



CONFIDENTIAL UNIT EXCLUSION (CUE)

Mahtab Maghsudlu, MD, MPH
Associate Professor
Vice President for Research & Education
High Institute in Transfusion Medicine



Outline

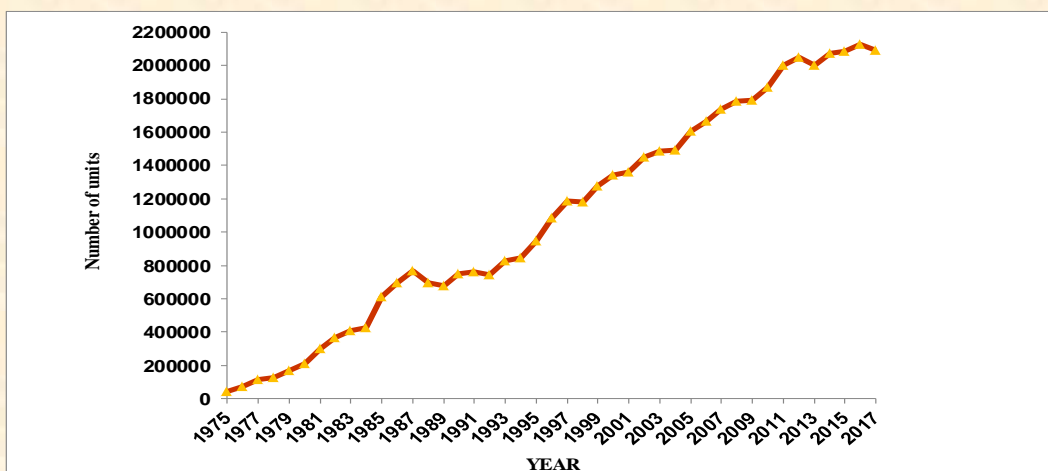
- ▣ Background
- ▣ Methods to increase blood safety
- ▣ CUE (history, administration, statistics and information, advantage and disadvantage, effectiveness)
- ▣ Conclusion

Conclusion: Mission for BTS around the world

- Safe donation
- Safe blood
- Self - sufficiency

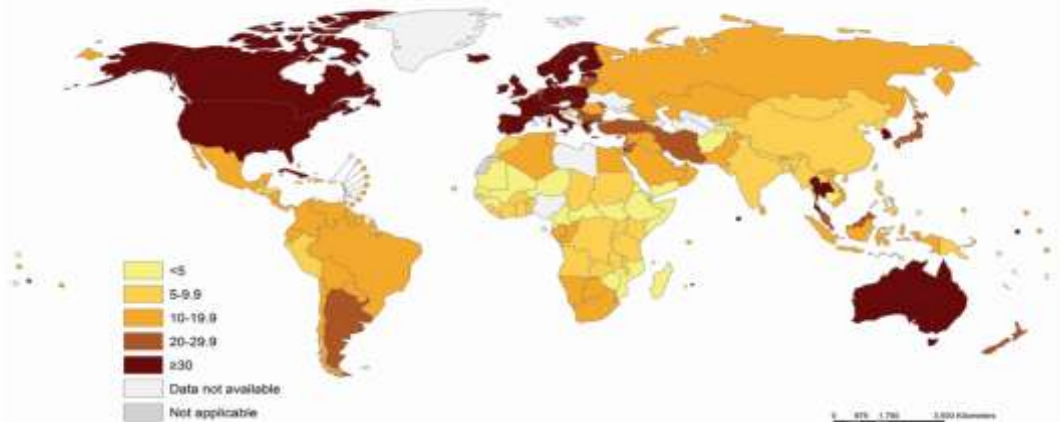


Trend of Whole Blood Donation in Iran 1974-2015



26 blood donations per 1000 population in Iran, 2017

Figure 3. Whole blood donations per 1000 population, 2013



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Producer: Blood Transfusion Safety (BTS)
World Health Organization

World Health Organization
© WHO 2016. All rights reserved.

