

TRANSFUSION SERVICE IN CROATIA

Irena Jukić, CITM

IPFA, Zagreb, 16.05.2017.



LEGISLATIVE AND REGULATORY FRAMEWORK

Legislation (in accordance with EU Directives):

- **Law on Blood and Blood Components (NN 79/06; NN 124/11)**
- **Ordinance on the Certain Technical Requirements for Blood and Blood Components (NN 80/07; NN 79/13; NN 13/16)**
- **Ordinance on the Quality Assurance of Blood and Blood Components in the Authorized Healthcare Institutions (NN 79/06; NN 18/09)**
- **Ordinance on the System of Traceability of Blood Components and Monitoring of Serious Adverse Events and Serious Adverse Reactions (NN 63/07, NN 18/09)**
- **Ordinance on the Areas, Professional Workers and Medicinal-Technical Equipment for the Activities of Planning, Collection and Testing of Blood and Processing, Storage and Distribution of Blood Components (NN 41/10)**

Professional Standards:

- **Council of Europe. Guide to the use, preparation and quality control of blood components (Current version)**



ORGANIZATION / STRUCTURE OF THE NATIONAL BLOOD TRANSFUSION SERVICE

- **Government-oriented system**
- **Ministry of Health has responsibility by law for:**
 - **national BTS policy**
 - **the supply of safe blood products**
 - **recruitment of donors (led by Red Cross + CITM)**
 - **licencing for work, accreditation for production and testing**



FINANCING: FUNDING / COST RECOVERY

- **BTCs are financed by blood products they deliver to the hospitals and by patients pretransfusion and serological testing.**
- **Costs are covered by the Health Insurance.**
- **The prices of blood products are the same throughout the whole country and have to be approved by the MoH.**
- **The prices are lower than that in EU!**
- **We have to respect all the requirements from EU Directives**



CROATIAN NATIONAL BLOOD TRANSFUSION SERVICE

- **Donors – 100 %** voluntary, non remunerated
- **Promotion** – Red Cross and NBTS
- **Collection** – NBTS
- **WB donation:**
 - 42 donations per 1000 inhabitants,
 - blood bags â 450 mL,
 - women - once every 4 months, men - once every 3 months
- **Platelet (apheresis) donors** - up to 12 times per year.
- **TTI donor screening** – by national law
 - serological: HBV, HCV, HIV, syphilis;
 - molecular: ID NAT (triplex)
- **Self-sufficiency** - in supply of labile blood products.
- **Not self-sufficiency** - in supply of stabile plasma products.



REORGANISATION INFORMATISATION

NBTS

1996-1998
2000-2004

- 4 proposals were presented to MoH (4 Ministers)
- proposals were not recognized (decentralization vs centralization)
- No of blood collection centres spontaneously decreased from 35 to 21 – they could not meet the growing demands!

2006
2007
2009

- 2006/09: EU-Croatia Accession Negotiations, Request: Reorganization and Computerization; New legislation - in line with the EU Directives: 1 Law and 3 of the Ordinance; the draft of National Blood Policy.
- 2007: IPA project - HR2009-03-28-11 Strengthening the institutional capacity for blood, tissues and cells (MoH + CITM + CHC Zagreb). A precondition of acceptance: Reorganization and Computerization of NBTS!
- 2007: MoH approved the project of computerization of NBTS. CITM was in charge of implementation.

2007-2014

- Reorganization NBTS - in 3 phases of centralization:
 - 1st Phase – Collection and production (2010 – 2014) ☐ 8/21
 - 2nd Phase - Serological testing of TTI (2010 – 2014) ☐ 5/8
 - 3rd Phase - ID NAT testing of TTI (2013) ☐ 1/8
- Informatization of NBTS - (2007 – 2014) ☐ 1 IT system

WE STARTED WITH ANALYSES SAFETY, QUALITY , COST,..

- **Analyses of all steps and all aspects:**
 - promotion**
 - transportation**
 - collection**
 - production**
 - storage**
 - testing**
 - quality control**
- **It included all the costs (materials, tests, payments,...)**



MICROORGANIZATION OF REGIONAL BLOOD ESTABLISHMENTS AND CITM

QUALITY MANAGEMENT EDUCATION HOSPITAL TRANSFUSION ACTIVITIES

- **Collecting blood and plasma from voluntary blood donors - regional**
- **Centralized testing of samples of donors blood - regional**
- **Centralized production of blood components - regional**
- **Storage and distribution of blood components according to the needs: regional**
- **Storage of plasma for fractionation and sending it to the center for processing**
- **Consular service (regional)**
- **National IT transfusion program networking**
- **Responsible person: MD specialist of transfusion medicine**



MICROORGANIZATION OF HOSPITAL TRANSFUSION UNIT

**QUALITY ASSURANCE
EDUCATION
EMERGENCY SERVICE**

Activities and responsibilities:

- **reception and issuance blood components, decision for transfusion therapy, monitoring and control over transfusion therapy, haemovigilance**
- **Imunohematology: red blood cells, platelets, granulocytes, pretransfusion testing**
- **Peripheral stem cells: collection, preparation, storage**
- **Hemostasis: testing and diagnostics of hereditary diseases**
- **Serology testing of patients**
- **Consular service: immunocytochemical diagnosis, therapeutic apheresis, haemostasis disorders**
- **National IT transfusion program networking**
- **Responsible person: MD specialist of transfusion medicine**



Year

2001.

No.unit

153.586

2008.

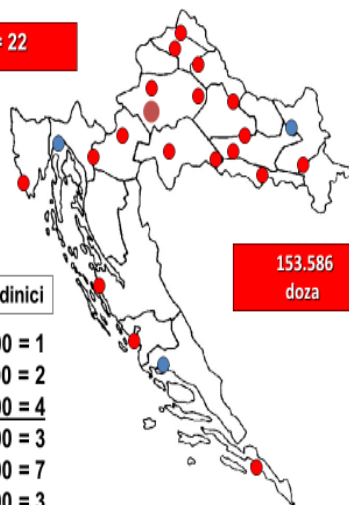
166.347

2013.

170.042

Transfuzijske jedinice u RH koje uzimaju krv -
2001.g.

Br. tr. jed. = 22



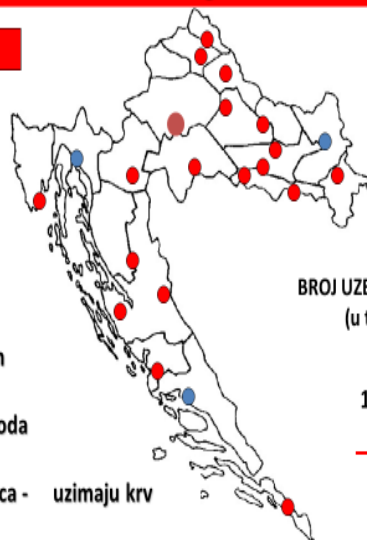
153.586
doza

Uzete doze krvi / tr. jedinici

> 65 000 = 1
od 10-12 000 = 2
od 5-10 000 = 4
od 3-5 000 = 3
od 2-3 000 = 7
od 1-2 000 = 3
< 1 000 = 2

Transfuzijske jedinice u RH koje uzimaju krv -
2008.g.

N = 21



BROJ UZETIH DOZA
(u tisućama)

>80 = 1
10-14 = 3
5-10 = 3
3-5 = 2
2-3 = 7
1-2 = 4
< 1 = 1

● HZTM samostalan

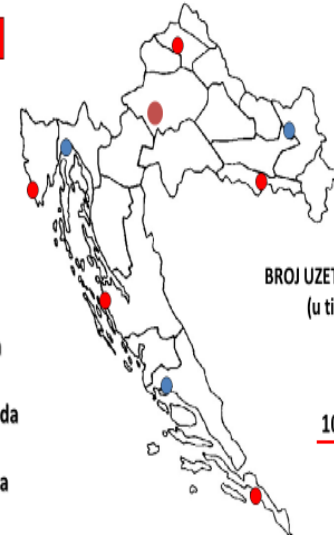
● 3 Regionalna zavoda

● 17 bolnička jedinica - uzimaju krv

166.347
doza

Transfuzijske jedinice u RH koje uzimaju krv -
2013.g.

N = 9



BROJ UZETIH DOZA KRV
(u tisućama)

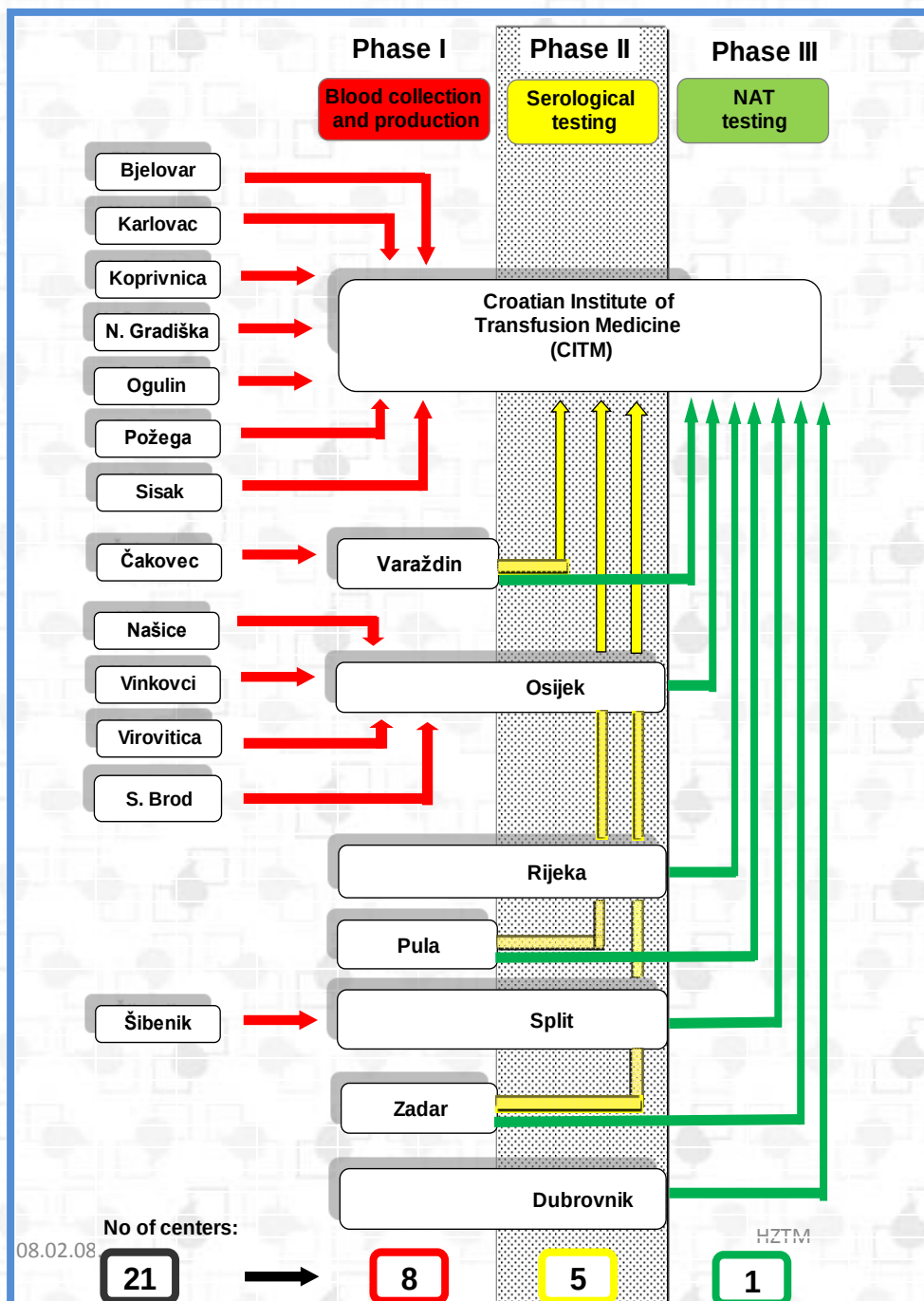
>90 = 1
10-20 = 4
2-5 = 4

● HZTM samostalan

● 3 regionalna zavoda

● 5 bolničkih jedinica





Reorganization of NBTS 1998 – 2014

Reorganization of NBTS - 3 phases:

