Gut

Blut ist knapp und teuer. Ein Forschungsprojekt unter Leitung des Universitätsklinikums Frankfurt/M. untersucht, wie sich der Einsatz von Fremdbluttransfusionen optimieren lässt.

Vor allem in Ferienzeiten und in Hitzeperioden lässt die Blutspendebereitschaft erheblich nach. Aber auch die demografische Entwicklung trägt mit dazu bei, dass Blut zunehmend zu einer knappen Ressource wird. Denn immer mehr älteren Patienten mit einem wachsenden Transfusionsbedarf stehen immer weniger mögliche Blutspender gegenüber. Die Weltgesundheitsorganisation (WHO) fordert daher seit 2011 die Einführung eines Patient Blood Management (PBM).

Gleichzeitig bedeuten Bluttransfusionen immer auch ein potenzielles Risiko für den Patienten. Studien zufolge könnte die Gabe von Fremdblutkonserven mit einer erhöhten Mortalität, Morbidität und einem erhöhten Infektionsrisiko verbunden sein. Unnötige Transfusionen sollten daher vermieden werden.

Vor diesem Hintergrund hat das Universitätsklinikum Frankfurt/M. zusammen mit den Unikliniken in Bonn, Kiel und Münster ein Projekt zum Patientenblutmanagement gestartet. Ziel ist es, die Patientensicherheit zu erhöhen und den Einsatz von Fremdbluttransfusionen durch drei Maßnahmen zu optimieren: durch die spezielle Vorbehandlung von Anämie-Risikopatienten vor elektiven operativen Eingriffen, durch eine strenge Indikationsstellung zur Bluttransfusion und durch Maßnahmen zur Minimierung des Blutverlustes während und nach der Operation *(Kasten)*.

Frankfurt übernimmt dabei für Deutschland die Federführung in diesem Bereich der Versorgungsforschung. „Das ist die erste größere Untersuchung weltweit zu diesem Thema", erklärte Prof. Dr. med. Kai Zacharowski, Direktor der Klinik für Anästhesiologie, Intensivmedizin und Schmerztherapie. „Wir freuen uns, dass wir dieses wichtige Anliegen der WHO gemeinsam mit unseren Partnern erstmalig in Deutschland in die Praxis umsetzen können." Insgesamt sollen bis Ende 2015 mehr als 100 000 Patienten in die Studie einbezogen werden.

Auch in ökonomischer Hinsicht könnte sich das PBM für die Krankenhäuser rechnen: Das Universitätsklinikum Frankfurt etwa wendet für das Management von Blutkonserven einschließlich Laborleistung derzeit sieben Millionen Euro jährlich auf. Circa zehn Prozent dieser Kosten ließen sich nach Schätzungen der Experten durch das PBM, zum Beispiel aufgrund weniger Komplikationen und kürzerer Liegezeiten, einsparen.

Umgesetzt wird das Projekt in enger Kooperation mit den chirurgischen Kliniken. Während der Implementierungsphase bis September und danach finden Fortbildungen für Ärzte und Pflegepersonal auf allen chirurgischen Stationen statt, berichteten die Projektkoordinatoren Priv.-Doz. Dr. med. Patrick Meybohm und Dr. med. Dania Fischer. Nach der vollständigen Einführung wird das PBM-Programm bei allen stationär aufgenommenen erwachsenen chirurgischen Patienten eingesetzt.

Die Klinik für Anästhesiologie, Intensivmedizin und Schmerztherapie des Universitätsklinikums Frankfurt koordiniert zusammen mit dem Institut für Transfusionsmedizin und Immunhämatologie, DRK-Blutspendedienst Baden-Württemberg – Hessen, das Projekt. Das PBM stößt auf großes Interesse: 15 weitere Kliniken wollen sich anschließen. Die Begleitforschung übernimmt das Institut für Biostatistik und mathematische Modellierung am Universitätsklinikum Frankfurt. Infos: www.patientbloodmanagement.de.

