



Perhimpunan Dokter Transfusi Darah Indonesia (PDTDI)



BLOOD SAFETY STATUS IN INDONESIA

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OUTLINE

- Background
- Blood services in Indonesia
- Regulation related to blood safety in Indonesia
- Method and algorithm of blood screening
- Blood safety status
- Challenges to achieve nationally standardized blood safety
- Conclusion

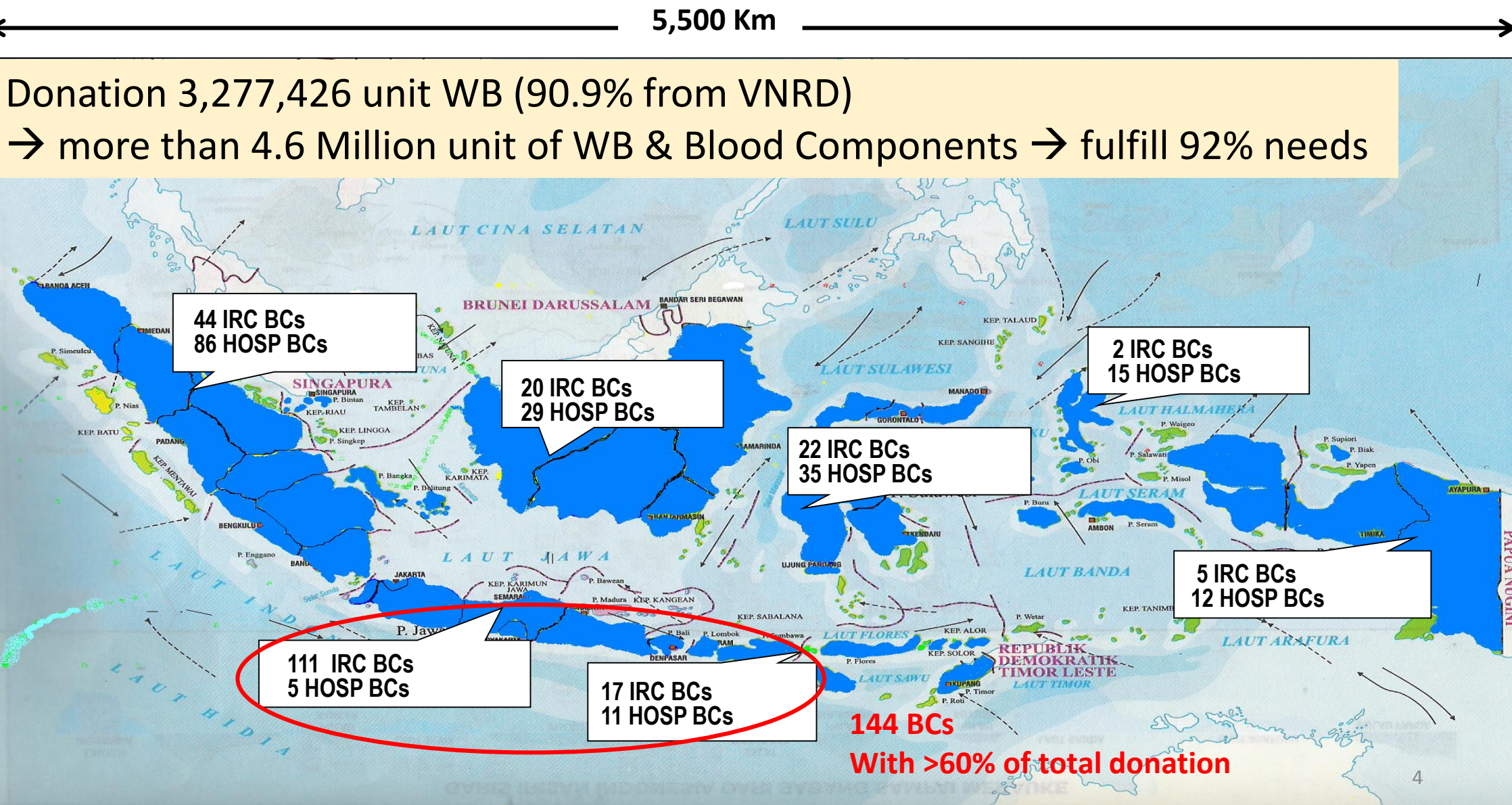


BACKGROUND

- Blood transfusion saves lives but carries risks
- Transfusion Transmitted Infections (TTIs) can be prevented
- TTIs caused by transfusing blood from donors with chronic asymptomatic infections
- Appropriate donor's selection and effective TTI's blood screening result in safe blood for transfusion
- TTIs will impact on community health