- I. Collection and production (8)
- II. Serology testing (5)
- III. NAT testing (1)

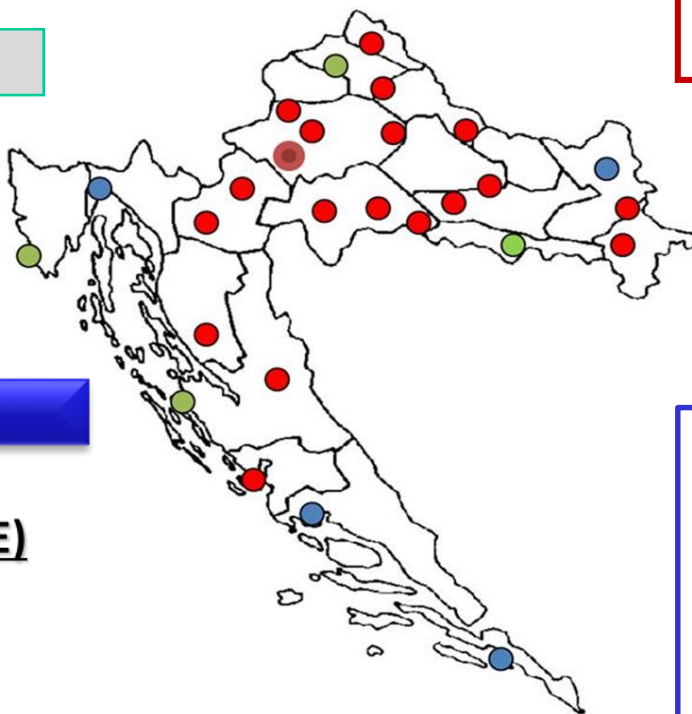


CROATIAN NATIONAL BLOOD TRANSFUSION SERVICE (NBTS) 2015

CRO population 4.284.899

M = 48,2 %; W = 51,8 %

2015:
191.442 units
(42/1000)



35 transfusion centres

8 – Blood Establishments (BE)

1 – CITM (ZG)

4 - Regional (OS, RI, ST, DU)

3 - Subregional (VA, ZD, .PU)

35 – Hospital Blood Banks (HBB)

8 – part of BE

27 – Hospital Units

105.288	HZTM
26.771	KBC Osijek
18.817	KBC Split
14.243	KBC Rijeka
11.456	OB Varaždin
5.287	OB Zadar
5.484	OB Pula
2.445	OB Dubrovnik

1/36.

HZTM



2016.

