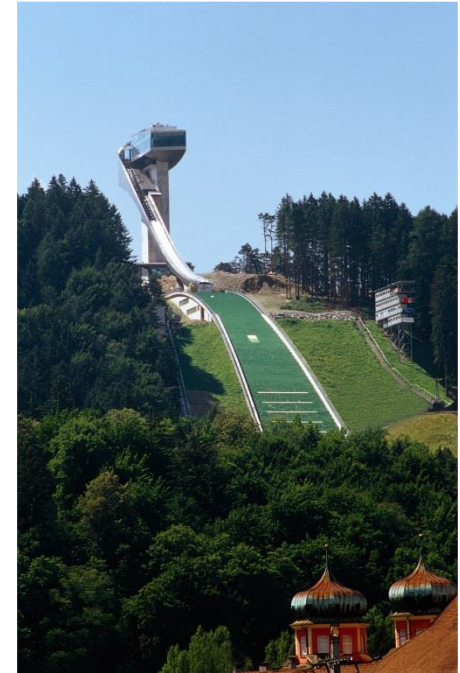


Blood Donation Services in Austria - Legal Background, Structure and Tasks



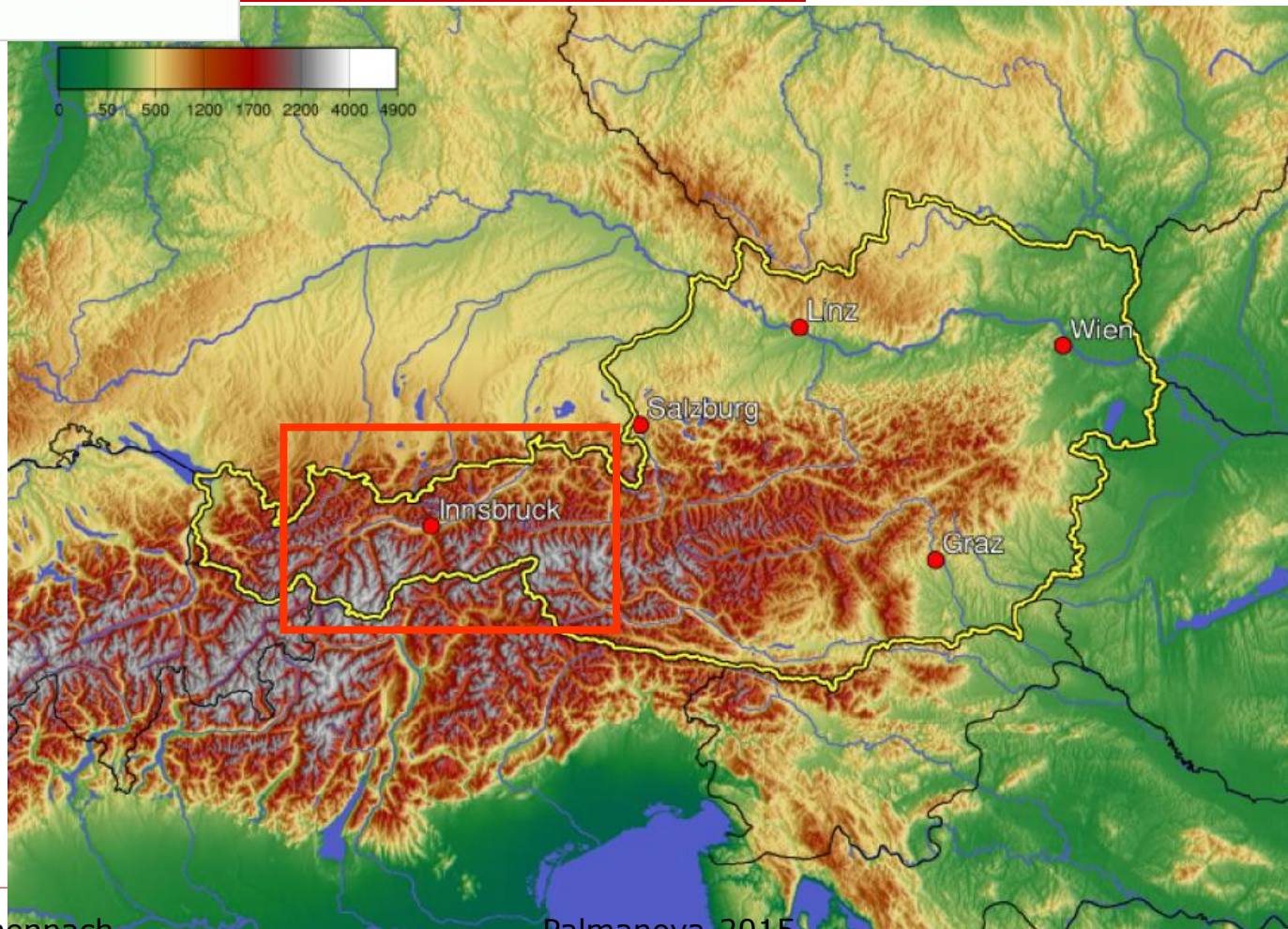
H. Schennach

**Zentralinstitut für Bluttransfusion und Immunologische Abteilung,
Landeskrankenhaus-Universitätskliniken, Innsbruck**