BLOOD SERVICES IN INDONESIA 2015



REGULATION RELATED TO BLOOD SAFETY IN INDONESIA

Health Law
No. 36/2009,
Article 86,
Point 3:

- Every bag of blood should be screened toward TTIs before transfusion to prevent infection transmission

Gov. Reg
No. 7/2011
on Blood
Services
Article 11:

- TTI's blood screening should be done by competent technicians
- Blood screening should be done **at least toward** HIV-AIDS, Hepatitis B, Hepatitis C, and Syphilis
- Blood screening should follow the **standard**

MoH Decree No. 91/2015 on National Standard for Blood Services

Only blood with non reactive result of TTIs testing can be distributed to hospitals

TTIs testing kit used should be evaluated & approved, **minimal to screen:** *HBsAg, anti-HIV1/HIV2, anti-HCV, Syphilis*

Evaluated and approved NAT for HIV, HBV and HCV can be added

Samples used can not be diluted (eq due to anticoagulant or pooling process)

Every initial reactive result should be retested *induplicate*



METHOD OF BLOOD SCREENING

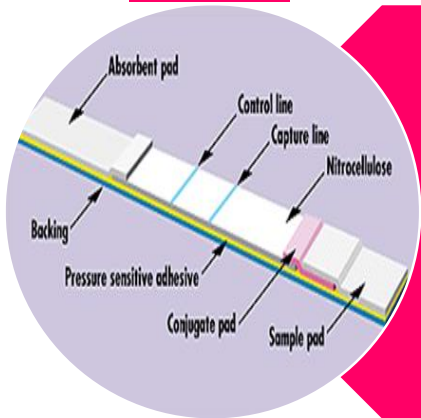
EIA



Standard method : EIA

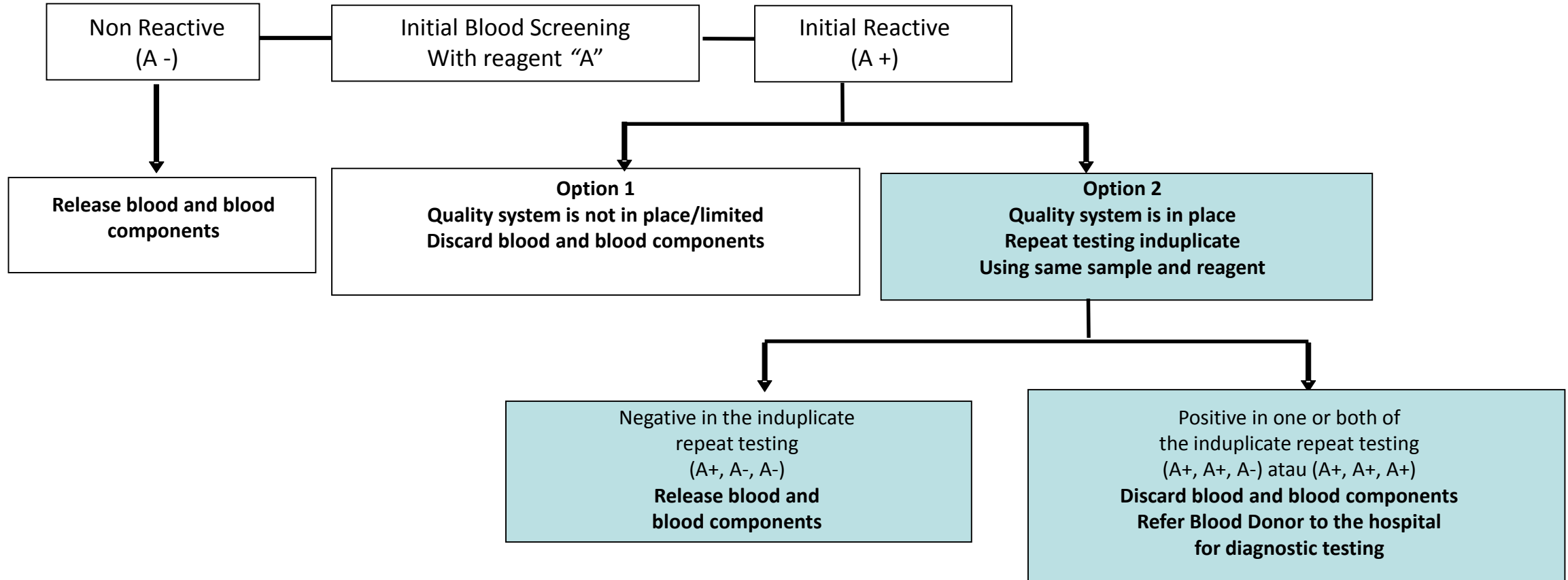
The TTIs testing is pushed to be centralized for standardization