7 BE

● 1 national BE

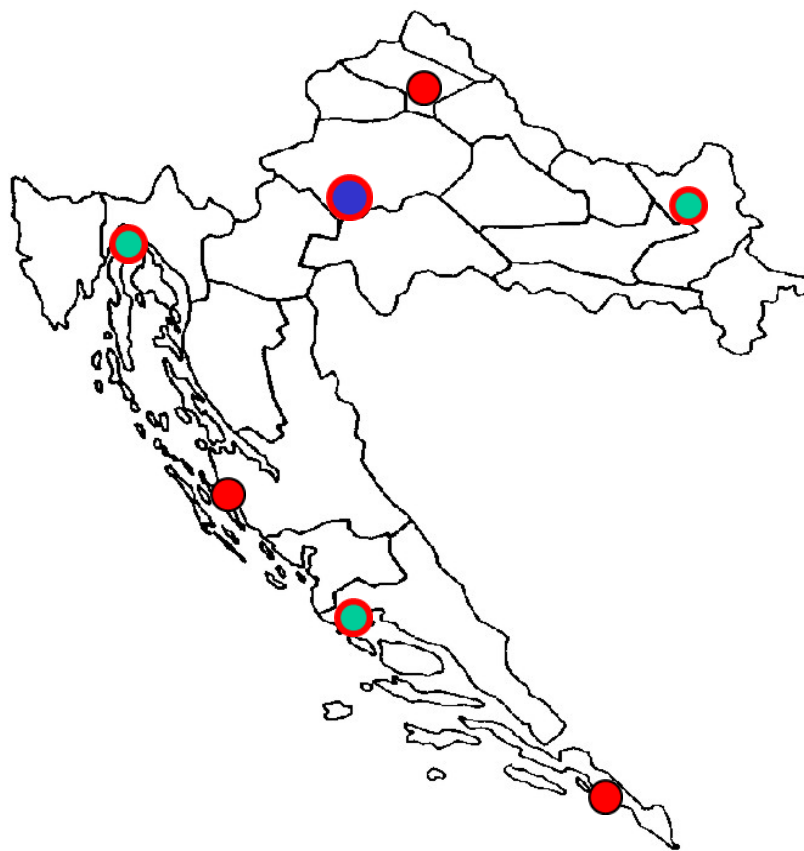
CITM Zagreb

● 3 regional BE

Osijek, Rijeka, Split

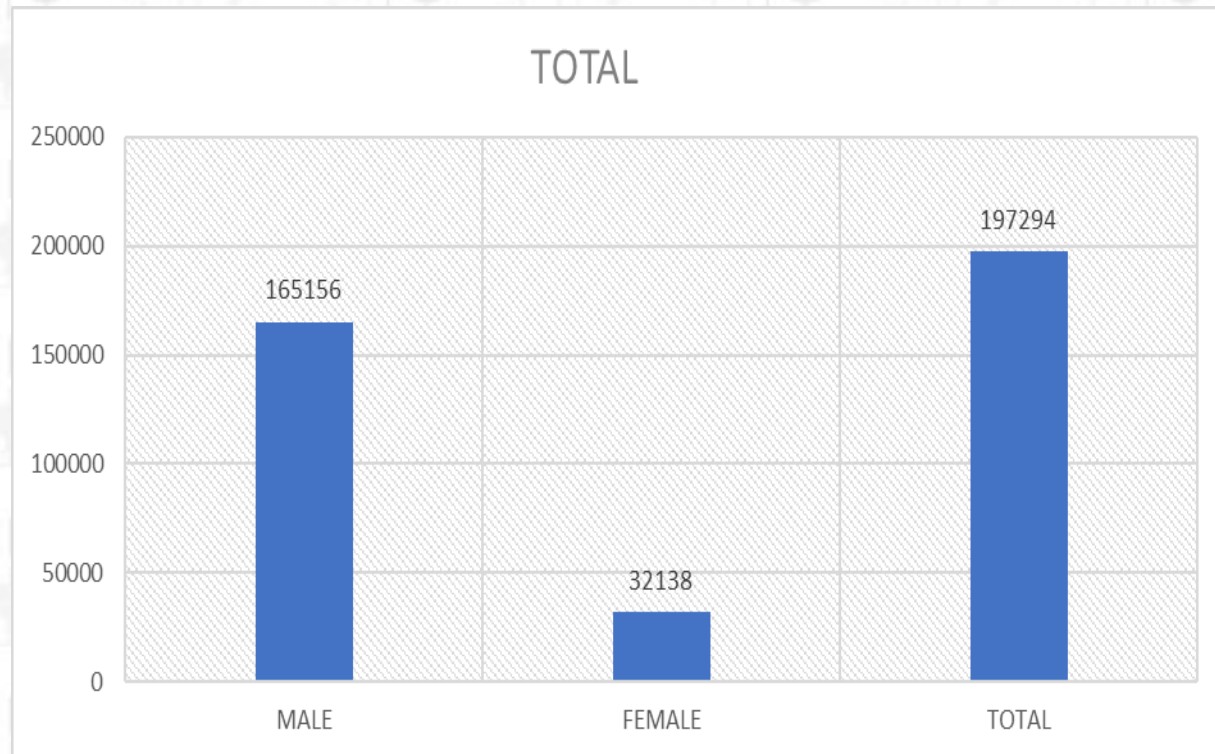
● 3 subregional BE

Dubrovnik, Varaždin,
Zadar



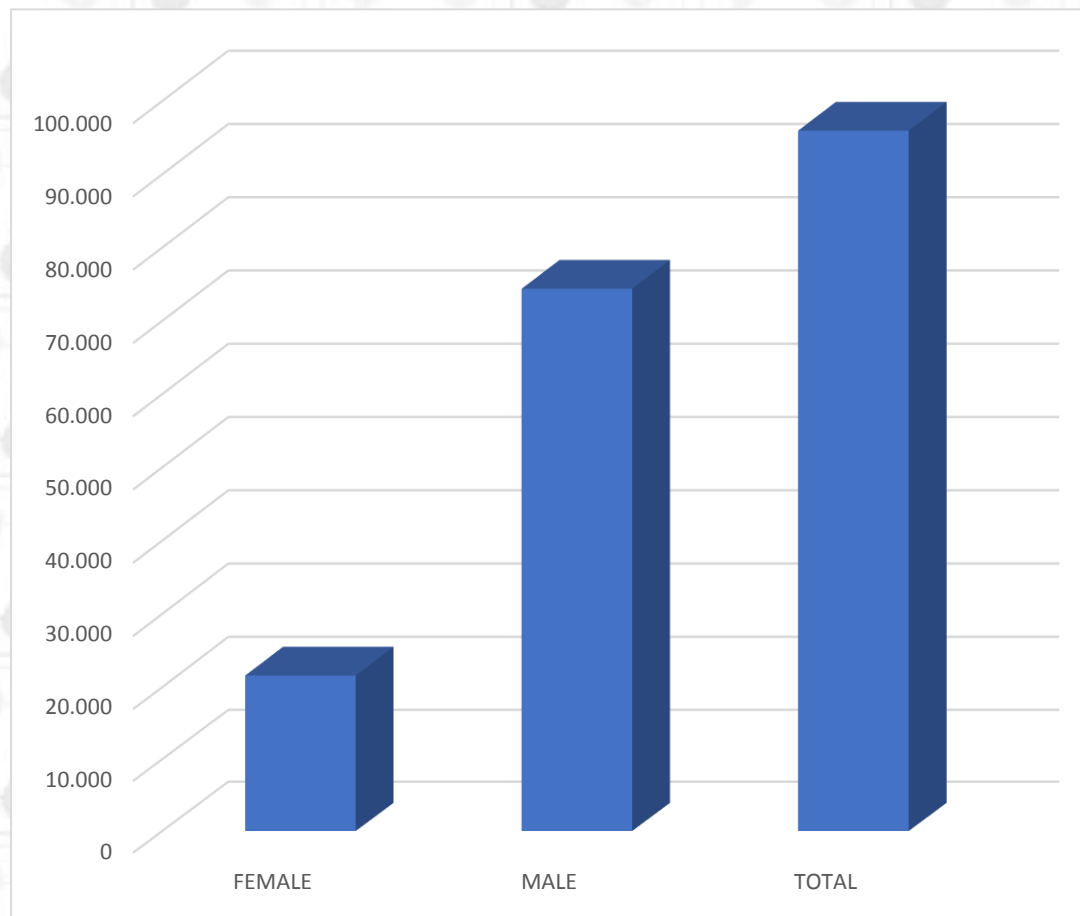
Blood collection 2016. – 197.294

Gender	Accessed	Rejected	Give blood
MALE	182473	17317	165156
FEMALE	45177	13039	32138
TOTAL	227650	30356	197294



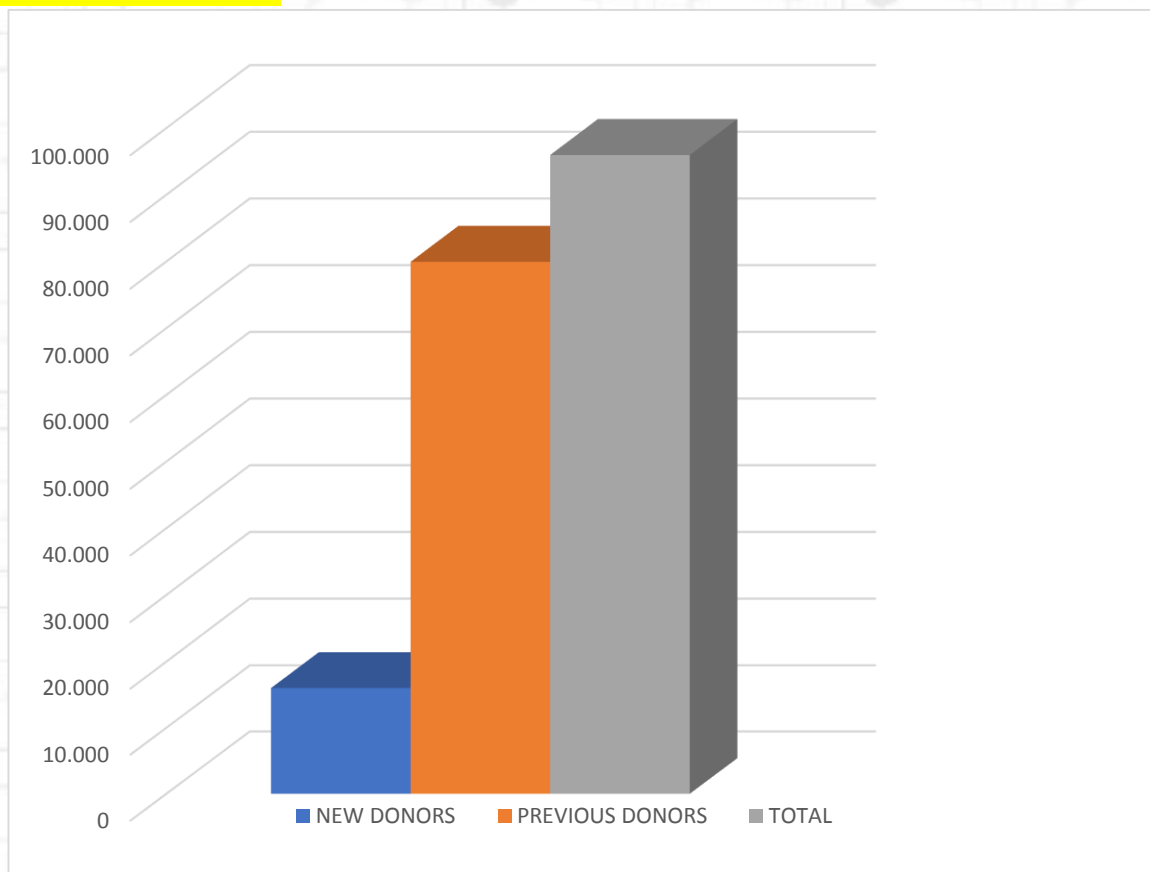
The ratio of male and female donors

Gender	No	%
FEMALE	21.581	22.5
MALE	74.377	77.5
TOTAL	95.958	100.0



The ratio of new and regular donors

	NEW DONORS (%)	REGULAR DONORS (%)	TOTAL
FEMALE	5.377	16.204	21.581
MALE	10.638	63.739	74.377
TOTAL	16.015 (16.7%)	79.943 (83.3%)	95.958 (100%)



PRODUCTION - 2016.

- **TOTAL 512.364 blood components**
- **index 2.68**

Blood component (BC)	No BC	Destroyed BC	Destroyed (%)
RBC	191 040	4.461	2.34
Platelet	131.126	9.352	1.38
FFP	75.838	17.112	22.56
Plasma for fract.	102.687	27.592	26.87
KRIO	10.737	387	3.60
QC	14.166	332	2.27



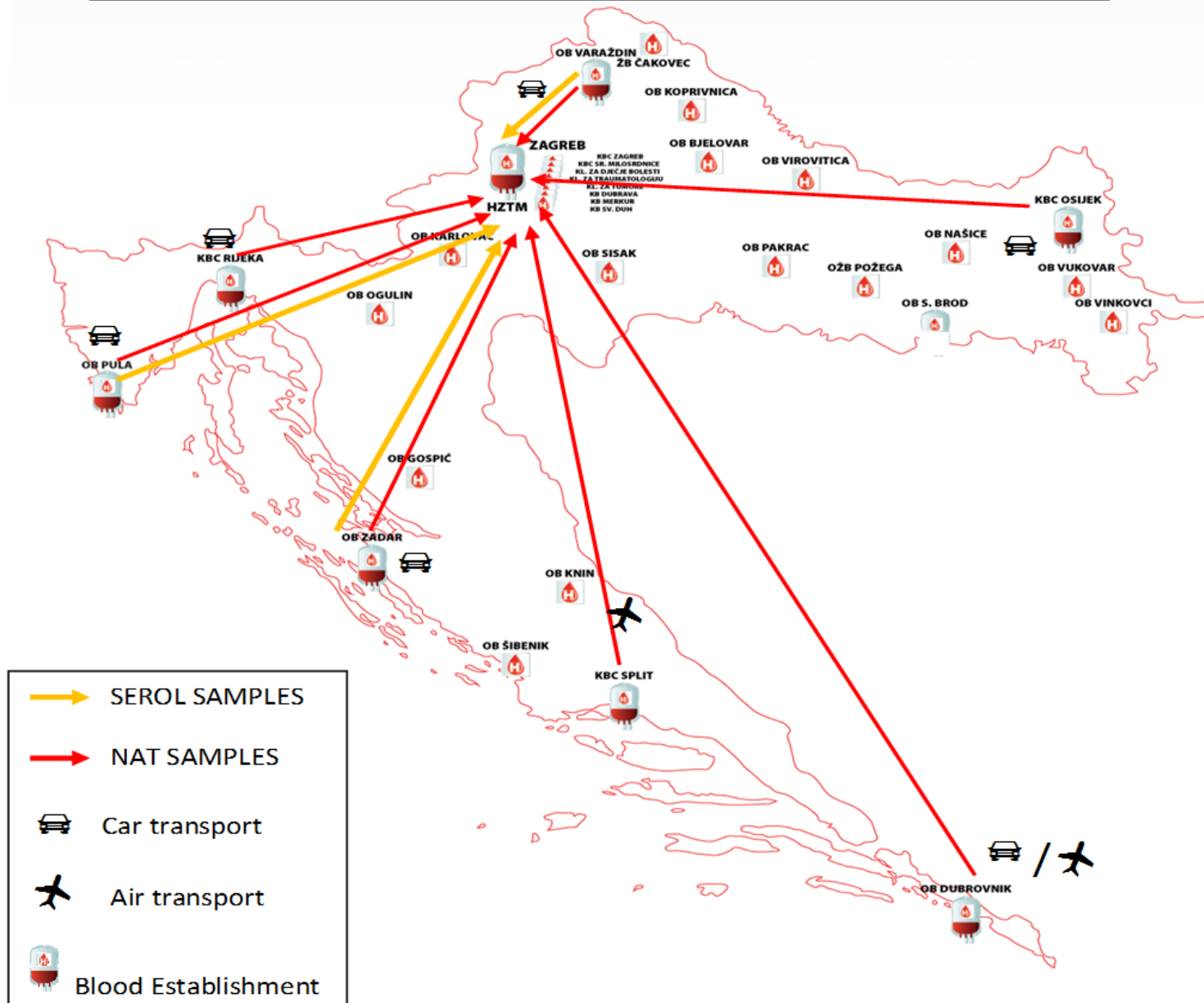
EQUIPMENT in BEs

All BEs have:

- **standardized blood collection equipment (scale mixers, welders, cellular separators, validated blood bags, ...)**
- **standardized production equipment (centrifuges, welders, shock freezers, connectors, extractors,.)**
- **controlled coolers for blood storage, freezers at -25 ° C for plasma**
- **validated serological testing machines for TTI**
- **validated machines for immunohematological testing**



NBTS Croatia – ORGANIZATION OF BLOOD DONOR'S SAMPLES TRANSPORT from 7 Blood Establishments to CITM (NAT and Serological Infectious Markers testing)



TTI confirmatory testing

- Results for Croatia 2016.

POZITIV		HBV	HCV	HIV	Sifilis
ID-NAT and serol. test		13	4	3	np
Only serol. test		0	3	0	5
ID NAT test	WP inf.	1	0	0	np
	Ocult HBV inf. (OBI)	2			
TOTAL		16	7	3	5



Three-Year Experience in NAT Screening

- Number of repeated reactive blood units (A total of **545,463** donations)

Testing	HBV	HCV	HIV-1
NAT* and serology**	32	16	9
Serology	1	6	0
ID-NAT	50	0	1
Total	83	22	10

*Procleix Ultrio Plus Assay.