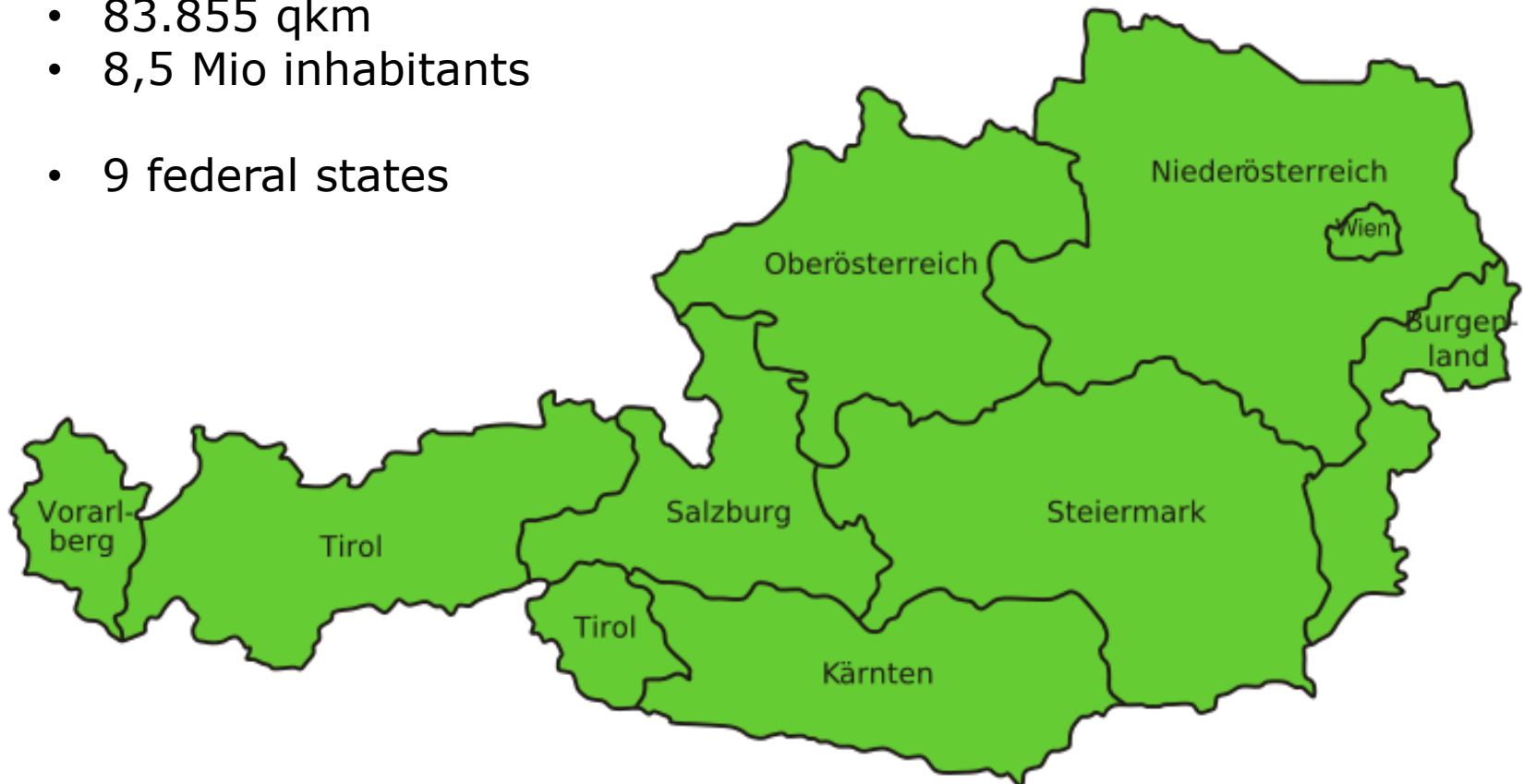


: The HEART of the Alps

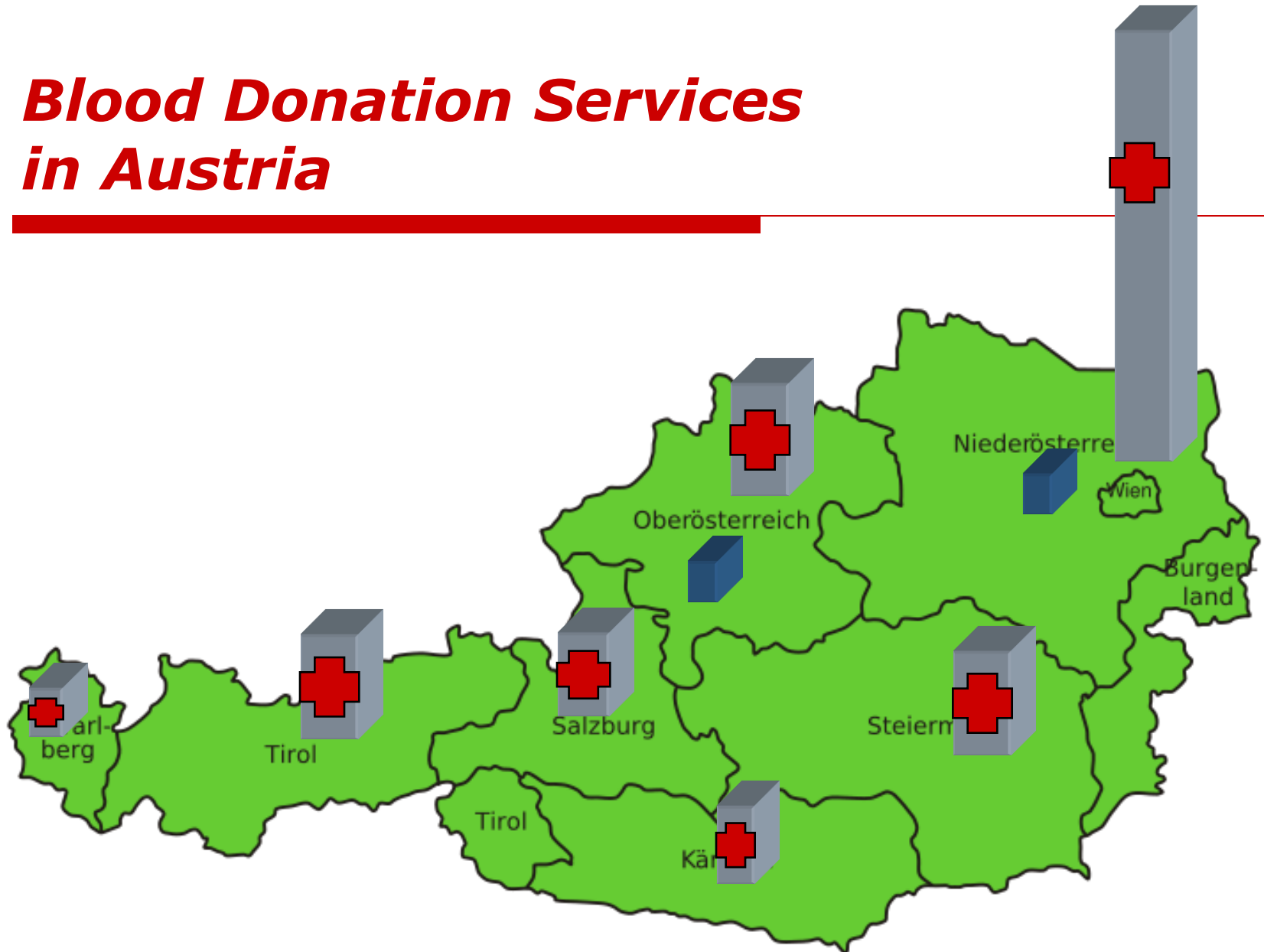


Austria

- 83.855 qkm
- 8,5 Mio inhabitants
- 9 federal states



Blood Donation Services in Austria

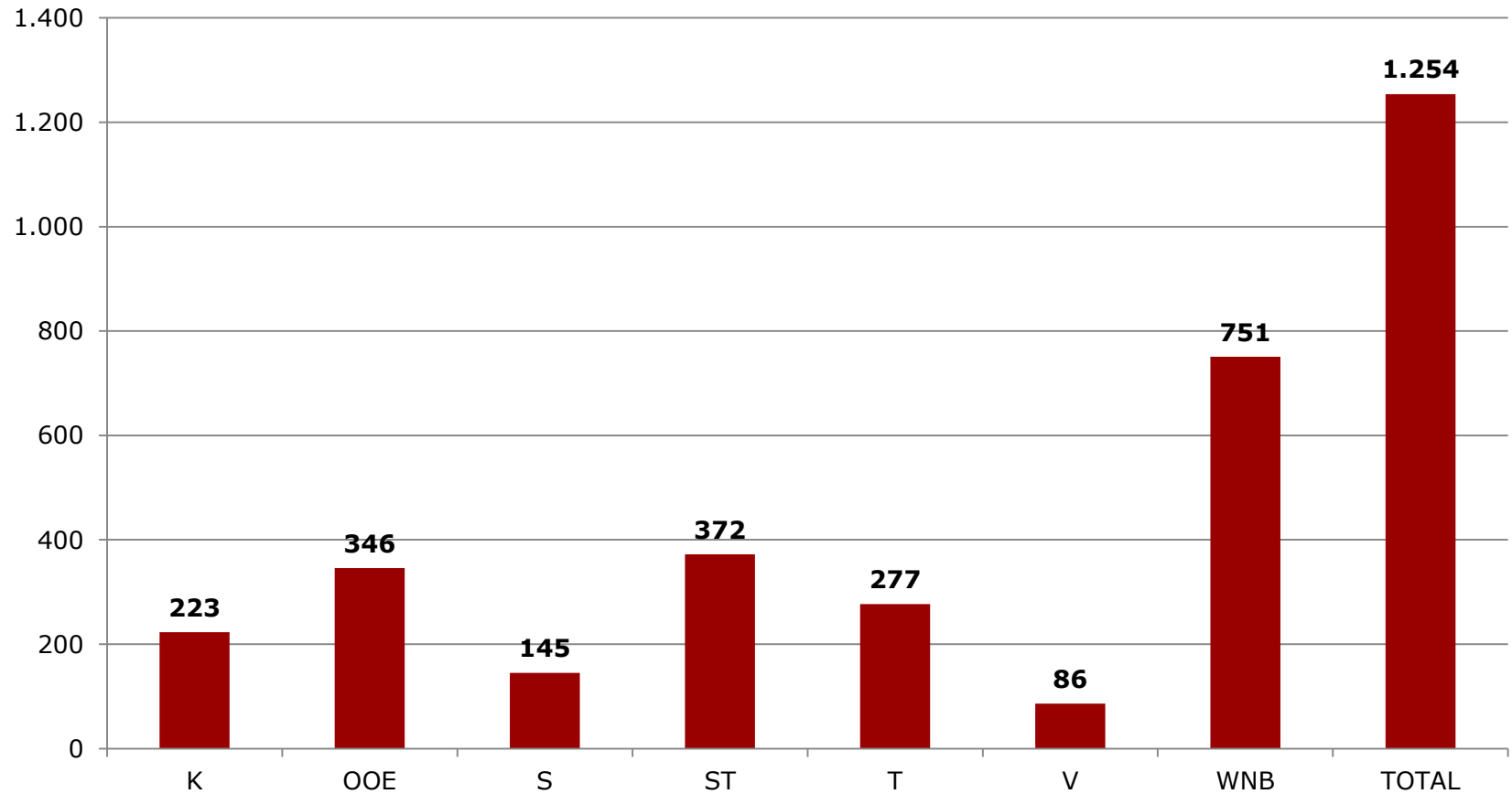


How and how much blood for transfusion is donated in Austria?