Heike E. Krüger-Brand

KLINISCHE UMSETZUNG

Die erste Komponente des PBM bilden die **Vorbehandlungen von anämischen Risikopatienten** vor operativen Eingriffen. Durch ein standardisiertes Prüfverfahren wird ermittelt, wie massiv der Blutmangel ist und wie hoch das Risiko für eine Bluttransfusion wäre. Hierfür werden unter anderem spezielle Geräte zur nichtinvasiven Messung des Hämoglobinwertes eingesetzt. Bei Bedarf wird ein interdisziplinäres Fachkonsil einberufen, das medizinische Maßnahmen festlegt, durch die die Blutarmut reduziert und damit der Einsatz von Blutkonserven beim Eingriff ohne gesundheitliche Risiken vermieden werden kann.

Die zweite Säule zielt auf den möglichst rationalen Einsatz der Blutkonserven auf Basis der Querschnittsleitlinien zur Therapie mit Blutkomponenten und Plasmaderivaten der Bundesärztekammer ab. Hierfür wurde eine **Transfusionsbedarfs-Checkliste** entwickelt, mit der in jedem Einzelfall die Entscheidung für oder gegen den Einsatz einer Blutkonserve überprüft wird.

Die dritte Säule umfasst weitere Maßnahmen, die den Blutverlust während und nach der OP minimieren. Dazu zählt beispielsweise die **restriktive Handhabung von Blutentnahmen**. So werden statt der üblichen Röhrchen zur Blutentnahme kleinere aus der Kinderklinik eingesetzt und die Entnahmeintervalle vergrößert. Bei Risikooperationen werden routinemäßig Cell-Saver-Geräte genutzt, die das Patientenblut auffangen und als Eigenblutkonserve aufbereiten. Wärmedecken verhindern zudem ein Auskühlen der Patienten, da bei Unterkühlung die Blutgerinnung eingeschränkt funktioniert. Eine patientennahe Gerinnungsdiagnostik (ROTEM-und Multiplate-Analyse) wird auf den chirurgischen Stationen umgesetzt.

PBM: National and PaBloE

Patient Blood Management

Wir sind dabei!

German Medical Association: Deutsches Ärzteblatt 2013;110:A1546

Nach 24-Stunden-Schicht

Ärztin (27) verwechselt Blut-Konserve

PATIENT TOT!