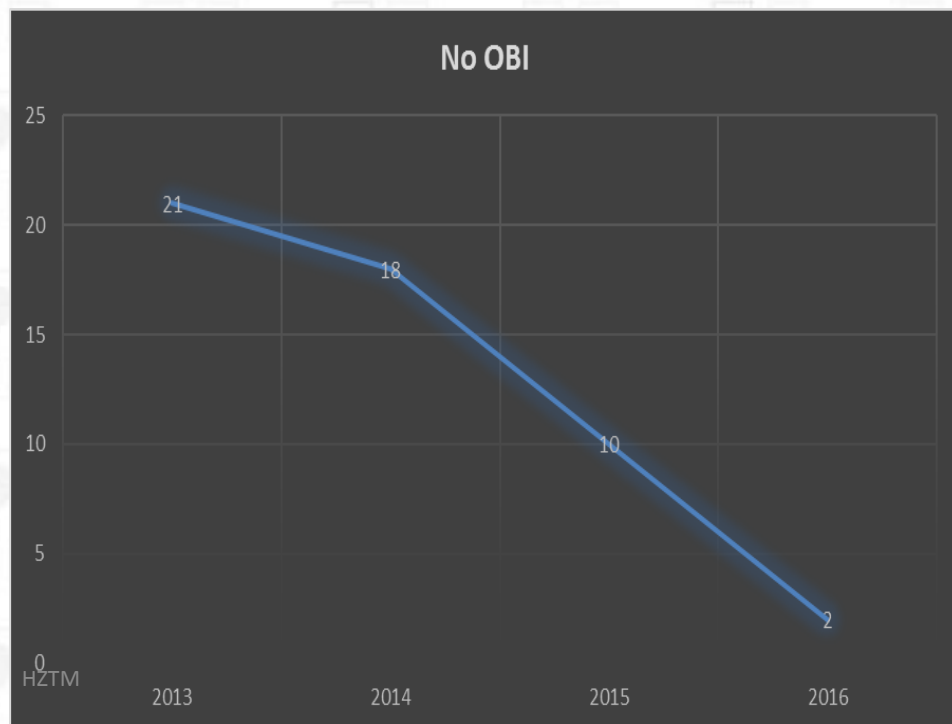
** HBV HBsAg tests (ELISA/CMIA); HCV a combination of anti-HCV and HCV Ag/Ab (ELISA/ELFA), HIV-1 a combination of 3 HIV Ag/Ab assays (ELFA/ELISA/CMIA) and anti-HIV, HIV-Ag and imunoblot test

Safic et al: Three-Year Experience in NAT Screening of Blood Donors for Transfusion Transmitted Viruses in Croatia, Transfus Med Hemother 2017;44:1-6



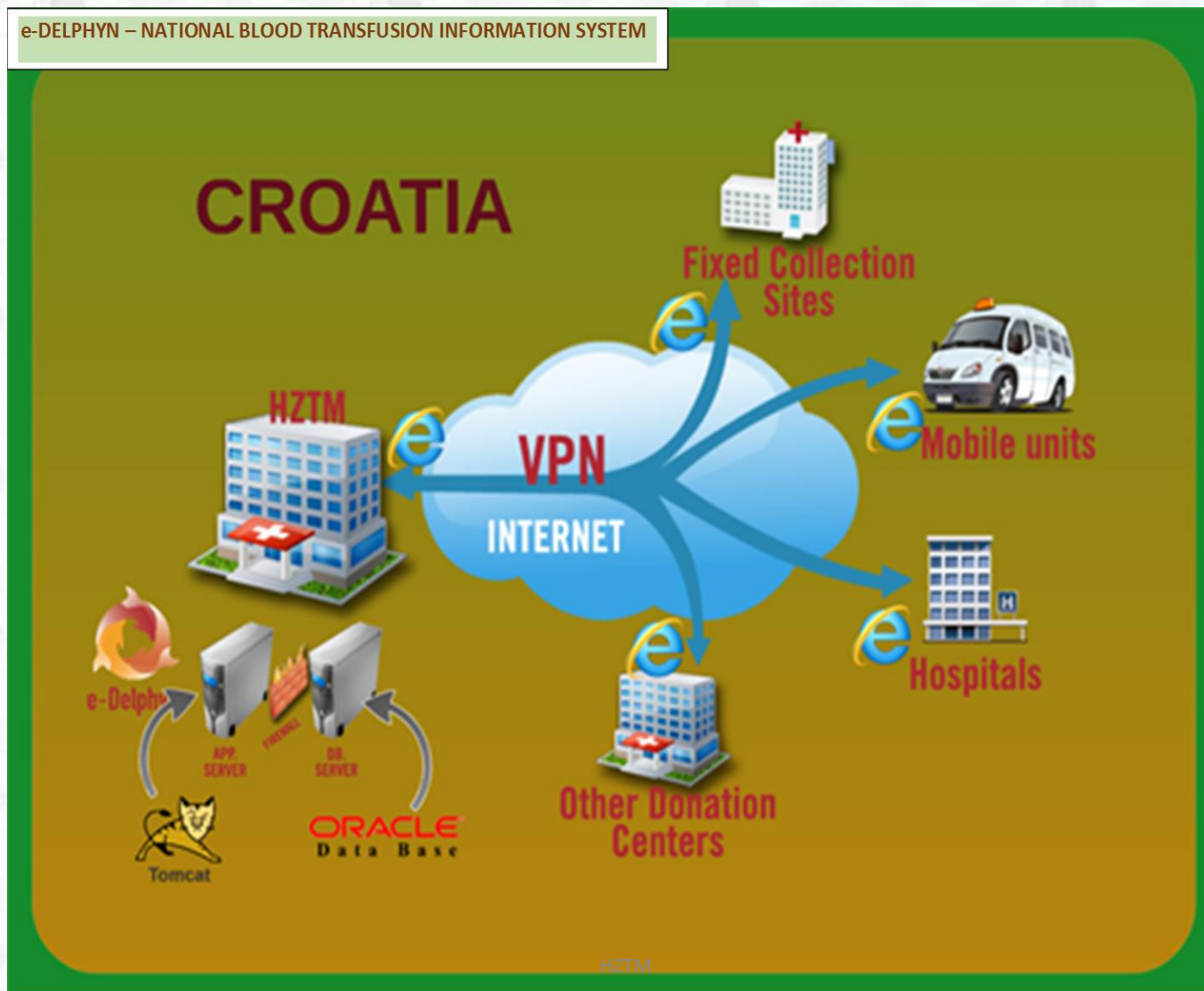
Experience in NAT Screening (OBI)

Year	No blood unit	No OBI pozitivnih	Prevalen / 10 ⁵
2013.	183.072	21	11
2014.	183.410	18	10
2015.	193.312	10	5
2016.	197.294	2	0.1



NATIONAL IT SYSTEM (e-Delphin) – schema from Hemasoft

e-DELPHYN – NATIONAL BLOOD TRANSFUSION INFORMATION SYSTEM

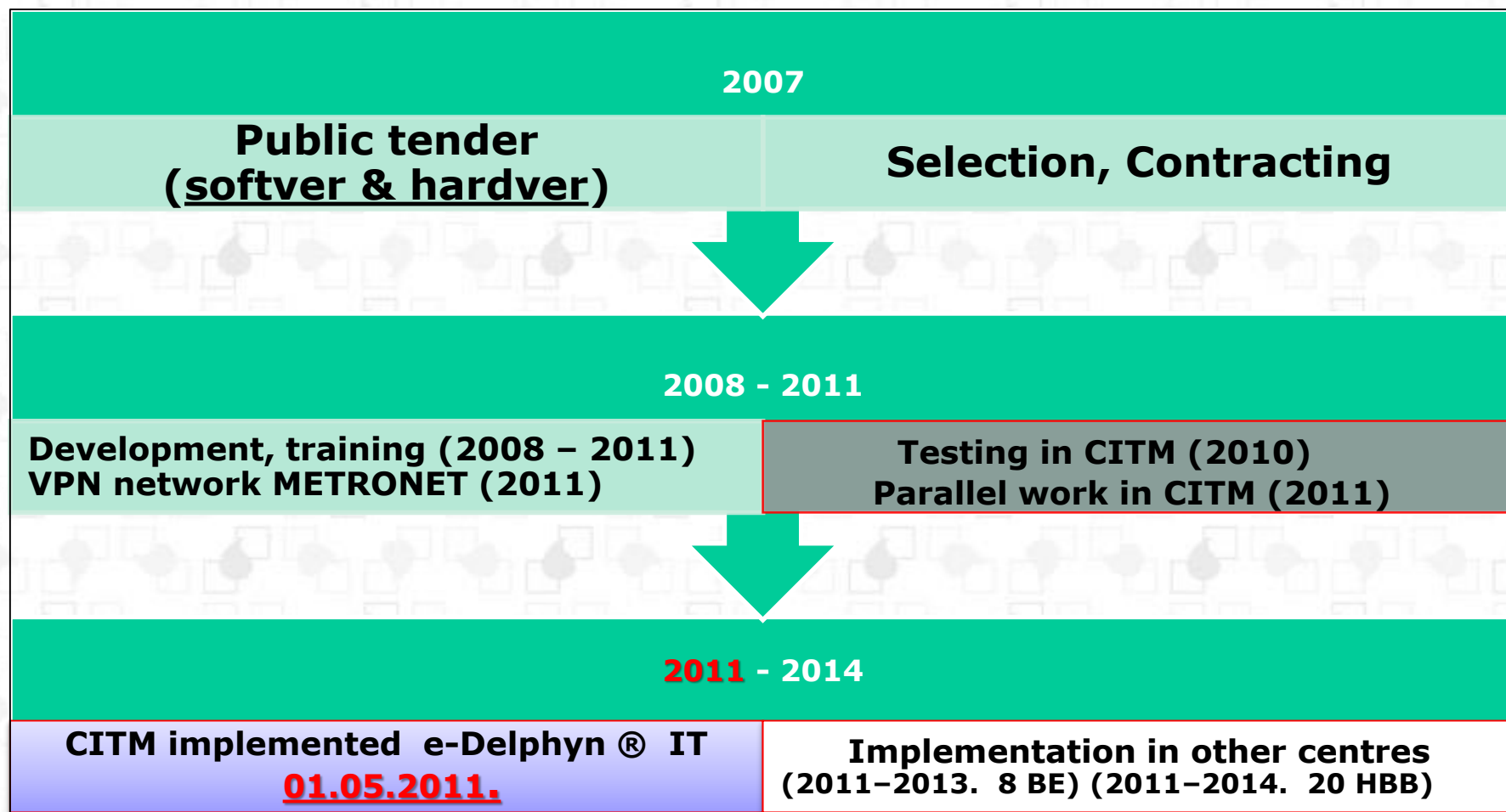


ADVANTAGES

- **Using modules for:**
 - **Donor Management**
 - **Transfusion Treatment**
 - **LIS**
 - **QC of Blood Components**
- **Support one-way and bi-directional interfaces with all analysers and instruments**
- **Data migrated from a local made software**
- **Interfacing with all components of the system**
- **Centralized – Sharing informations and functionalities among Blood Establiments and Hospital Blood Banks**



Implementation of e-Delphyn ® IT in NBTS 2007. – 2014.