RAPID



The validated and approved rapid test can only be used in Blood Centers at remote areas

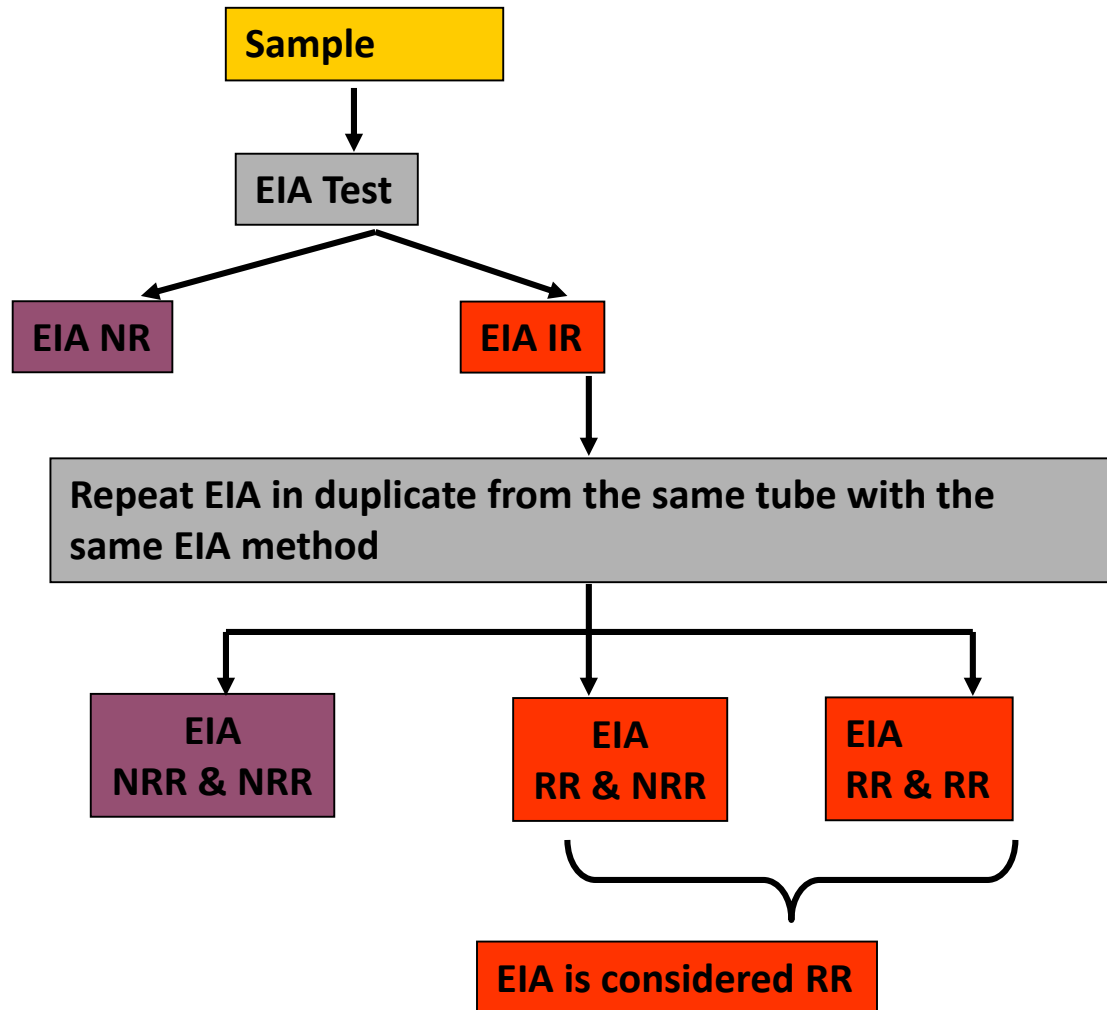