Transfusion Risk - Infectious

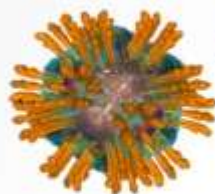
- Hepatitis B & C, HIV (definite)
- WNV (definite)
- Dengue Fever (definite)
- Bacteria (definite)



HTLV



HBV



HCV



HIV



Syphilis



METHODS TO MAXIMIZE SAFETY FROM DONATED UNITS

Self deferral
 Physician interview
Confidential unit exclusion
 Donor deferral registry
 Laboratory testing
 Call back
 Modification of blood unit after collecting
 (leukocyte removal or physicochemical)procedures for pathogen inactivation

Blood Safety Layers

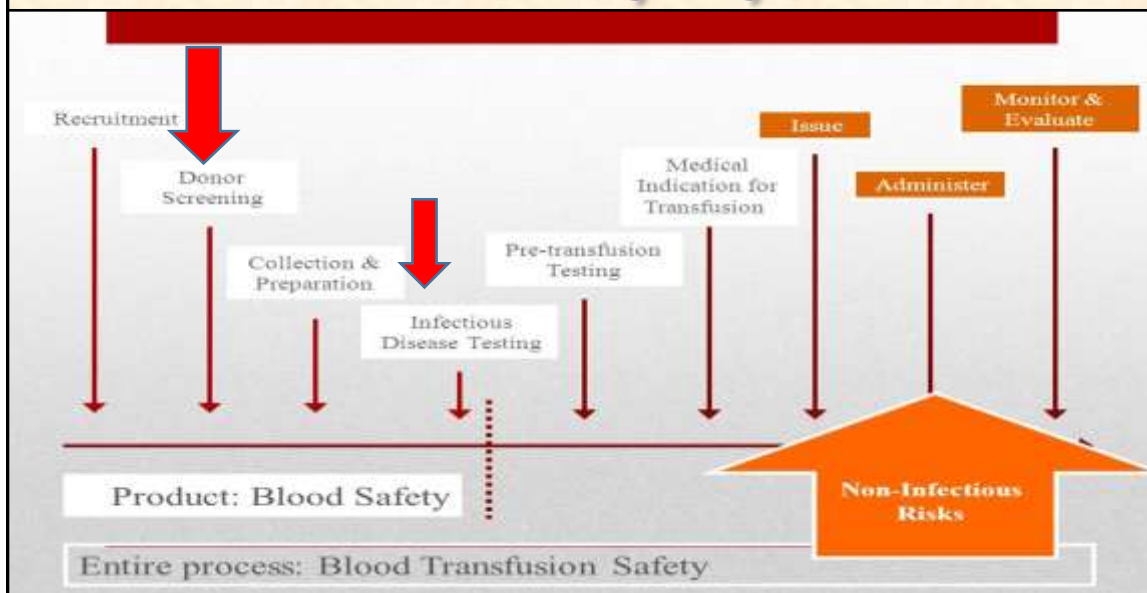
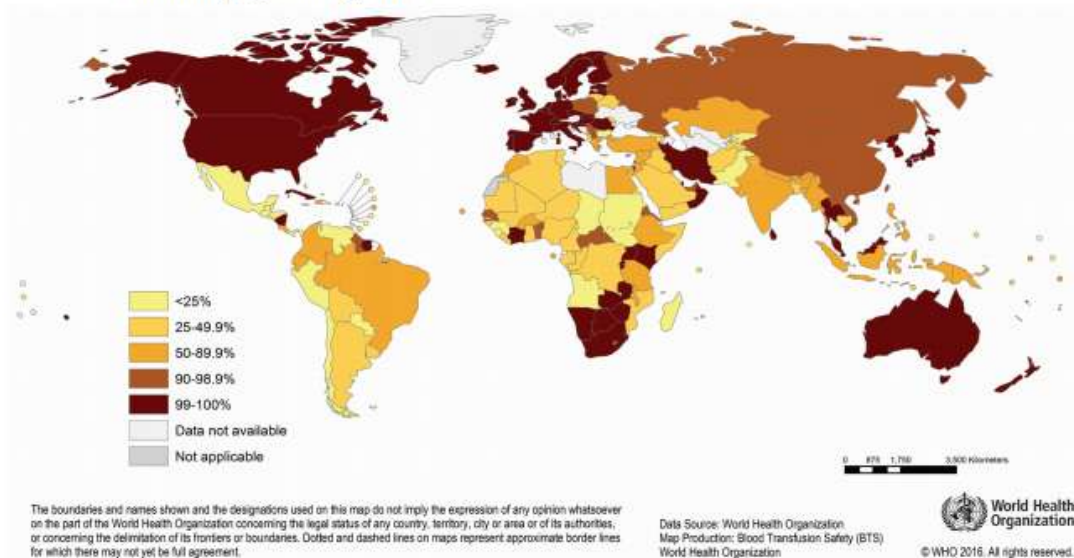