HARD WORKING TIME (STEP BY STEP)

- **Board in CITM**
- **Responsible person from HemaSoft in CRO**
- **Responsible IT team in CRO**
- **A lot of meetings**
- **A lot of problems (solved!)**
- **Daily contacts**



e-Delphyn TODAY IN NBTS

POSITIVE

- Cooperation between everyone
- Standardisation in collection
- Standardisation in production
- Increasing quality of transfusion treatment
- Haemovigilancia
- Blood supply management
-

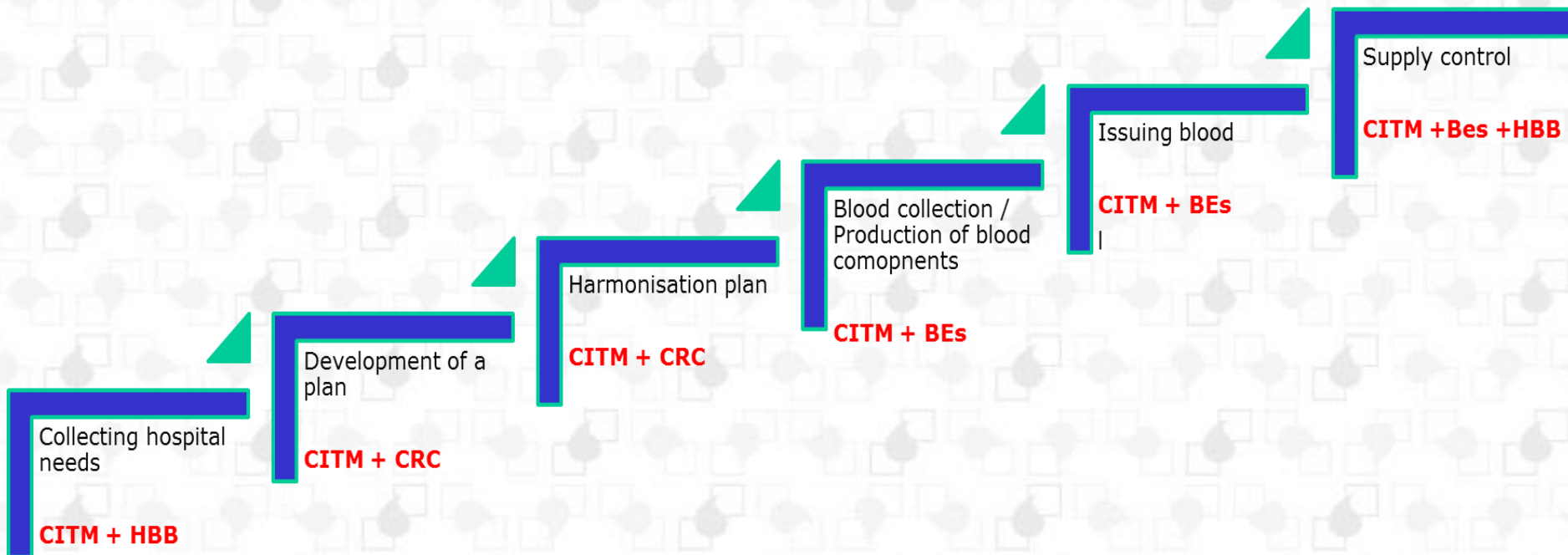
NEGATIVE

- Nothing at the moment 😊
- At the end – now is easy 😊

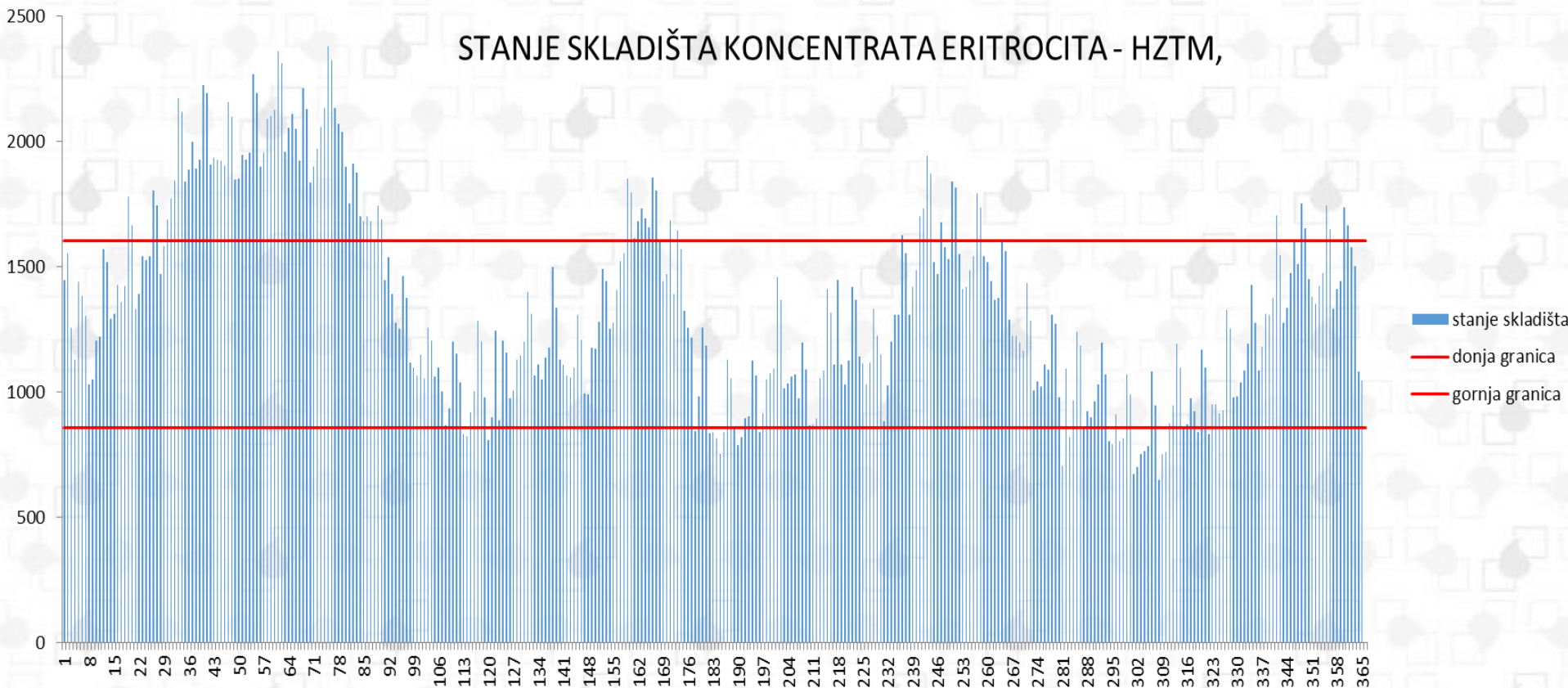


SUPPLY – REQUIREMENTS

Striking a balance between the "inputs" and "outputs"