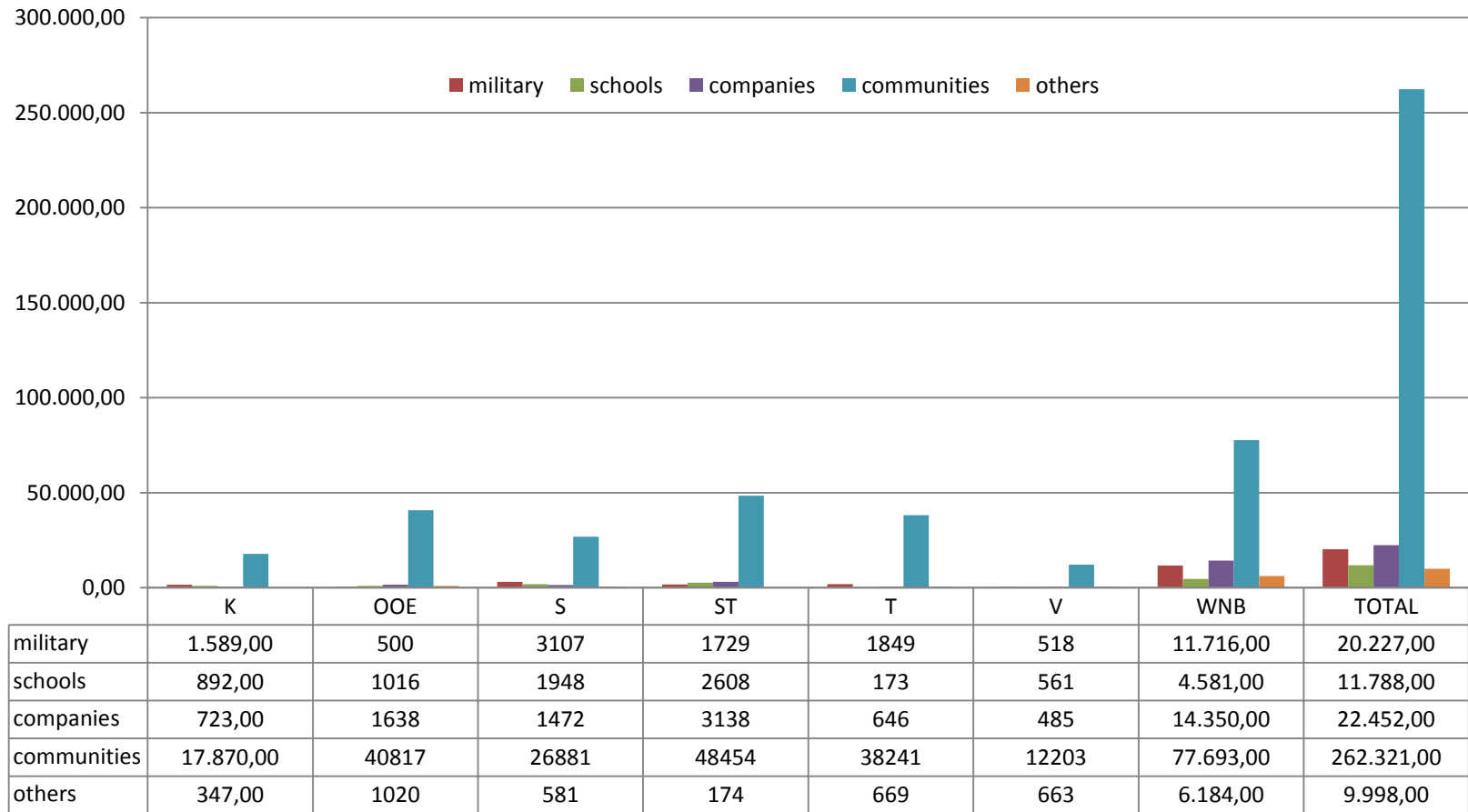




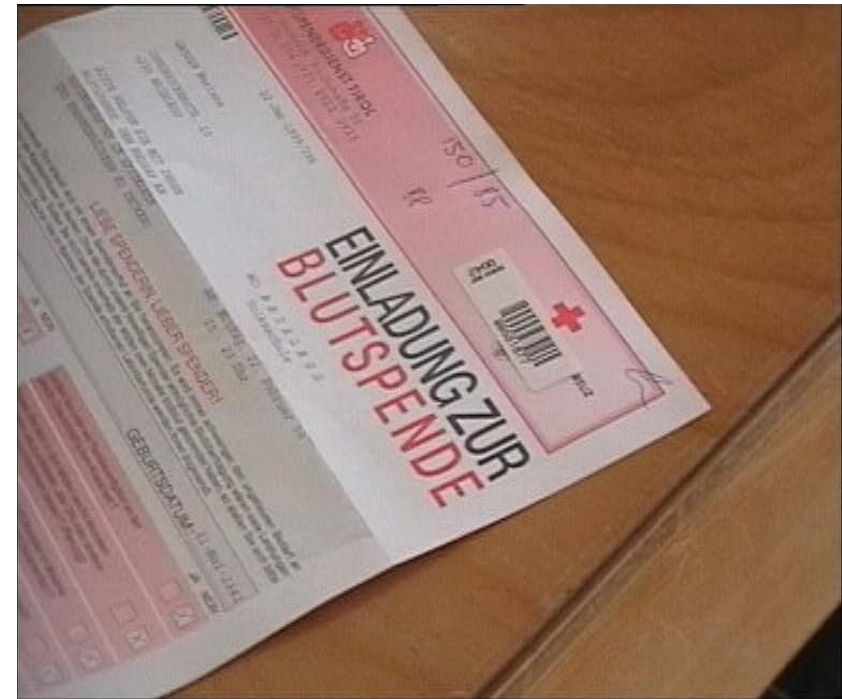
Nr of mobile sites



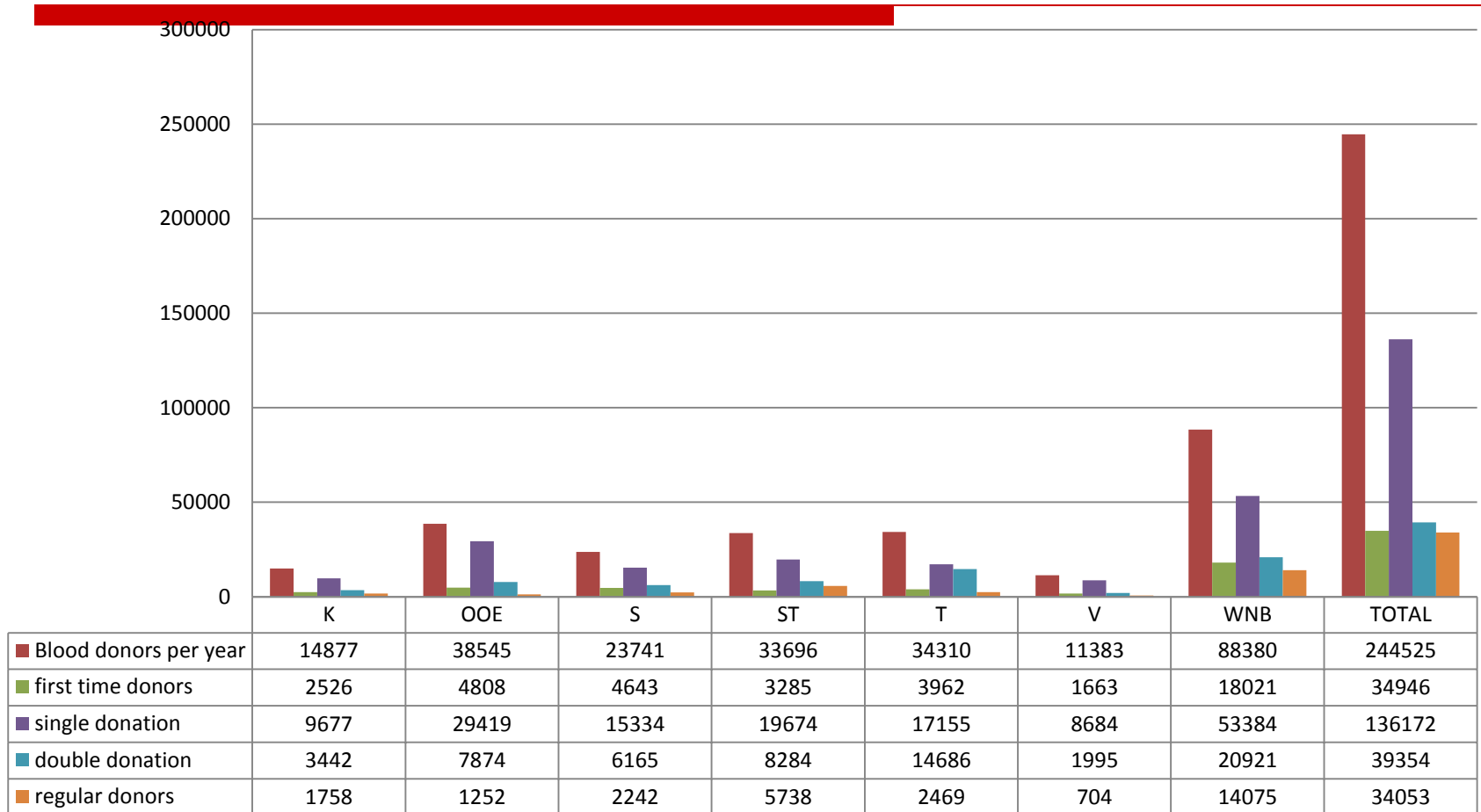
Origin of the whole blood donations



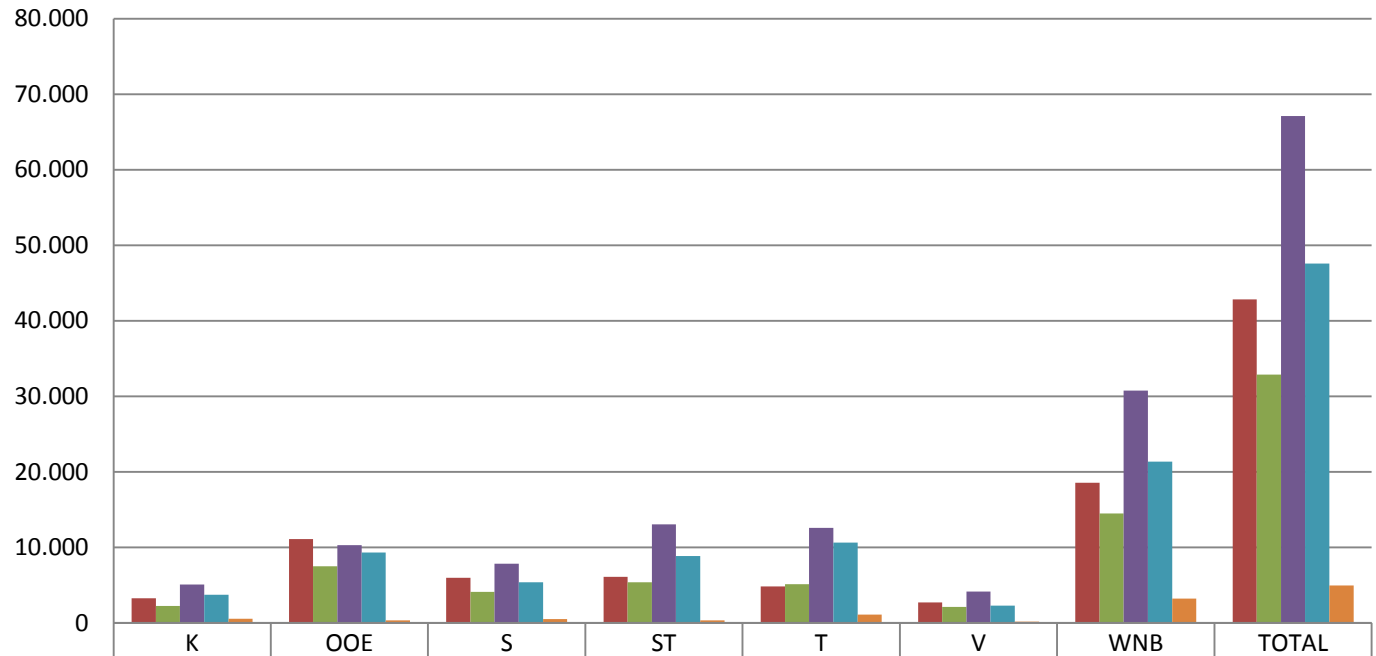
Donor questionnaire



Donors: Voluntary, non-remunerated