Von PETRA BRAUN

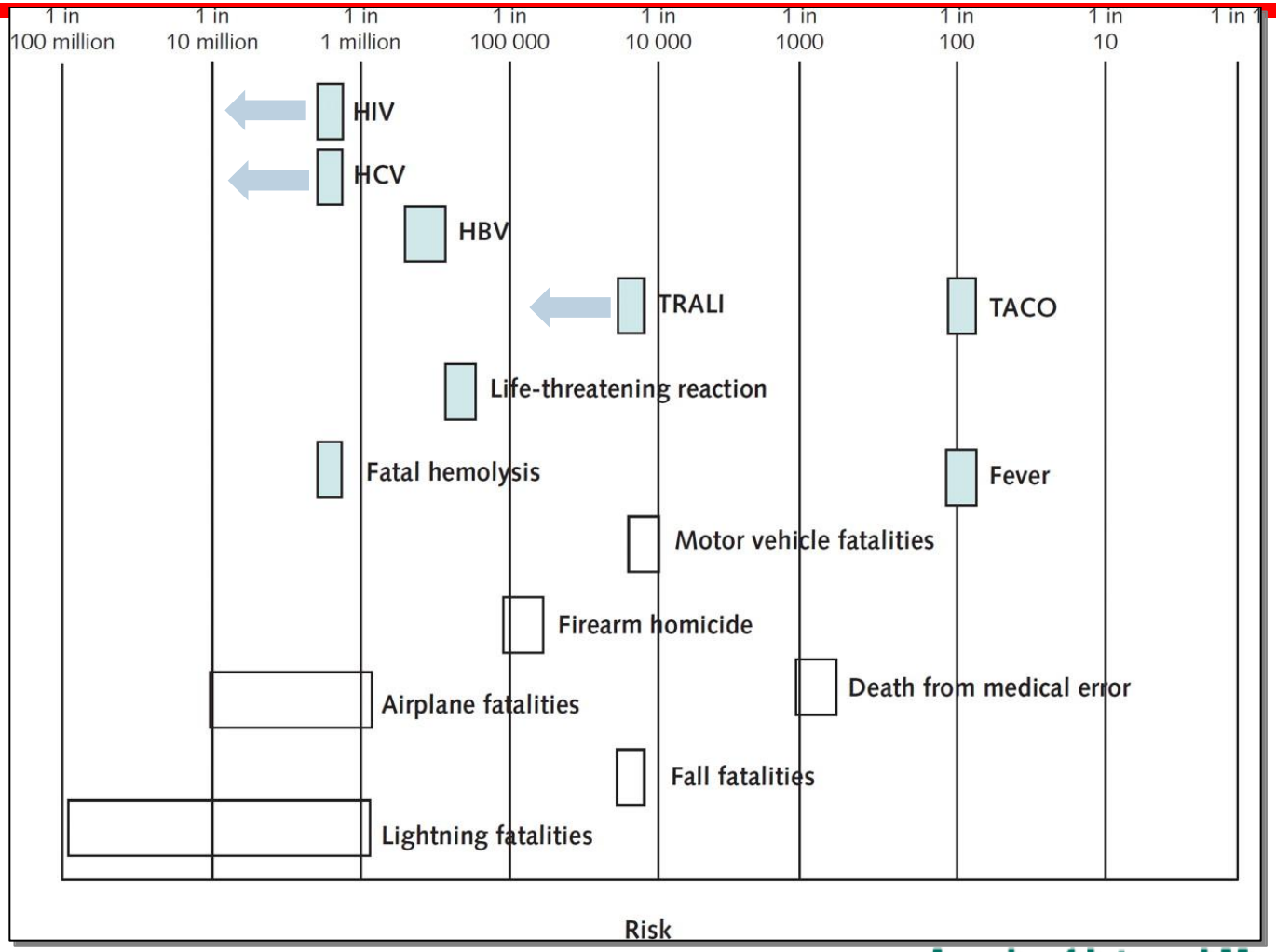
Köln – **Es war ein tödlicher Fehler – trotzdem wurde er nicht bestraft.**

Weil eine junge Ärztin (27) zwei Blutkonserven vertauschte, starb ein Patient (63) in einer Kölner Klinik.

Das war im Juli vergangenen Jahres. Jetzt wurde der Fall am Amtsgericht Köln verhandelt. Die Ärztin Katja S. (Name geändert) wurde wegen fahr-