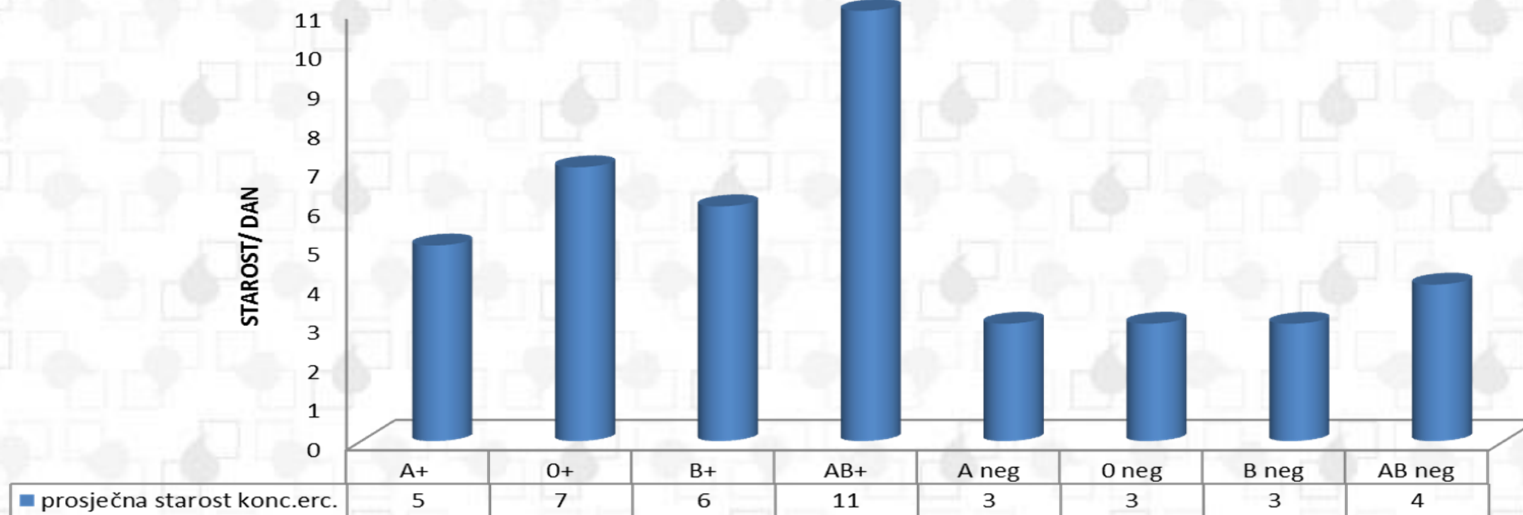
SUPPLY OF RED BLOOD CELLS



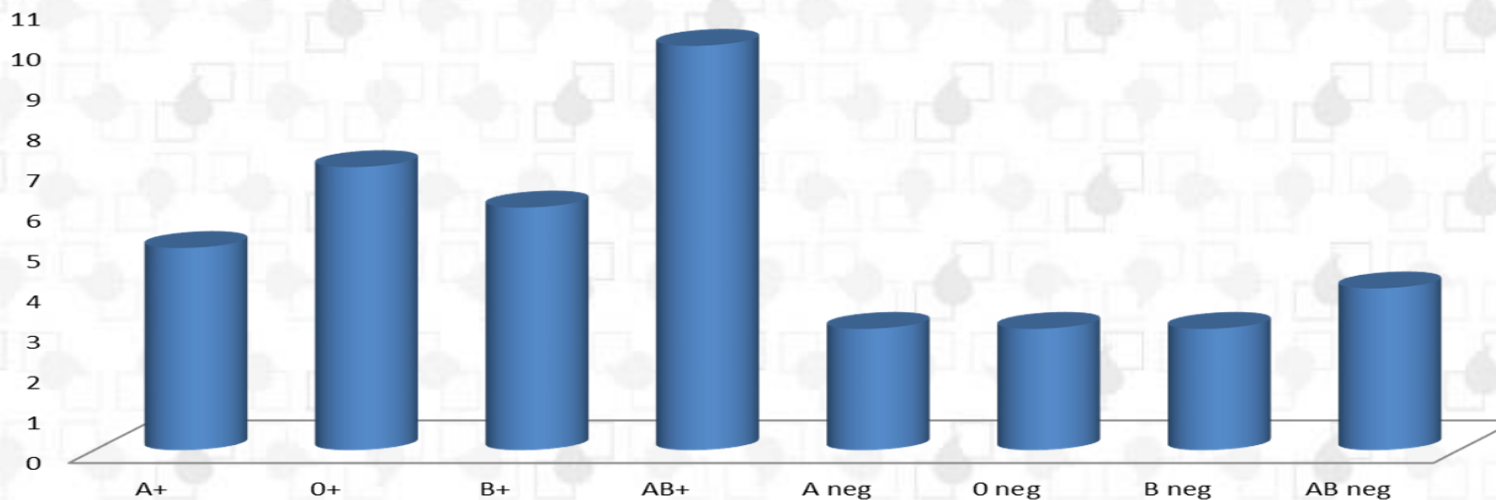
- Optimal supply levels calculated according to the five-days needs
- Set upper and lower limits of RBC according the needs and documents (RU OKP-023)



AVERAGE AGE RBC ON STOCK

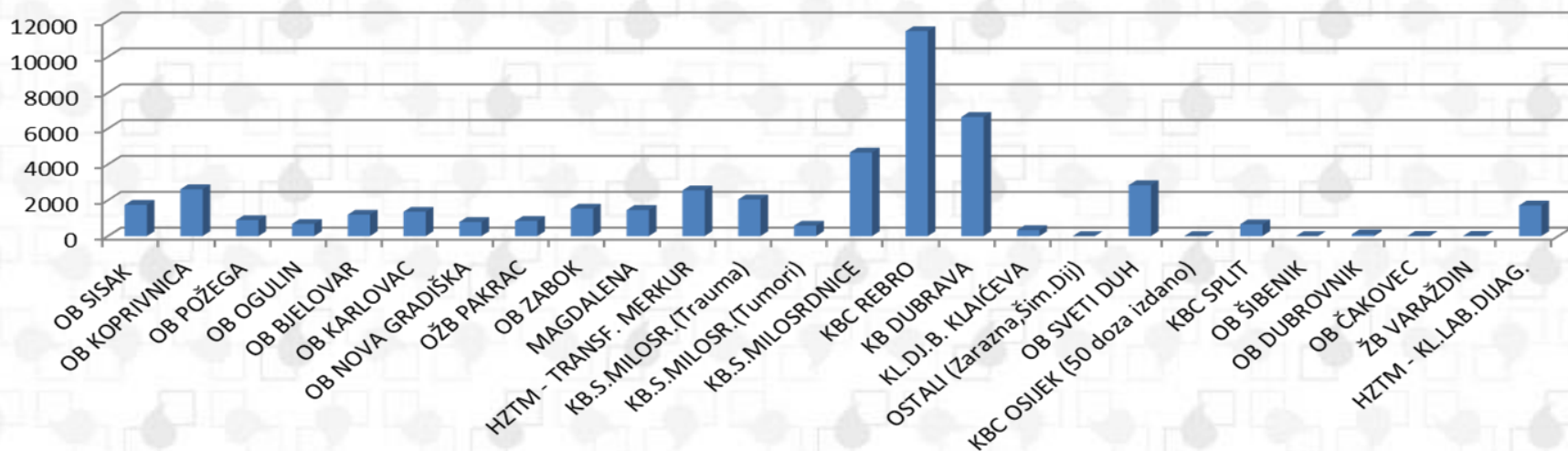


AVERAGE AGE RBC AT THE TIME OF ISSUE

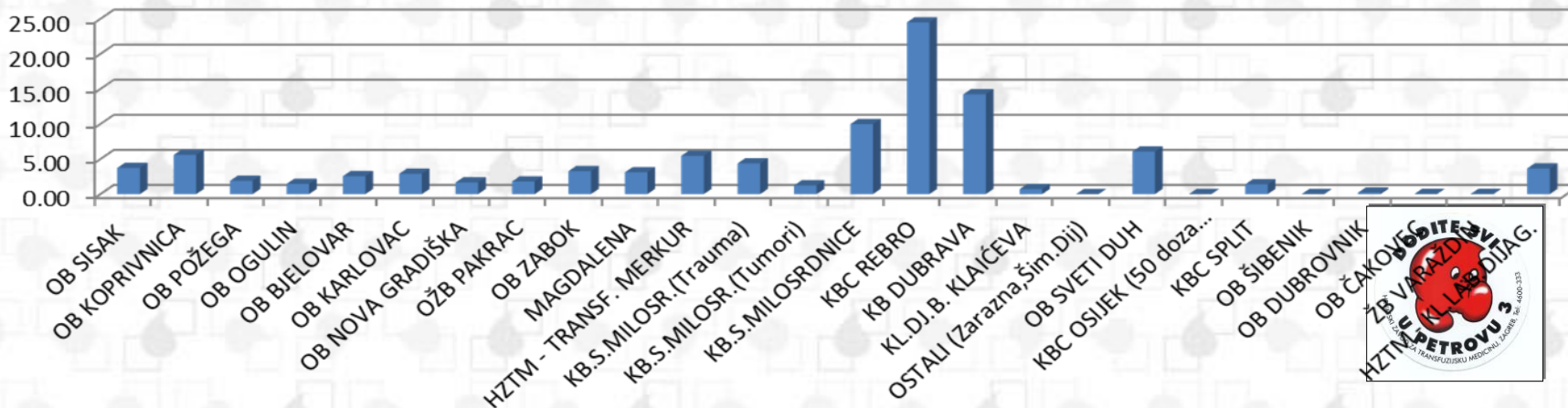


ISSUING OF RBC (total)

UKUPNO IZDANO



% od ukupno



ORDERING

- **Hospitals under 40 km - daily orders**
 - **electronic ordering**
 - **their drivers pick up blood components during 24 hours**
- **Hospitals over 40 km - orders two times a week**
 - **electronic ordering**
 - **their drivers pick up RBC and FFP on Tuesdays and Thursdays**
 - **platelets are driven according to the needs (possibly every day)**
- **When needed, blood components are sent by plane (to Dubrovnik, to Split)**



TODAY...

- **Today we have:**
 - **all data about all our donors in Croatia**
 - **all data about all blood components which are produced in Croatia**
 - **all data about all results of all laboratory testing in Croatia**
 - **most of data about recipients (because few hospitals are not still in our IT network!)**
- **Also, we have daily contacts with our colleagues in other centres, and monthly meetings with our customers (HBB)**
- **We are a small country but we have really high level of transfusion safety**
- **But, this is never-ending story**



Medical data of blood donors and patients in the same national IT system e-Delphyn ®



www.shutterstock.com · 146542787



gg4260335 www.gograph.com

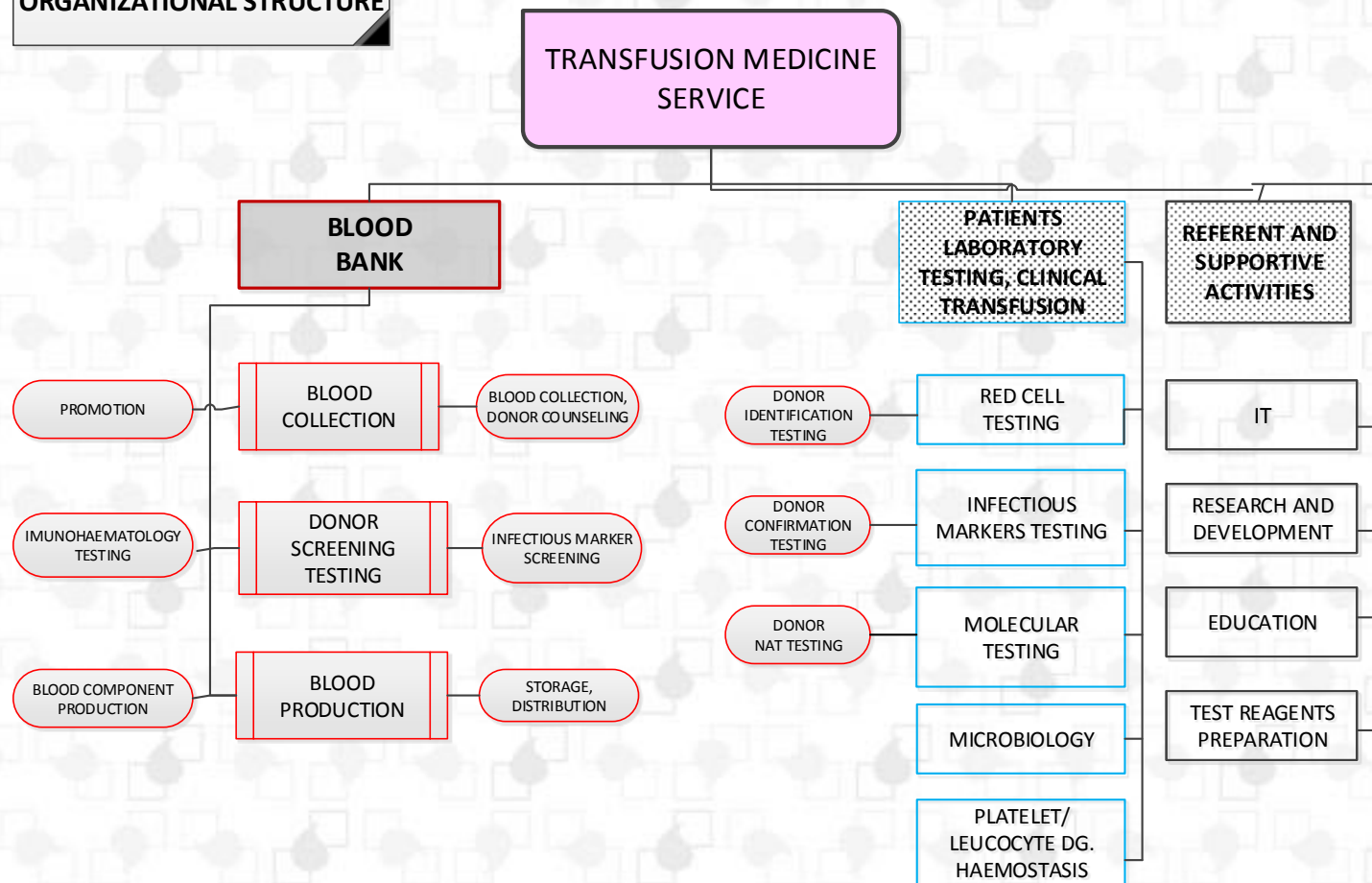
CROATIAN INSTITUTE OF TRANSFUSION MEDICINE