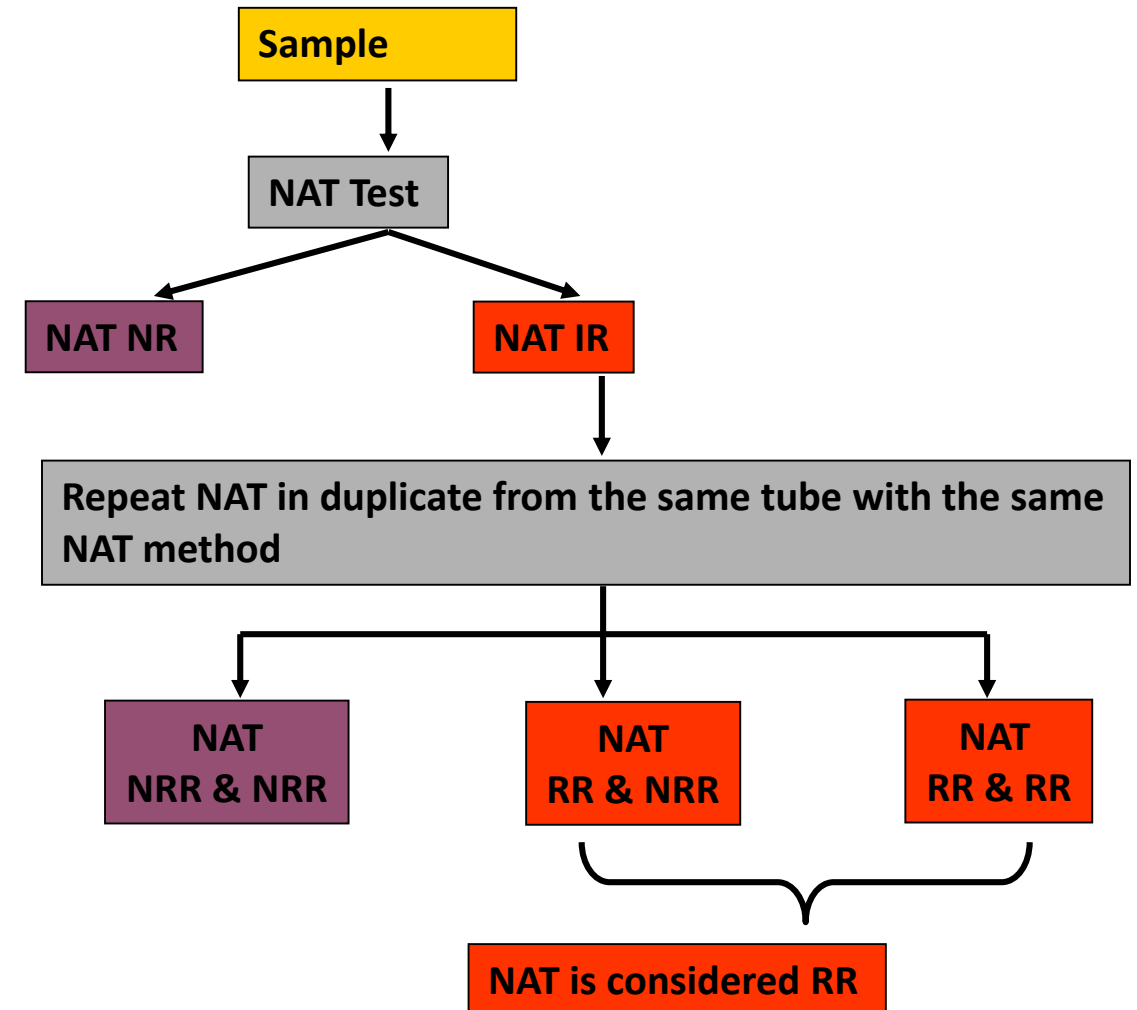
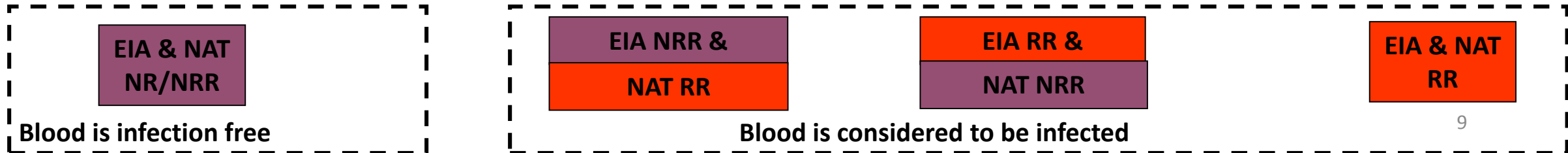
BLOOD SCREENING ALGORITHM (*)