Adverse Events of RBC Transfusion Contrasted with other Risks

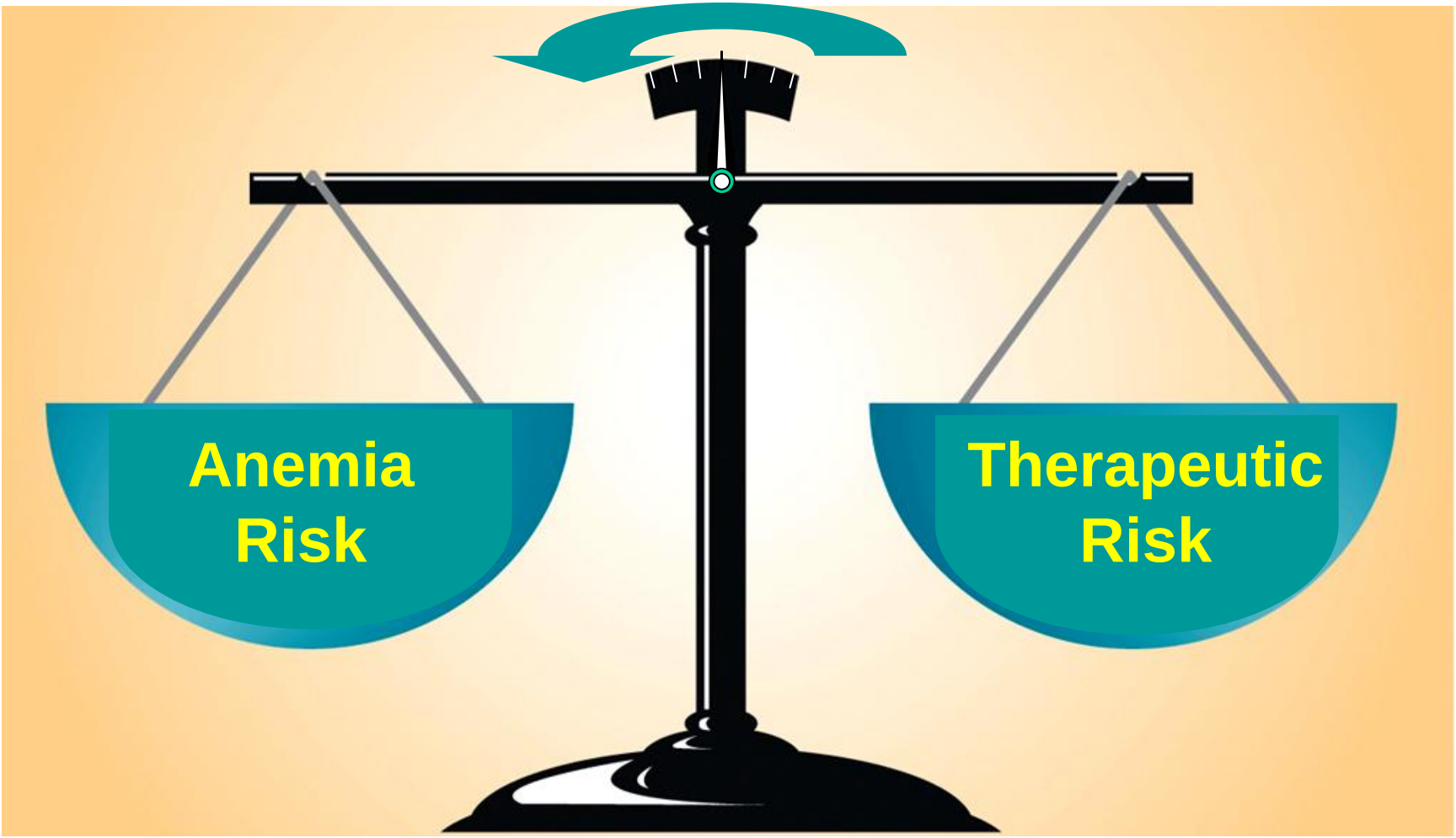
Carson J L et al. Ann Intern Med doi:10.1059/0003-4819-156-12-201206190-00429



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Annals of Internal Medicine

Risk-Benefit Balance



Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

Future Challenges

- Motivation of healthy blood donors in the 21st century
- Evidence based use of blood components
- Evidence-based use of growth factors
- Bloodless medicine
- Synthetic blood
- Stem cell derived blood cells

Conclusions I

- Modern high-performance medicine in Europe is impossible without voluntary non-remunerated blood donation.
- Blood products in Europe can be considered among the safest medical drugs available.
- Blood donation culture in Europe still permits a safe and secure blood supply in most countries.
- Demographic changes will influence the need for blood components while the potential donor population shrinks.
- A number of novel developments may influence the need of blood components.