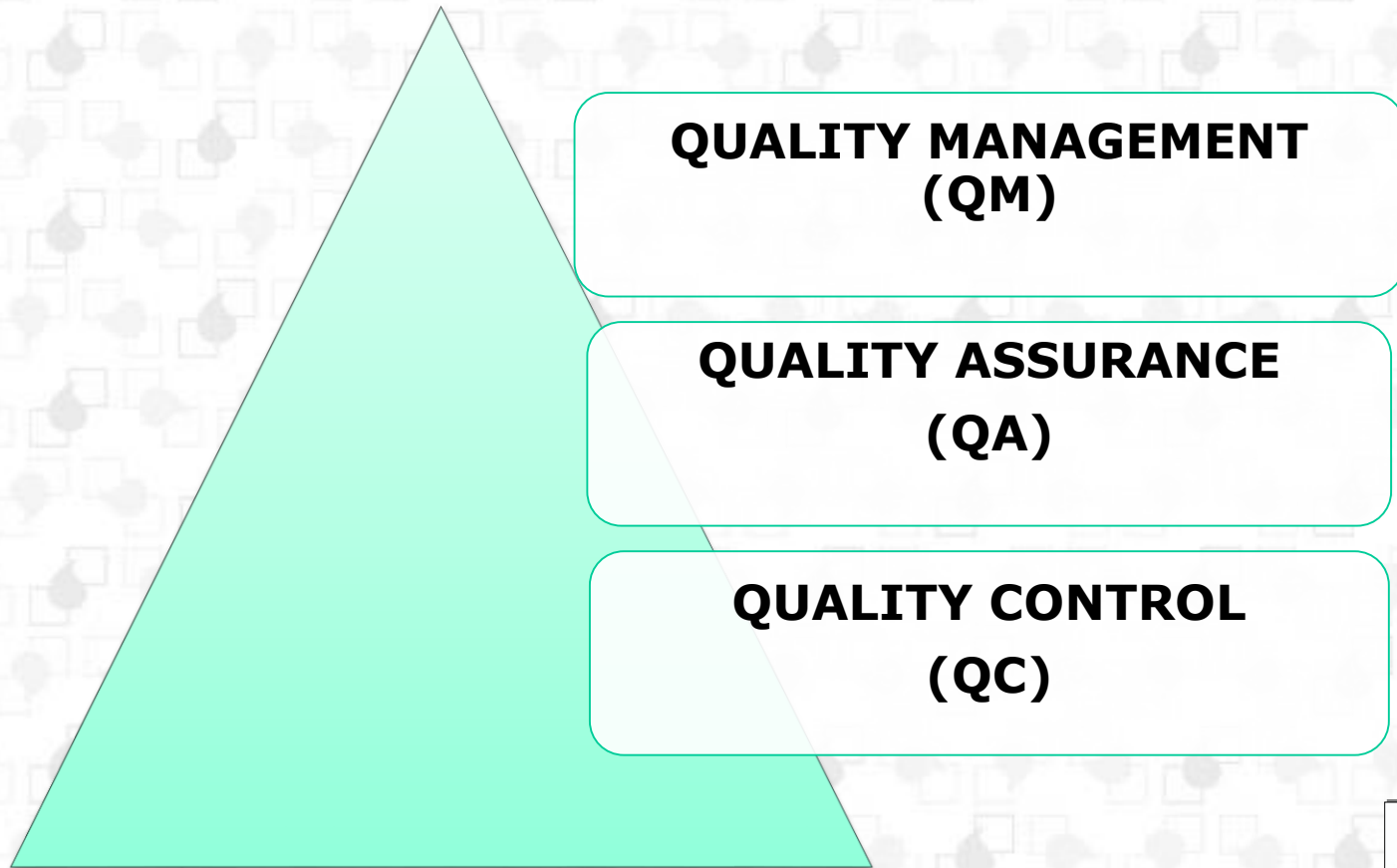
365 DANA U GODINI

VAMA NA USLUZI
HRVATSKI ZAVOD ZA TRANSFUZIJSKU MEDICINU

TRANSFUSION MEDICINE ORGANIZATIONAL STRUCTURE



ORGANISATIONAL STRUCTURE OF QUALITY MANAGEMENT (QM)



„Referral Centre of Ministry of Health for
Transfusion Medicine”

(1996.)



POTVRDA O ODOBRENJU

Potvrđujemo da je sustav upravljanja kvalitetom društva:

Hrvatski zavod za transfuzijsku medicinu
Petrova 3
10000 ZAGREB
Republika Hrvatska

odobren od Lloyd's Register Quality Assurance
prema sljedećoj normi za sustave upravljanja kvalitetom:

ISO 9001:2008

Sustav upravljanja kvalitetom primjenjuje se na sljedeće područje:

**Prikupljanje, ispitivanje, prerada, pohrana i
distribucija krvi i krvnih pripravaka.**
**Pružanje usluga laboratorijskog ispitivanja
krvi bolesnicima i trudnicama**

Potvrda o
odobrenju broj: LRC 0120220

Prvo odobrenje: 31. siječnja 2001.

Potvrda izdana: 2. veljače 2013.

Potvrda vrijedi do: 13. siječnja 2016.

Malinot

Izdao: Lloyd's Register Quality Assurance
Italy Srl za i u ime Lloyd's Register Quality
Assurance Limited



Ovaj dokument predmet je usluge na polju:

Via Cadorna 60, 00198 Roma (RM) 20500, Italy

For and on behalf of: 11, Abchurch Lane, London EC4M 3DF, United Kingdom

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HRVATSKI ZAVOD ZA TRANSFUZIJSKU MEDICINU

POLITIKA KVALITETE

Hrvatski zavod za transfuzijsku medicinu je neprofitna, ovlaštena zdravstvena ustanova koja obavlja transfuzijsku, laboratorijsku i farmaceutsku djelatnost. Državni je zavod i Referentni centar za transfuzijsku medicinu Ministarstva zdravlja Republike Hrvatske.

U okviru transfuzijske djelatnosti obavlja prikupljanje, ispitivanje, preradu, pohranu i distribuciju krvi i krvnih pripravaka.

U okviru laboratorijske djelatnosti obavlja eritrocitnu dijagnostiku, dijagnostiku krvlju prenosivih bolesti, molekularnu dijagnostiku, trombocitno/leukocitnu dijagnostiku i hemostazu te mikrobiološka ispitivanja.

U okviru farmaceutske djelatnosti proizvodi parenteralne otopine i medicinske proizvode za jednokratnu upotrebu.

Hrvatski zavod za transfuzijsku medicinu se obvezuje:

- primjenjivati važeće hrvatske i europske zakone, norme i preporuke u svim područjima poslovanja;
- sve radnike uključiti u neprekidno poboljšavanje sustava kvalitete u skladu s normama ISO 9001, ISO 13485 (ISO 15189, ISO/IEC 17025 te zahtjevima dobre proizvodnje) i dobre laboratorijske prakse;
- pratiti stručna iskustva i novosti, provoditi istraživanja i trajno primjenjivati nove znanstvene spoznaje radi postizanja veće sigurnosti davatelja i bolesnika te veće sigurnosti i djelotvornosti proizvoda i usluga;
- provoditi pravodobne, sustavne oblike komunikacije s korisnicima i radnicima u cilju sigurnosti i djelotvornosti proizvoda, uzajamno korisne suradnje, ispunjavanja njihovih zahtjeva i povećanja zadovoljstva;
- osigurati trajnu izobrazbu i osobni razvoj u stručnom i znanstvenom području te poticati kreativnost, motivaciju i timski rad radnika;
- primjenjivati poslovne i etičke norme i biti otvoren i prilagodljiv prema suradnicima i korisnicima naših proizvoda i usluga;
- objektivno, sustavno procjenjivati dobavljače i razvijati s njima partnerske odnose;
- obavještavati zajednicu o važnosti davanja krvi i provoditi izobrazbu o mogućim rizicima i komplikacijama u cilju njihovog sprječavanja i povećanja samodostatnosti i sigurnosti transfuzijskog liječenja bolesnika;
- planirati i organizirati rad provjerenim i učinkovitim poslovnim procesima temeljem procjene rizika na djelotvoran i ekonomičan način;
- uspostaviti ciljeve i mjerljive pokazatelje za proizvode i procese, redovito ih pratiti i obrađivati i temeljem tih pokazatelja donositi stručne i poslovne odluke.

Ostvarenje ciljeva ove politike kvalitete, sigurnost i zadovoljstvo korisnika naših proizvoda i usluga te dobrovoljnih davatelja krvi, obveza je Uprave i svih radnika i mjerilo kvalitete našeg poslovanja.

U Zagrebu, 19. prosinca 2012.

Prim. Irena Jukić, dr.med.
Ravnateljica HZTM

Accreditation Certificate



Potvrda o akreditaciji Accreditation Certificate

Ovime se utvrđuje da je
This is to recognize that

HRVATSKI ZAVOD ZA TRANSFUZIJSKU MEDICINU
Laboratorijska dijagnostika i klinička transfuzija
Petrova 3, HR-10000 Zagreb

osposobljen prema zahtjevima norme
is competent according to
HRN EN ISO 15189:2008
(ISO 15189:2007; EN ISO 15189:2007)
za/to carry out

Serološka i molekularna dijagnostika krviju prenosivih bolesti
Eritrocitna dijagnostika i hemostaza
Mikrobiološko ispitivanje sterilnosti uzoraka tkiva
Serological and molecular diagnostics of blood borne diseases
Red blood cell diagnostics and haemostasis
Microbiological sterility testing of tissue samples

u području opisanom u prilogu koji je sastavni dio ove potvrde o
akreditaciji.
for the scope described in the annex which is the constituent part of this
accreditation certificate.

Br./No.: 7445
Klasa/Ref.No.: 383-02/12-35/001
Urbroj/Id.No.: 569-02/2-14-
Zagreb, 2014-03-17

Akreditacija istječe: Accreditation expiry: 2019-03-16
Prva akreditacija: Initial accreditation: 2014-03-17

HAA je potpisnica multilateralnog sporazuma s Europskom organizacijom za akreditaciju (EA)
HAA is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement

Ravnateljica:
Director General
Mr. sc. Biserka Bajzek Brezak, dipl. ing.