Figure 8. Proportion of voluntary non-remunerated donations (whole blood and apheresis donations combined) by country, 2013



Testing

The risk of serological and NAT positive results among remunerated donors 2012?

Serological testing - positive samples: Remunerated vs. non-remunerated donors

Hepatitis B (HBsAg)	1.54 times higher*
Hepatitis C (anti-HCV)	3.11 times higher*
HIV 1/2 (anti-HIV 1/2)	statistically insignificant (too small sample)
Syphilis (TPHA)	2.1 times higher*

NAT testing (in serological negative donations) - positive samples:

Hepatitis B (HBV-RNR)	4.47-7.33 times higher*
Hepatitis C (HCV-DNR)	22.56-58.33 times higher*
HIV 1 (HIV1-DNR)	statistically insignificant (too small sample)

*- the difference is statistically significant

Sources:

National Blood Centre statistics

CONFIDENTIAL UNIT EXCLUSION

At the time of donation donors should be offered a procedure by which they could designate confidentially whether or not their blood should be transfused to others

The rationale for CUE was to provide an opportunity for those donors who felt pressured to donate especially in mobile teams that most of donors know each other. (from peers, fellow employees, employers , and)

WHEN CUE IMPLEMENTED IN IRAN?

CUE implemented in IRAN

- ❑ Since 2002 the confidential unit exclusion (CUE) became mandatory and implemented in all blood centers(after workshop for physician and other staff)
- ❑ According to a published study in Tehran BTC 0.6% of donors who select CUE was seropositive in at least one screening tests.)



HOW CUE IS PERFORMED IN IRAN?

GIVING A BROCHURE TO DONOR AT TIME OF REGISTRATION



**DONOR CHOSE THE ANSWER AND PUT IT
IN YELLOW BOX(CUE BOX) BEFORE
DONATING BLOOD**



Confidential Unit Exclusion (CUE)



IN SOME OF BLOOD COLLECTION CENTERS
CUE IS DONE ELECTRONICALLY

CUE

- ▣ In IBTO there is a Confidential Unit Exclusion (CUE) system.
- ▣ to give the donor two bar code label that only a computer scanner can read
- ▣ One bar cod affixed to the donation from and the other is discarded .

CUE

- Is to give the donor two bar code label that only a computer scanner can read

Be used for transfusion

Discard the blood after testing

- Since the staff cannot read the stickers, the donation process continues regardless of which sticker is selected.
- After the donor leaves, the sticker is read to determine whether the blood should be made available for transfusion or not.



WHAT HAPPEN TO BLOOD BAGS AFTER CUE?

AFTER DONATING BLOOD RESPONSIBLE PERSON FOR SENDING BLOOD BAGS TO PREPARATION UNIT CHECK ALL CUES AND PICK OUT "NO "ANSWERS AND SEND THESE BLOOD BAGS AND PILOTS TO QC UNIT SEPARATELY.