Conclusions II

- **The future need for blood products in Europe depends on different factors:**
  - **Novel surgical procedures and blood saving techniques will diminish the need.**
  - **New drugs in hematology and oncology might reduce the need of allogeneic blood components.**
  - **Restrictive triggers for transfusion and patient blood management (PBM) are currently investigated and might have a significant impact on the demand for allogeneic blood components.**
  - **Competitive drugs (erythropoietin and other ESAs, thrombopoietin and other TRAs, etc.) might further reduce the demand.**

Conclusions III

- **Safe Donors and safe donations:**
  - **The safety of blood donors is of utmost importance and must not compromised at any time.**
- **Safe Blood:**
  - **Careful selection of blood donors has a high impact on the safety of blood components and on the safety of recipients.**
  - **From the medical and scientific points of view, there is no good reason not to defer blood donors even with moderate risk profiles if donor safety or safety considerations for the recipient require this.**
    - **e.g. deferral for risky behaviour**
    - **body temperature, blood pressure, pulse, hemoglobin level as minimal requirements**
- **As long as the safety of blood supply is not endangered, risks for blood donors and recipients should not be taken. This requires a clear evidence-based decision making.**

Acknowledgements

Markus M. Mueller

Thank you very much for your attention !

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen

VoxSanguinis
The International Journal of Transfusion Medicine

ISBT International Society of Blood Transfusion

Vox Sanguinis (2012) **102**, 134–139

ORIGINAL PAPER

DOI: 10.1111/j.1423-0410.2011.01531.x

Safety and frequency of whole blood donations from elderly donors

M. Müller-Steinhardt,[1,2] T. Müller-Kuller,[1,3] C. Weiß,[4] D. Menzel,[1,5] M. Wiesneth,[1,6] E. Seifried[1,3] & H. Klüter[1,2]

[1]*German Red Cross Blood Service Baden-Württemberg – Hessen, Mannheim, Germany*
[2]*Institute of Transfusion Medicine and Immunology, Medical Faculty Mannheim, University of Heidelberg, Mannheim, Germany*
[3]*Institute of Transfusion Medicine and Immunohaematology, Medical Faculty Johann Wolfgang Goethe University Frankfurt, Frankfurt, Germany*
[4]*Department of Medical Statistics and Biomathematics, Medical Faculty Mannheim, University of Heidelberg, Mannheim, Germany*
[5]*Institute of Clinical and Experimental Transfusion Medicine, Medical Faculty University of Tübingen, Tübingen, Germany*
[6]*Institute of Clinical Transfusion Medicine and Immunogenetics, Medical Faculty University of Ulm, Ulm, Germany*

Results Of all invited donors, 32·5% responded and contributed 0·98% (men) and 0·56% (women) to all WB units collected in 2010. The overall and systemic adverse reaction rate per 1·000 WB donations declined by age [men: 1·10 (95%CI: 0·84–1·35) vs. 0 (0–0·8), $P < 0·0001$; 0·99 (0·75–1·23) vs. 0 (0–0·8), $P < 0·0001$ and women: 1·80 (1·46–2·14) vs. 1·12 (0·1–2·66), $P < 0·0001$; 1·47 (1·17–1·78) vs. 1·12 (−0·43–2·66), $P = 0·0004$]. Mean donation frequencies were strongly correlated with increasing age (men: $r = 0·953$, $P < 0·0001$; women: $r = 0·913$, $P < 0·0001$) with peak values for 70-year-old male: 2·53 ± 1·37 vs. 1·79 ± 1·05, $P < 0·0001$ and female donors: 2·15 ± 1·06 vs. 1·52 ± 0·78, $P < 0·0001$.

Thank you very much for your attention!

www.blutspende.de

Institute for Transfusion Medicine and Immunohematology
Clinics of the Johann Wolfgang Goethe University Frankfurt / Main
German Red Cross Blood Donor Service Baden-Wuerttemberg – Hessen