HAA

Hrvatska akreditacijska agencija
Croatian Accreditation Agency



Potvrda o akreditaciji Accreditation Certificate

Ovime se utvrđuje da je
This is to recognize that

HRVATSKI ZAVOD ZA TRANSFUZIJSKU MEDICINU
Laboratorijska dijagnostika i klinička transfuzija
Petrova 3, HR-10000 Zagreb

osposobljen prema zahtjevima norme
is competent according to
HRN EN ISO/IEC 17025:2005
(ISO/IEC 17025:2005+Cor.1:2006;
EN ISO/IEC 17025:2005+AC:2006)
za/to carry out

Ispitivanje sterilnosti farmaceutskih otopina za parenteralnu
primjenu
Sterility testing of pharmaceutical solutions for parenteral use

u području opisanom u prilogu koji je sastavni dio ove potvrde o
akreditaciji.
for the scope described in the annex which is the constituent part of this
accreditation certificate.

Br./No.: 1444
Klasa/Ref.No.: 383-02/13-30/003
Urbroj/Id.No.: 569-02/2-14-
Zagreb, 2014-03-17

Akreditacija istječe: Accreditation expiry: 2019-03-16
Prva akreditacija: Initial accreditation: 2014-03-17

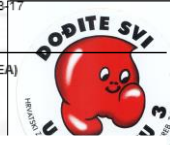
HAA je potpisnica multilateralnog sporazuma s Europskom organizacijom za akreditaciju (EA)
HAA is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement

Ravnateljica:
Director General
Mr. sc. Biserka Bajzek Brezak, dipl. ing.



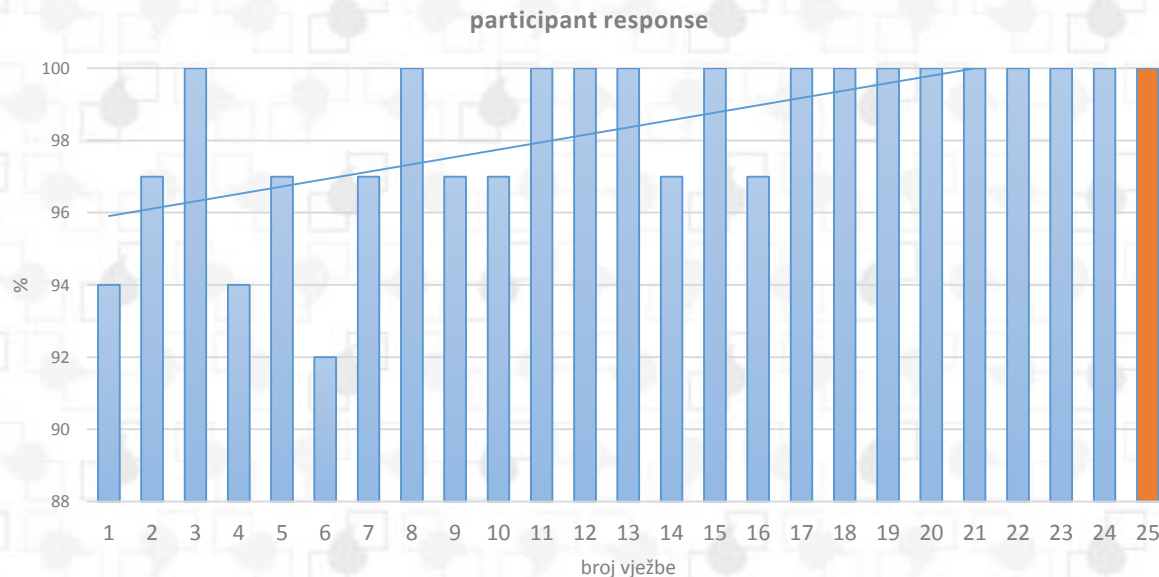
HAA

Hrvatska akreditacijska agencija
Croatian Accreditation Agency

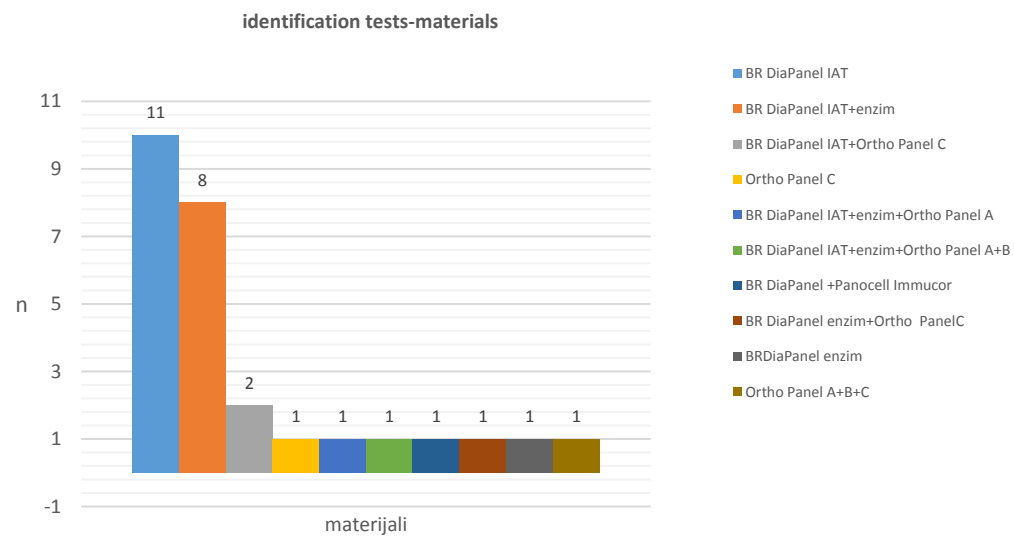
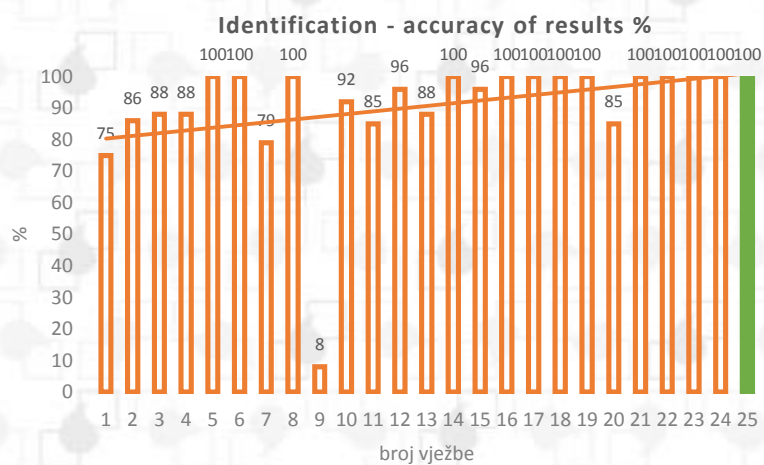


25 years of control

- since 1993. CITM has introduced laboratory control for all Croatia
- 36 laboratories participate in the control of immunohematological and serological testing today

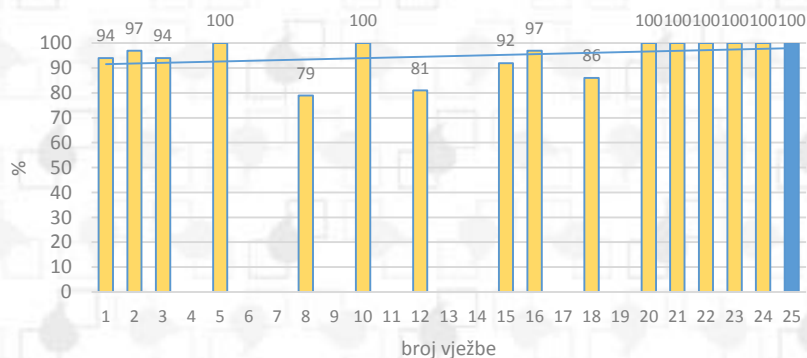


Results (25 years)

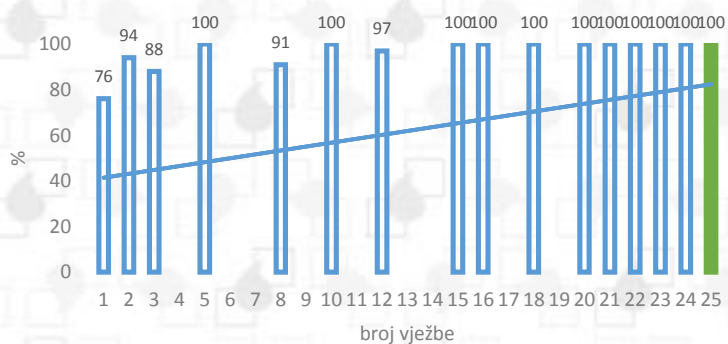


Results (25 years) – “a lot of data”

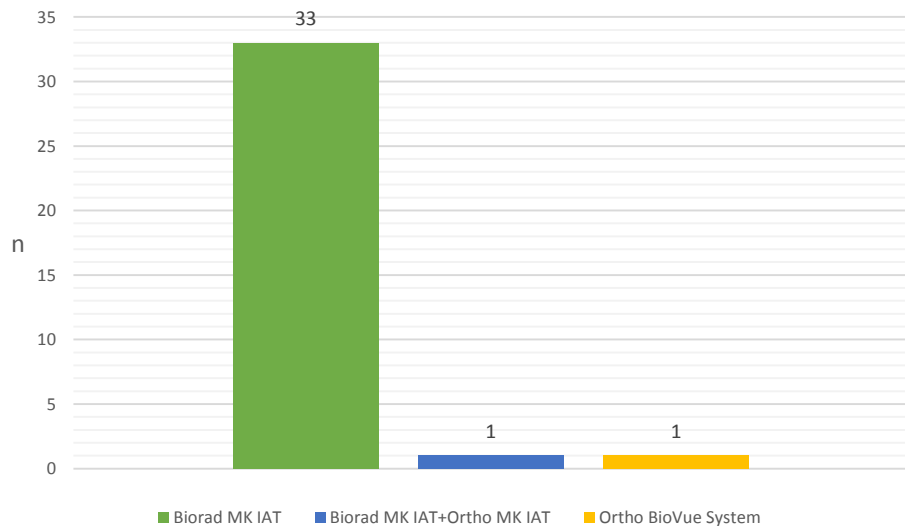
Cross matching - accuracy of results %



ABO blood type and Rh phenotype-accuracy of results



matching - techniques and materials



KEY ELEMENTS

- Clean vision
- Well defined frames
- Cooperation between all subjects in process
- Mutual respect and support
- Consistence, persistence
- Trust in self and in each other
- Don't give up - NEVER
- **Blood**, sweat and tears

**This is our way, maybe not the best,
but it works.**

At the end, each country has its own way.





**We still need a
lot of „good wind
in the back” and
paddling in the
same rhythm!!!**

**Thanks for your
attention!**



Cook with smile 😊



HZTM





Welcome to Croatia!

The most beautiful country in the world

Welcome to Zagreb!

Our capital and very hospitable town