ALL SCREENING TEST ARE DONE ON SAMPLES

BLOOD BAG IS DISCARDED

DONOR IS DEFERRED TEMPORARY

DONOR IS FOLLOWED UP

DONOR IS CONSULTED FOR ELIGIBILITY TO DONATE

TIME OF IMPLEMENTATION

In early 1983, the New York Blood Center introduced confidential unit exclusion .

The procedure was designed to allow members of groups at increased risk of AIDS to confidentially designate their donations for laboratory studies and not for transfusion.

In 1992 FDA analyzed available data on CUE sensitivity and specificity and stated that the CUE procedure was no longer mandatory ,and its use was left to discretion of each individual blood center.

In other countries, such as in the United Kingdom, Switzerland, Iran and Germany

It is still recommended.

Effectiveness of CUE

- The effectiveness of could differ among blood centers due to:
 - 1) various method of administer
 - 2) TTI epidemiology variability
 - 3) characteristics of laboratory test

City	Year(study)	population	CUE		OR At least one TTI	CI
مازندران	1384	16781	87	%0.5	3.3	(6.97-1.61)
Tehran	1385	14320	2864	%0.9	7.2	(9.8-5.32)
شیراز	1385	75314	537	%0.7	7.2	(11.93-4.31)
Tehran	1387	353612	2072	%0.6	5.8	(7.65-4.37)
		2000	1000		10.1	(78.98-1.29)
Shiraz	1391	101245	2365	%2.3	2.2	(4.97-0.96)
قم	3-1382	12935	204	%1.6	3.8	(6.01-2.42)
بوشهر	1385-1384	39921	909	%2.3	8.5	(12.31-5.84)
Yazd	1389-1383	255932	1172	%0.5	4.8	(7.57-3.1)
اصفهان	1390-1384	436894	1824	%0.4	8.6	(11.37-6.49)
یزد	1392-1388	120841	1117	%0.9	7.3	(13.39-3.93)
کردستان	1392-1390	73841	740	%1.0	3.9	(6.54-2.31)
کهگیلویه و بویراحمد	1393-1385	167341	1767	%1.1	5.5	(8.99-3.36)



Efficacy of the Confidential Unit Exclusion Option in Blood Donors in Tehran, Iran, Determined by Using the Nucleic Acid Testing Method in 2008-2009

Elham Farhadi ¹, Ahmad Gharehbaghian ^{1,2*}, Gharib Karimi ¹, Shahram Samiee ¹, Farzaneh Tavasolli ¹, Yahya Salimi ¹

Table 2. The Prevalence of HBV and HCV and the Use of CUE Determined Using Serologic Tests

ID Marker	Number of Donations	Number of Positive	P value	OR *	95% CI	Sensitivity	PPV
HBsAg			0.000	4.61	1.25-6.60	0.0261	0.0154
No	351540	185					
Yes	2072	32					
Anti-HCV			0.000	10.01	6.57-15.60	0.0558	0.0106
No	351540	372					
Yes	2072	22					

*Abbreviation: OR, odd ratio

Table 4. The Prevalences of HBV and HCV and the Use of CUE in the NAT Method in 2000 Units of Blood

ID Marker	Number of Donations	Positive Findings, No.	P value	OR *	95% CI	Sensitivity	PPV
HBV-NAT			0.0581	6.01	0.728-277.6	0.08271	0.006
No	1000	0					
Yes	1000	6					
HCV-NAT			0.3168	1	0.240-157.9	0.75	0.001
No	1000	0					
Yes	1000	4					


*Abbreviation: OR, odd ratio

Adequacy OR Safety?

Safety

Adequacy

Donor selection criteria and testing procedures have to be balanced to ensure an adequate blood component supply



Conclusion

Current studies in the country showed the prevalence of TTI in cue group was significantly more than in non cue group

The use of CUE contribute to an improvement safety of blood component

CUE is more relevant in 1)countries with high prevalence/incidence of TTI 2)where infection are not concentrated in specific population 3) molecular screening test are not feasible