Note:
"A" = assay
(-) = non reactive
(+) = reactive

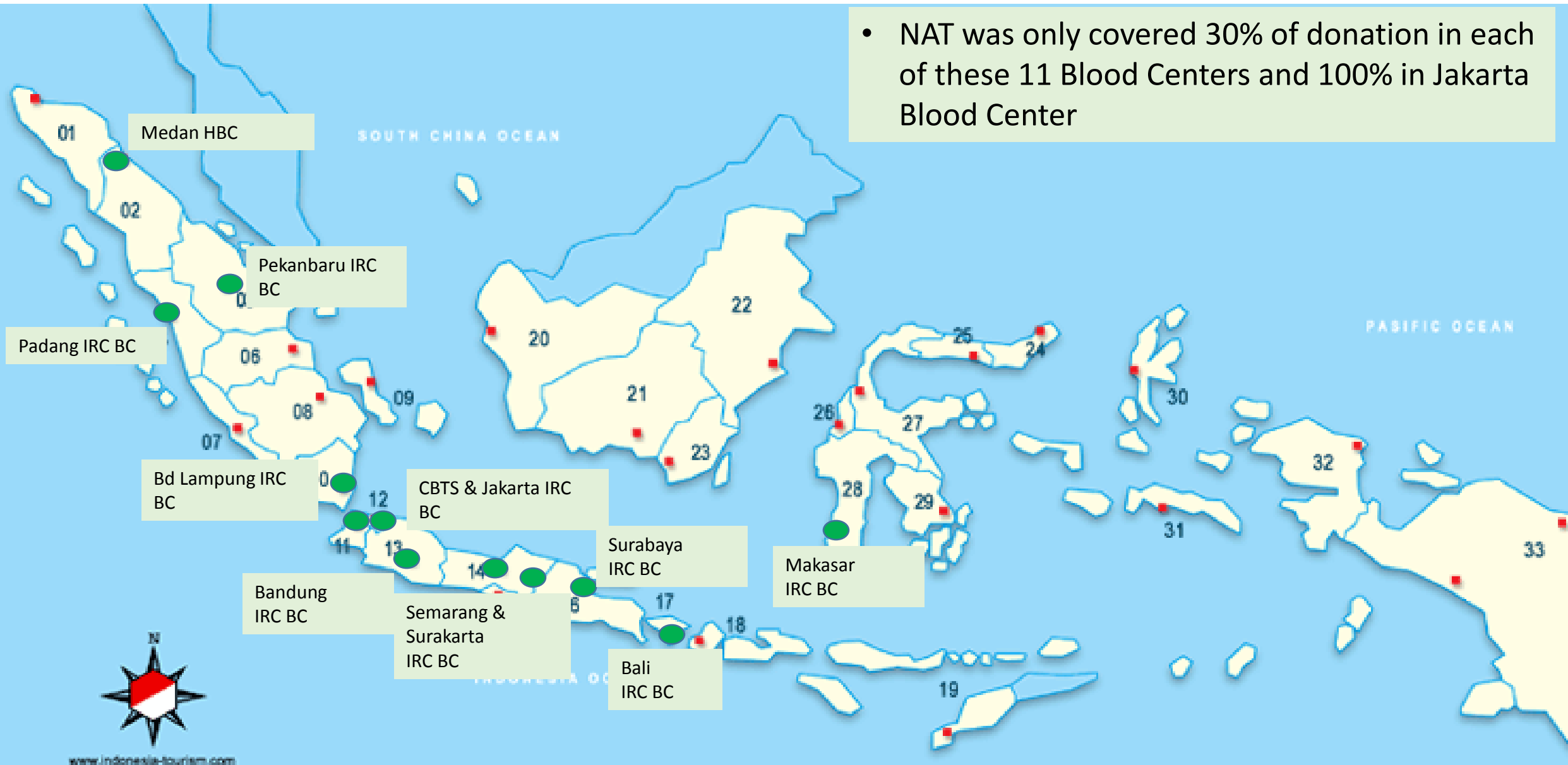
(*) WHO Recommendation: Screening Donated Blood for Transfusion Transmissible Infections. Geneva. 2010