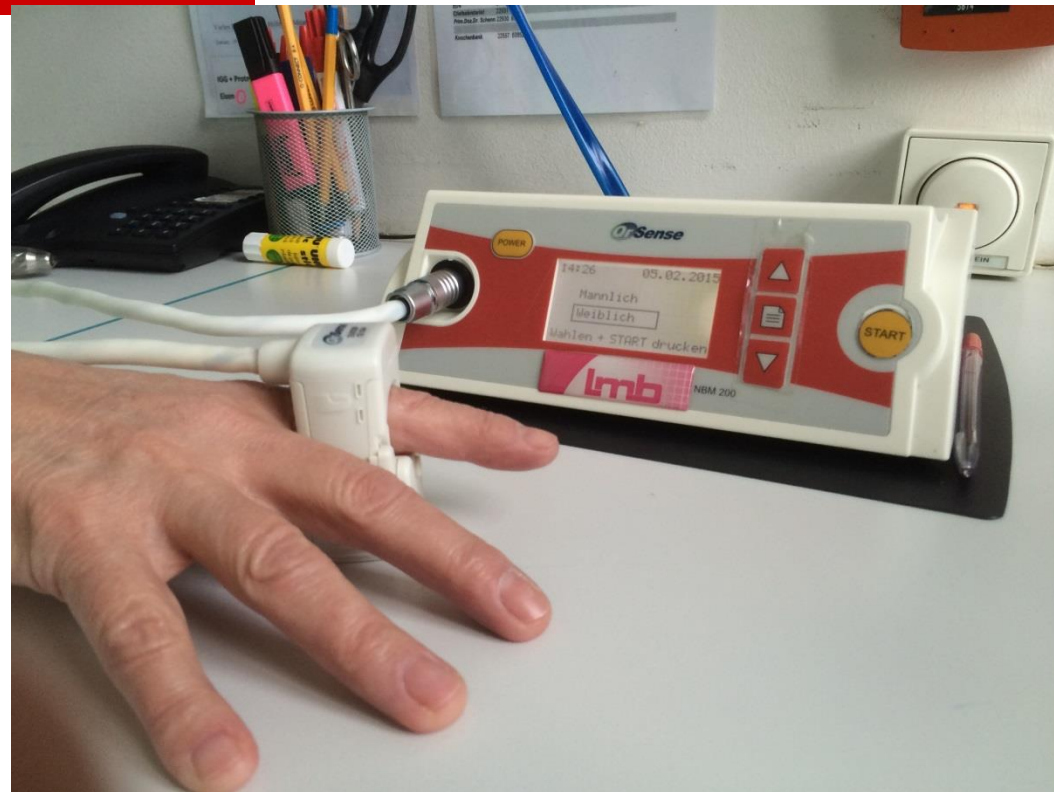
Age of donors



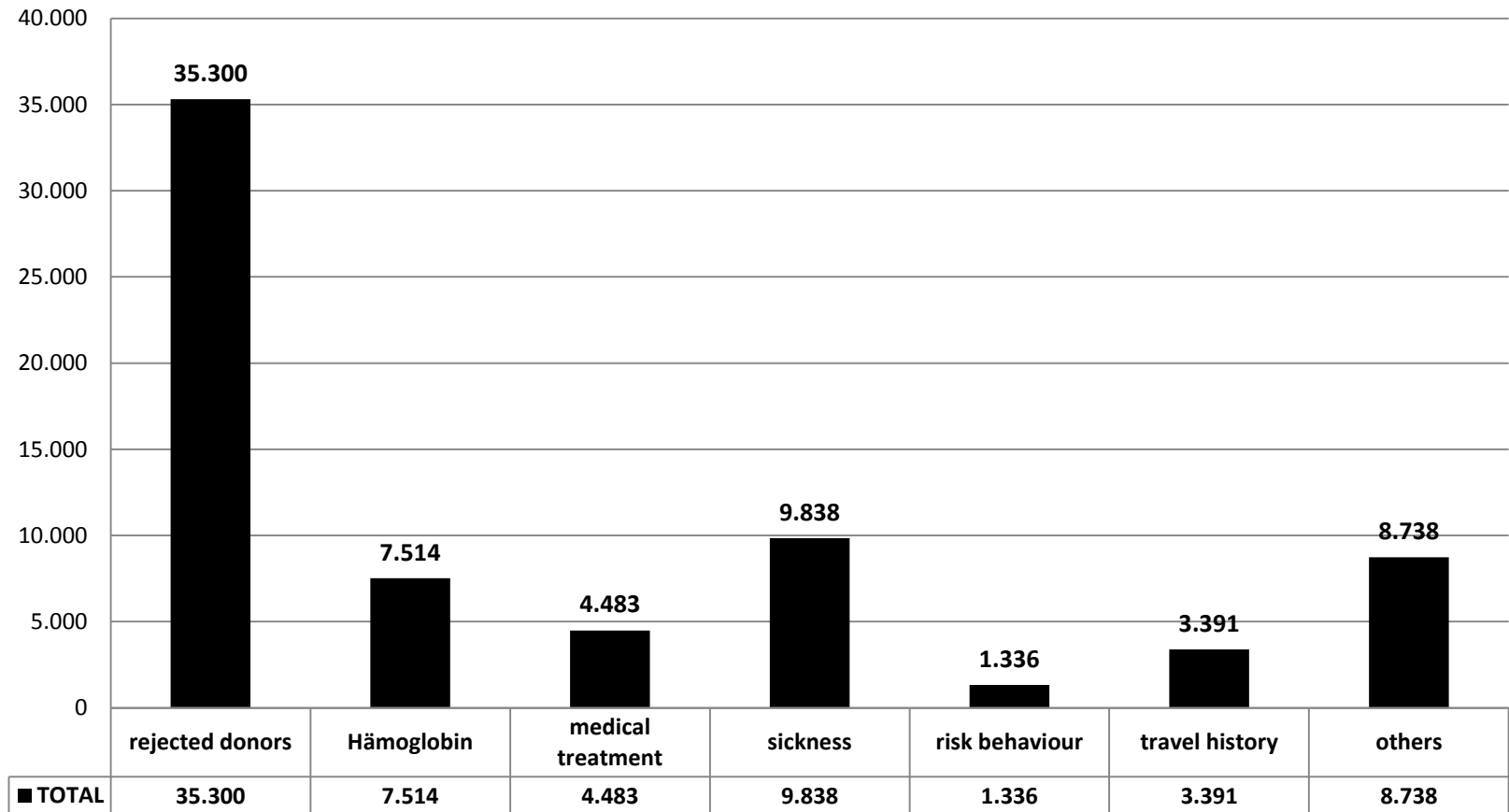
Donor examination



Haemoglobin- Determination



Nr. of rejected donors



Documentation of donor data



ROTES KREUZ BLUTSPENDEDIENST TIROL

1. Spende

SCHENNACH Harald
02-Okt-1959