ID-NAT & SEROLOGY TEST ALGORITHM IN INDONESIA



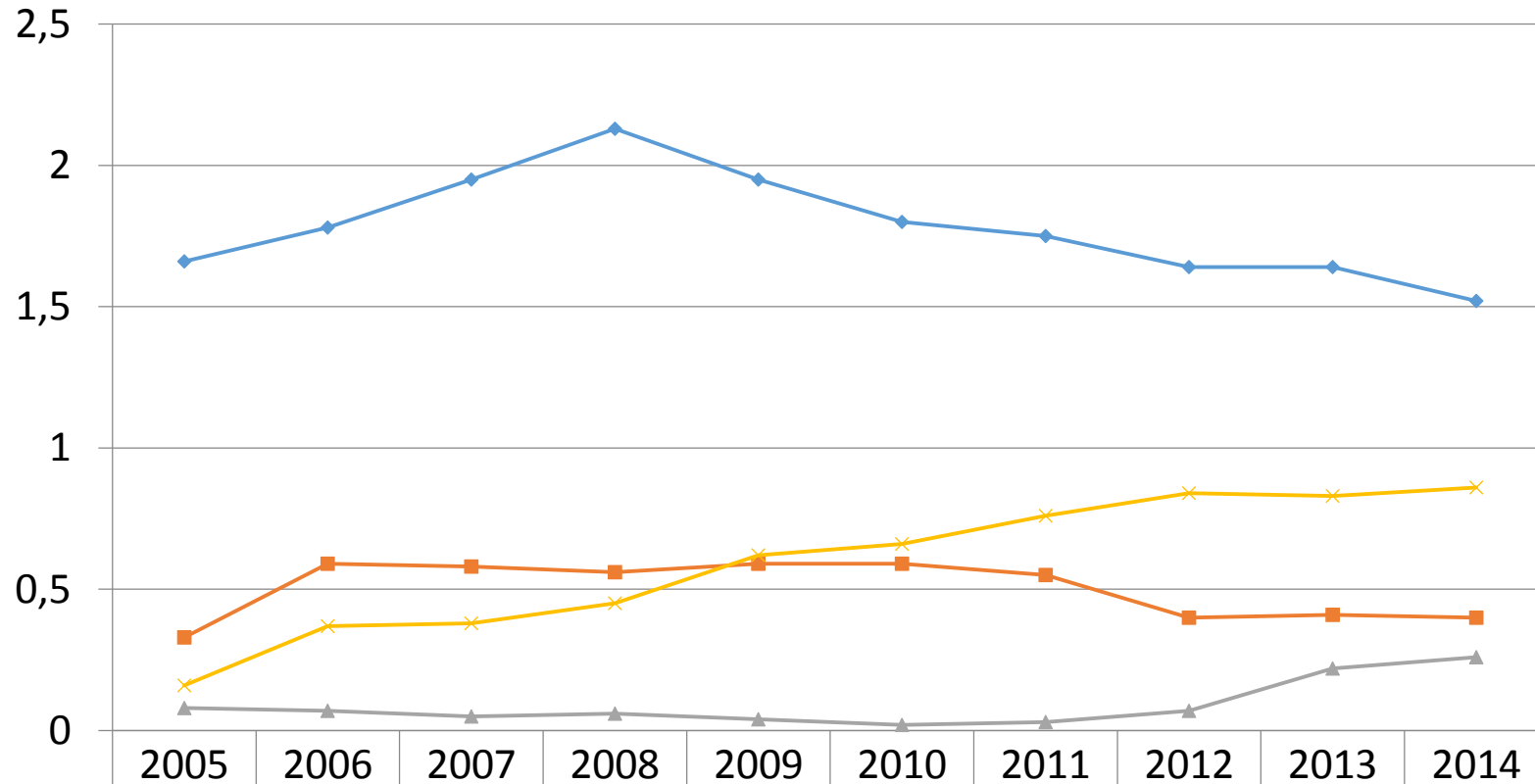
12 BLOOD CENTERS THAT RUN NAT

- NAT was only covered 30% of donation in each of these 11 Blood Centers and 100% in Jakarta Blood Center





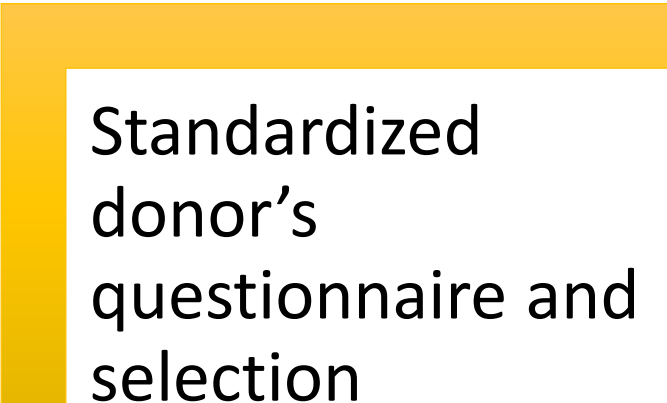
PERCENTAGE OF TTIS REACTIVE BLOOD 2005 - 2014



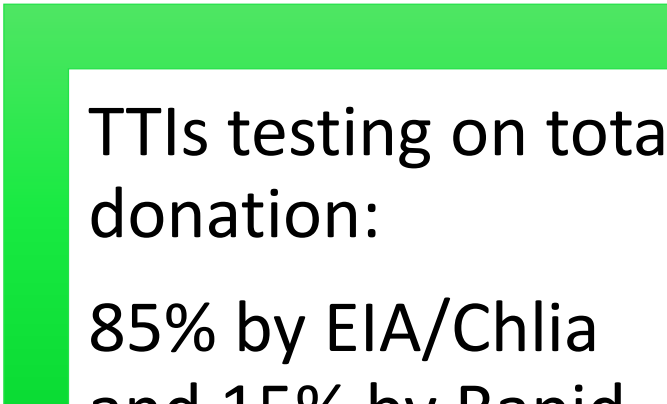
- ◆— Hepatitis B
- Hepatitis C
- ▲— HIV
- ×— Sifilis

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
—◆— Hepatitis B	1,66	1,78	1,95	2,13	1,95	1,8	1,75	1,64	1,64	1,52
—■— Hepatitis C	0,33	0,59	0,58	0,56	0,59	0,59	0,55	0,4	0,41	0,4
—▲— HIV	0,08	0,07	0,05	0,06	0,04	0,02	0,03	0,07	0,22	0,26
—×— Sifilis	0,16	0,37	0,38	0,45	0,62	0,66	0,76	0,84	0,83	0,86

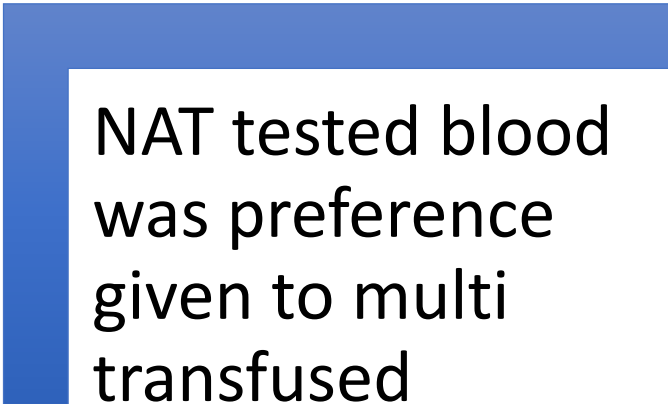
BLOOD SAFETY STATUS



Standardized
donor's
questionnaire and
selection

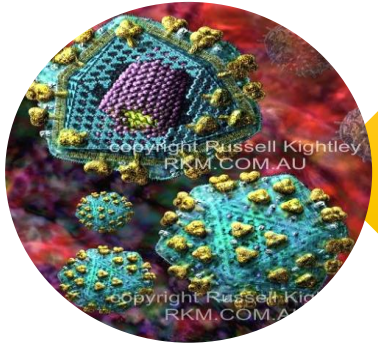


TTIs testing on total
donation:
85% by EIA/Chlia
and 15% by Rapid
Test. NAT only on 30-
100% donation at 12
Blood Centers

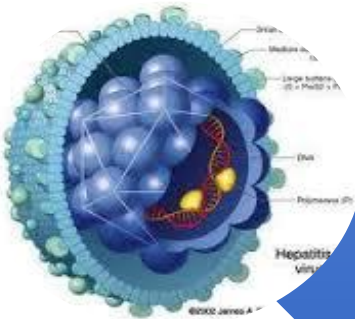


NAT tested blood
was preference
given to multi
transfused
patients

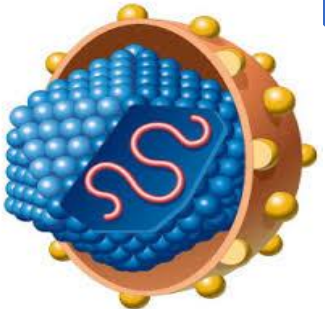
REGULATION OF “HIGH RISK” IVDS IN INDONESIA



- HIV was classified as class III
- MoH Decree No. 15/2015 on Laboratory Services for HIV & opportunistic infection → Registration after laboratory testing



- HBV and HCV was classified as class II, currently registration without laboratory testing for evaluation (before 2016)
- Voluntary laboratory testing was done by IRC Central BC
- MoH Decree is in process → HBV & HCV change to become class III IVDs, define requirements for performance evaluation and registration is done after evaluation



QUALITY ASSESSMENT

EQAS ON TTIS

- Regular NRL EQAS for IRC Central BC
- Yearly: for all Health Laboratories and 50 BCs, run by MoH
- Every 2 years : for all IRC BC, run by IRC Central BC

EQAS ON BG SEROLOGY

- Every 2 years : for all IRC BC, run by IRC Central BC

QC BLOOD PRODUCT

- Has been centralized in some areas

CHALLENGES TO ACHIEVE NATIONALLY STANDARDIZED BLOOD SAFETY



TTIs Lab & Facilities

- Validation and qualification
- Centralize the testing



Personnel

- Number and competency
- Regular training



TTI's IVDS

- Pre and post market evaluation
- Use only suitable advanced technology

PROPOSED SOLUTIONS

Establish national reference lab for pre & post market IVDs evaluation (National Institute of Health Research and Development). Registration should be released after evaluation.

Strong regulation and strategy to centralize the TTIs Testing in good infrastructure and geographic areas

**Continuous standardized training for personnel.
Accredited BCs that run the training**

Regular National EQAS on TTIs and Blood group serology for all Blood Centers

CLOSING

- Blood screening is a critical step to safe blood for transfusion
- Virus safety dependant on blood screening IVDs of high quality
- National system on IVD pre and post market evaluation can maintain only qualified IVDS will be marketed
- Testing centralization is one effort that can be proposed in good geographic and infrastructure areas
- GMP Certification and Laboratory Accreditation are tools to ensure quality of blood





Thank You
Till We Meet Again