Schäferstr. 7a
A-6200 JENBACH

99551815
BRIXL902
22-Feb-1999

99551815
BRIXL902
0056

99551815
BRIXL902
0056

PLASMA

ERY

ABNAHME
BRIXL902
0056

SCHENNACH Harald
99551815

15

RUFEN SIE DI...
STUNDEN AN!
Spezial-Formular...
ABO-Vorbestimmung

H. Schennach

Palmanova-2015

Donation



H. Schennach

Palmanova-2015



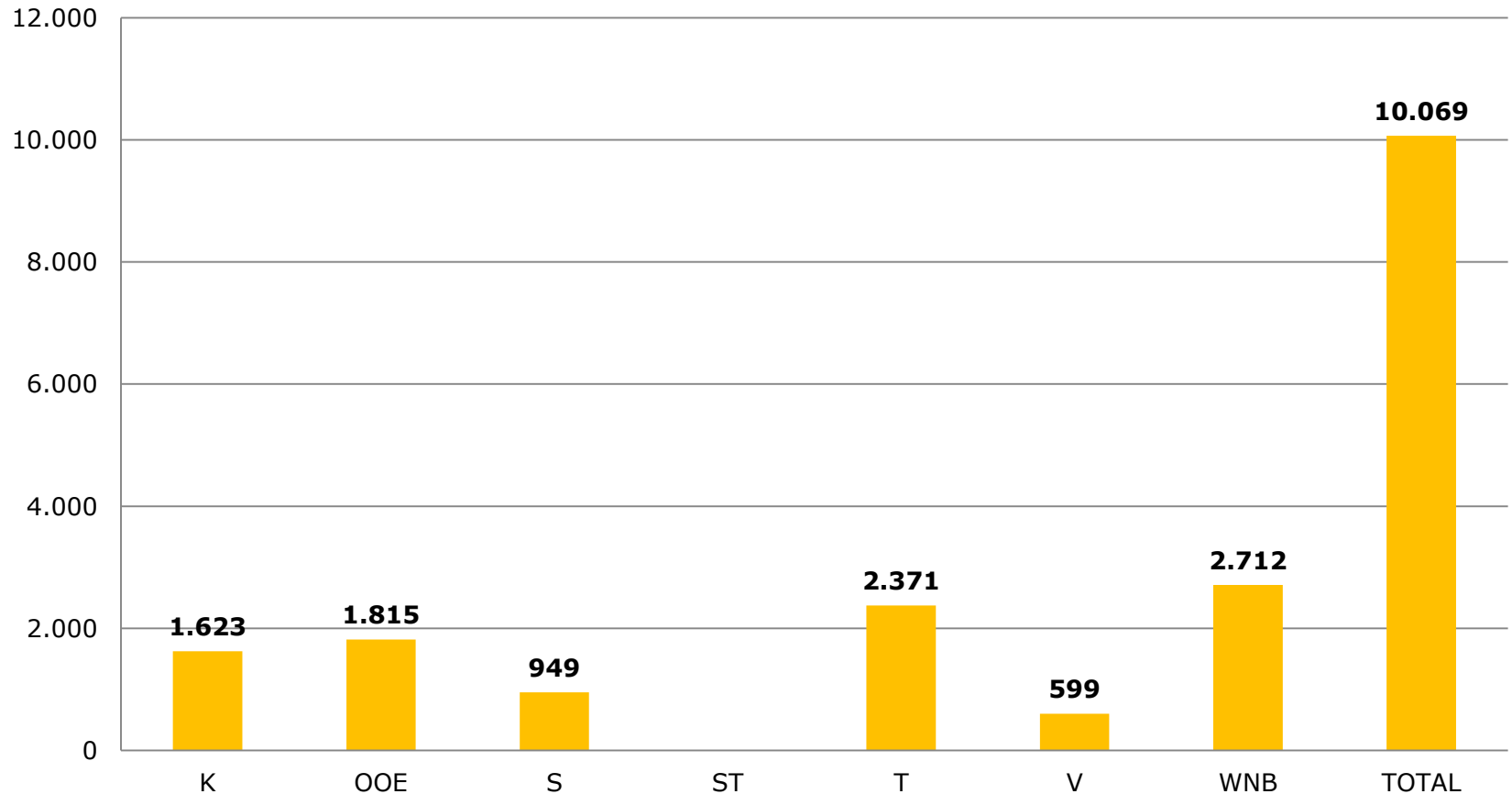


Preparation and Testing

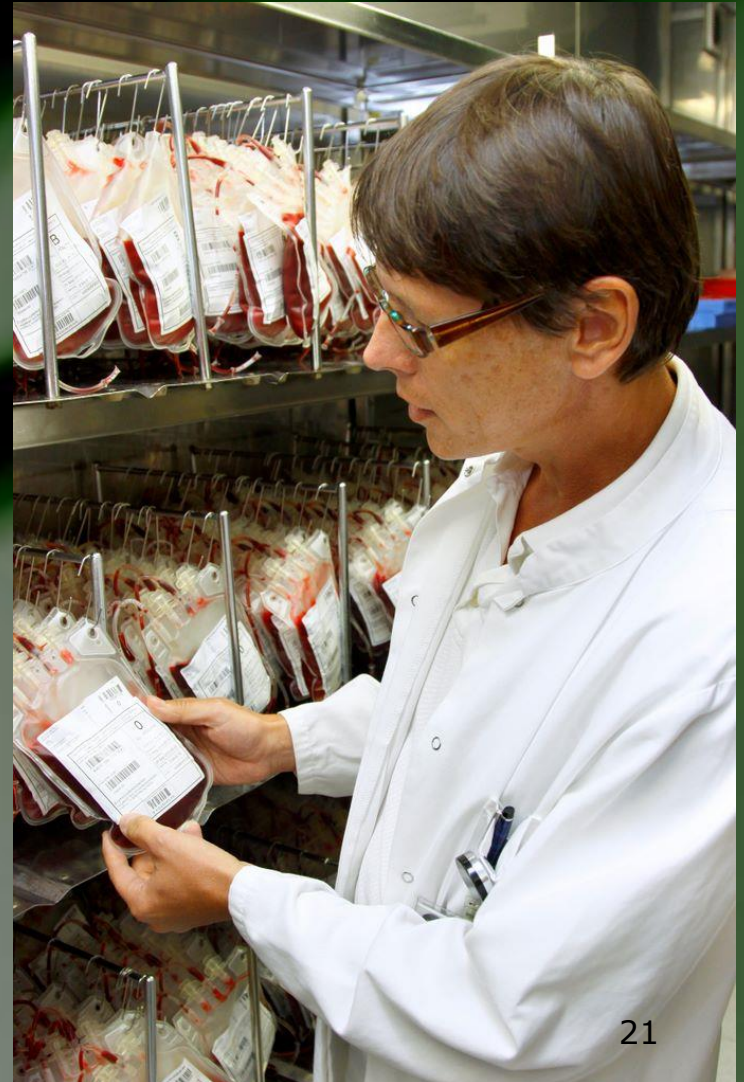




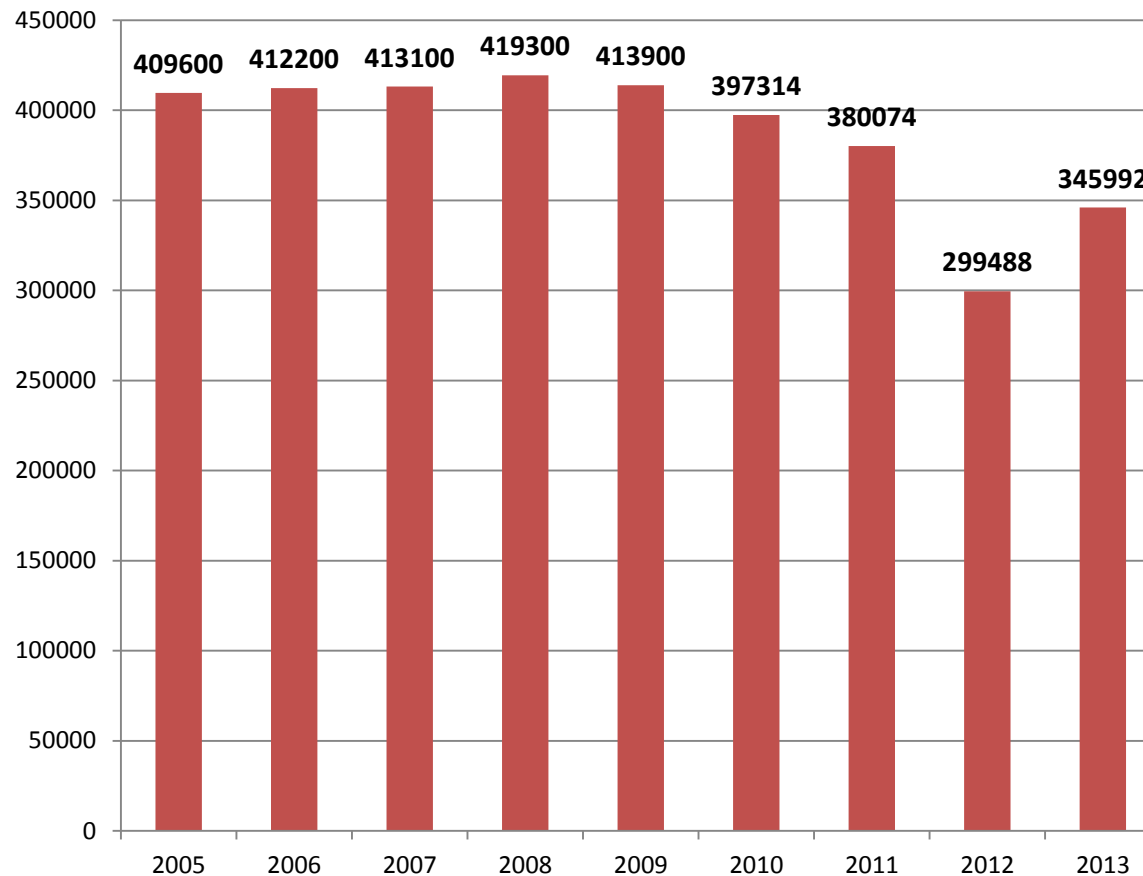
RC-Apheresis platelet donations



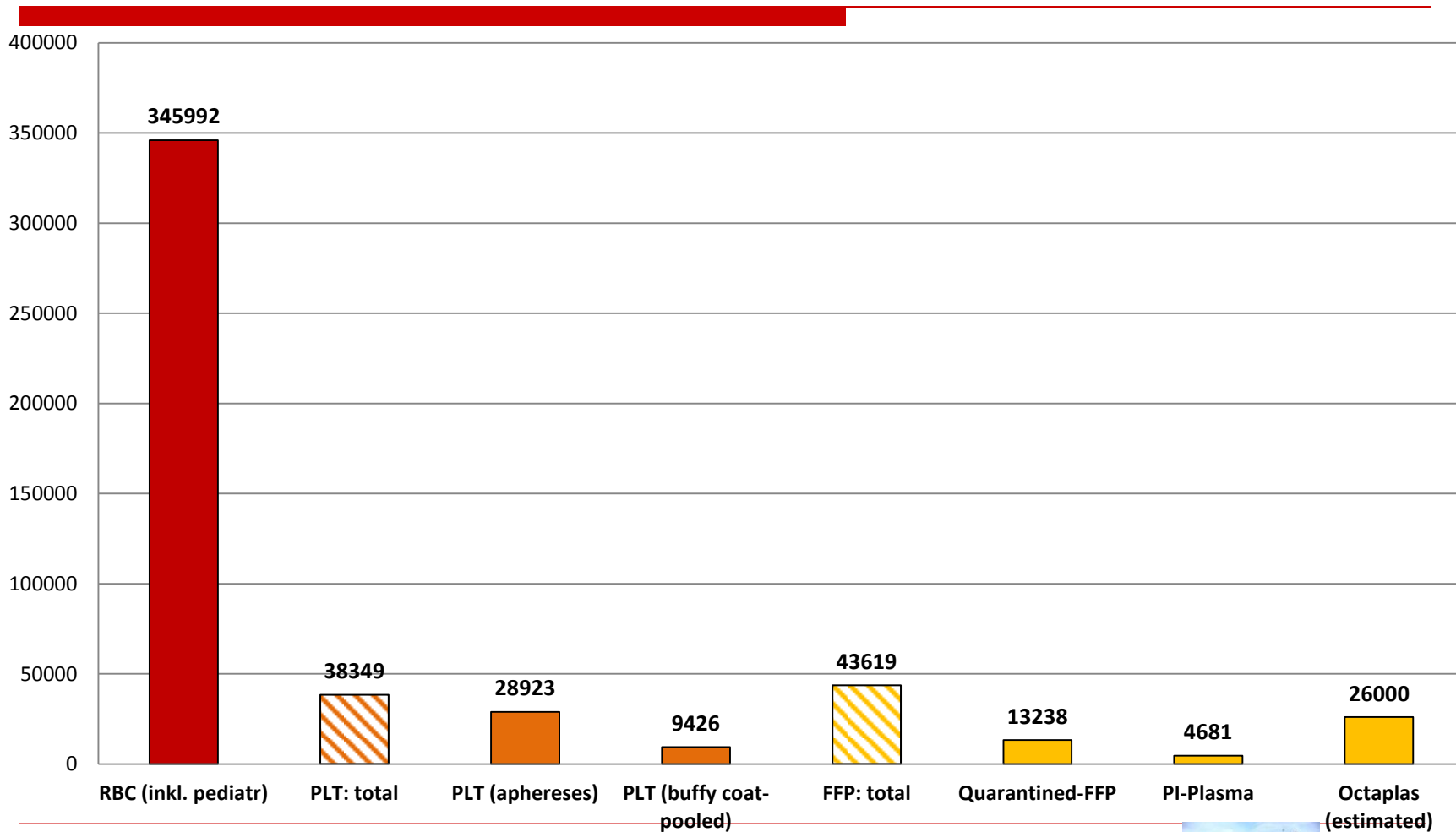
How much blood is needed in Austria?



RBC consumption 2005-2013 in Austria



Blood consumption 2013 in Austria



H. Schennach

Palmanova-2015



23

***Consumption per 1.000 inhabitants in Austria 2013
(8,5 Mio. inhabitants)***

Blood component	total	N/1000 inhabit.
RBC (incl. pediater. units)	345992	40,7
PLT: total	38349	4,5
PLT (apheresis)	28923	
PLT (buffy-coat, pooled)	9426	
FFP: total	43619	5,1
Quarantined plasma	13238	
PI-plasma (MB-treated)	4681	
Octaplas (estimated)	26000	



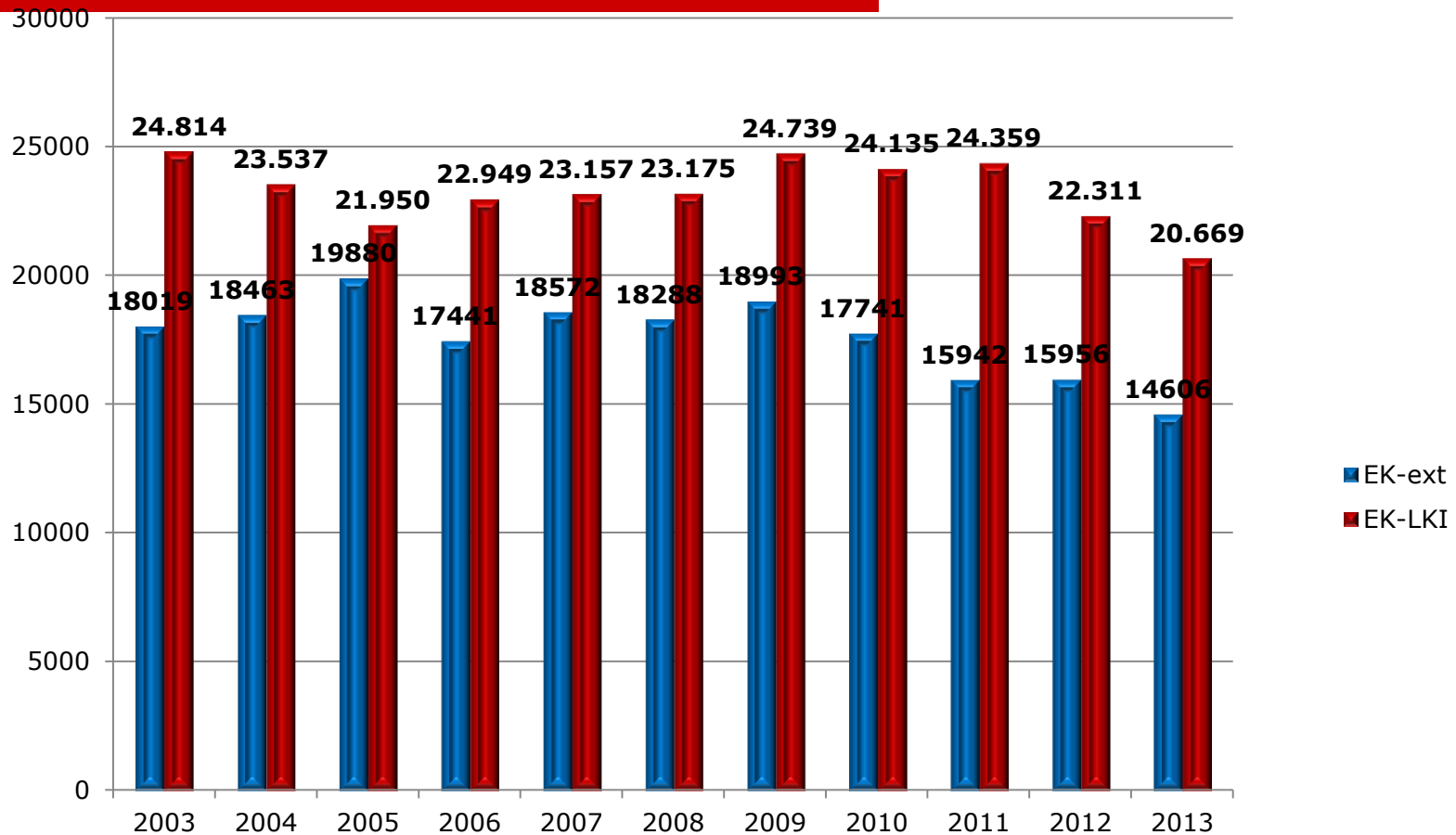
University Hospital Innsbruck



- 38 clinics
- 4 institutes
- 62 operating theatres
- 5344 employees:
1091 physicians,
1900 nurses
- all medical therapies
 - transplantation
(solid and non
solid organs)
 - major surgery



Issued Red Blood Cell Concentrates (RBC): University hospital vs other Tyrolean hospitals



What is the legal background?



Austrian Blood Safety Act 1999:

- Translates the EU-Directives
- Regulates
 - generally blood donation, including all forms of preparative apheresis, too.
 - management, licensing, minimal setting of donation sites, quality assurance and documentation
 - requirements concerning donor acceptance, donor selection, donor safety and identification.
- **Blood Donor Ordinance:**
 - Donor acceptance and examination,
 - medical history,
 - deferrals policy (temporarily, permanently), donation volumes, donation frequency and pre-donation testing
 - screening tests and
 - post-donation care are regulated in detail.



Pharmaceutical Act 1983

- ❑ **Blood, blood components and derivatives are pharmaceuticals** if they are used for medical purposes and therefore nearly all products for transfusion are subject to the pharmaceutical act and corresponding ordinances.
- ❑ This law **relates to principles of good manufacturing practices (GMP)** and sets quality requirements on the production and release of pharmaceuticals.
- ❑ It also **covers haemovigilance** and the mandatory reporting of serious adverse events and reactions.
- ❑ In 1998 by decree unique criteria for donor selection and identification based on international standards, and for HIV-testing of each blood donation were defined.

- ❑ **Pharmaceutical manufacturing ordinance 2005:**
 - A thorough **interpretation of good manufacturing practices.**
 - It is nowadays the major legal document in regard to inspections and the licensing procedures.



Other Standards

- ❑ Standards for hospital blood banks 2002
- ❑ Guideline for mobile donor sessions and fixed sites with blood, platelet and plasma donations – 2001. revised 2013
- ❑ Guidelines for blood group serology and transfusion medicine – 1996
- ❑ Act for medical goods 1996
- ❑ Plasmapheresis act 1975 and plasmapheresis ordinance 1978



Licensing, certification and accreditation



Must

- ❑ **Blood banks need a license on the basis of the pharmaceutical law**
 - The Austrian Federal Agency for Safety in Health Care is the competent authority
 - Bi-annual inspections by Agency for Health and Food Safety (AGES)
 - Site master file is the basic document
- ❑ **Blood donation sites and fixed locations are inspected by the local health departments**
- ❑ Most immunogenetic laboratories are based in BE and are accredited by the European Federation of Immunogenetics (EFI).



Voluntary

- Although certification of quality systems is not required by the specified laws and an uniform quality management system does not exist, all blood centres are **ISO 9001:2xxx** certified.
- Most quality systems are nowadays **hybrid systems of ISO 9001:2xxx and GMP.**



Tasks of blood establishments



Tasks of BE

- ❑ Service for 183 hospitals, either directly - if blood establishments are adjacent to hospitals - or indirectly by hospital blood banks
- ❑ Recruitment of donors,
- ❑ Preparation and screening of sufficient amounts of blood products for patient care in hospitals
- ❑ Compatibility testing
- ❑ Immunogenetics, genetics, immunology,
- ❑ Prenatal testing,
- ❑ Infectious disease testing
- ❑ Tissue banking and tissue engineering
- ❑ Therapeutical apheresis, immune absorption and photopheresis



Staff, qualification

□ Physicians:

- Specialization:
Specialist for
Transfusion Medicine
(6 years education)
- Licensed physicians
perform donor
examination on mobile
sessions



Staff, qualification

□ Medical technical assistants:

- Nowadays they are educated in medical colleges and finish with a bachelor`s degree

□ Biologists: Immunogenetics, research



Staff, qualification

□ Nurses:

- Can gain a specialization for apheresis operator

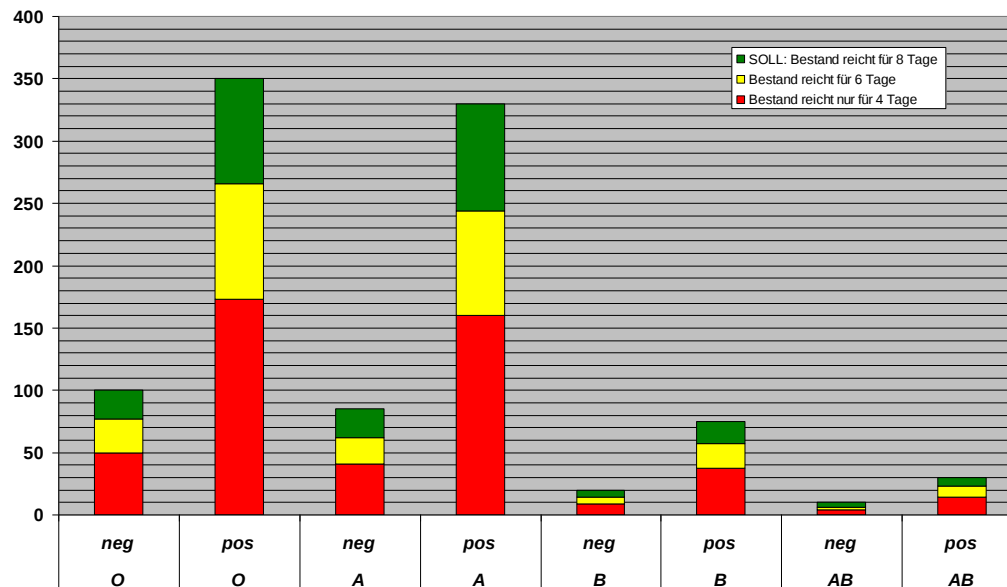


Emergency and disaster planning



Established Emergency-Coordination-Board

- Since 2007 regular meetings



Stammdaten

Zurücksetzen

What about plasma?



Plasma for fractionation

- Vienna is the „capital of plasma fractionation“:
 - 4 Mio/27 Mio liters of plasma worldwide are fractionated in Vienna
- 18 Plasmapheresis-sites
- 2013:
 - 40000 donors
 - 547840 liter donated

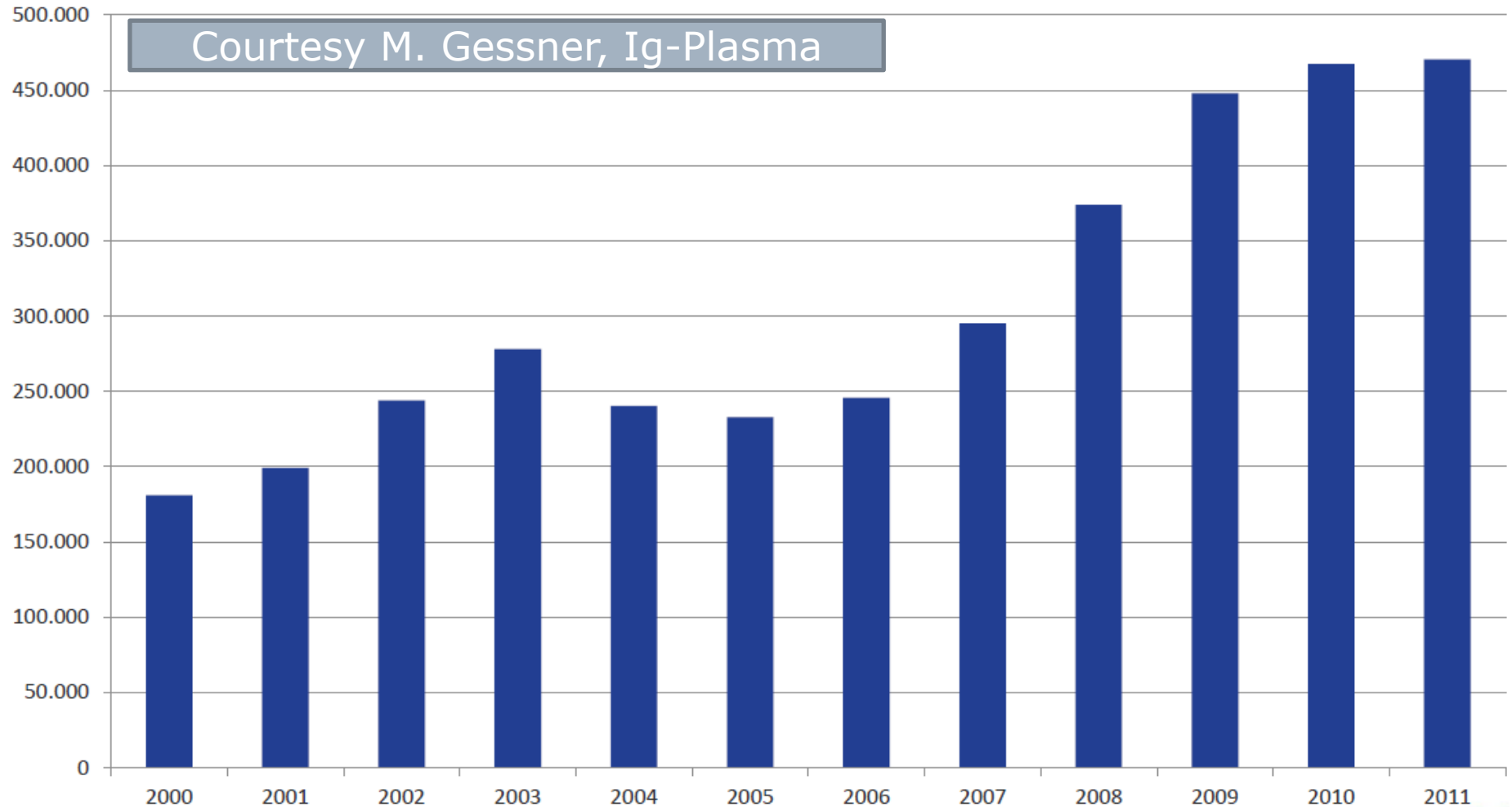


Location of the plasmapheresis centres



Plasmapheresis-Volume in liter, Austria 2000-2011

Courtesy M. Gessner, Ig-Plasma



Fractionated plasma per 1.000 inhabitants: Comparison of different countries

Country	total	N/ 1000 inhabit.
Austria	570000	67
Czech Republic	510000	51
Germany	3,2 Mio	39
USA	20 Mio	64



Thanks a lot for your attention!!

