

Safe Blood supply during Infectious disease outbreaks

a project of
Swiss Transfusion SRC
and
The University Hospital of Geneva

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Blood Demand in international comparision

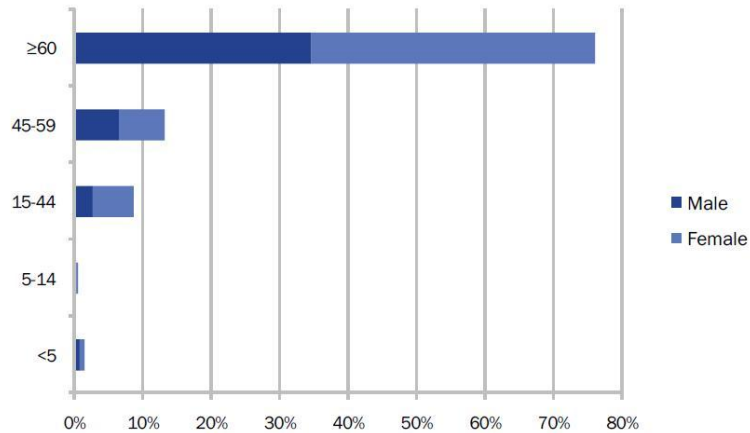
Industrialized countries



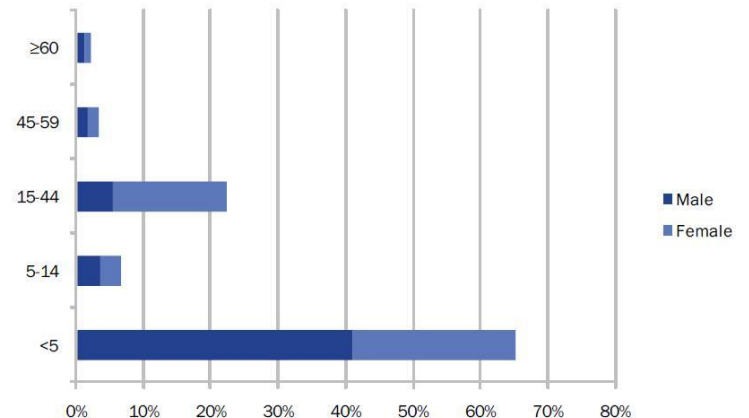
Sub saharian countries



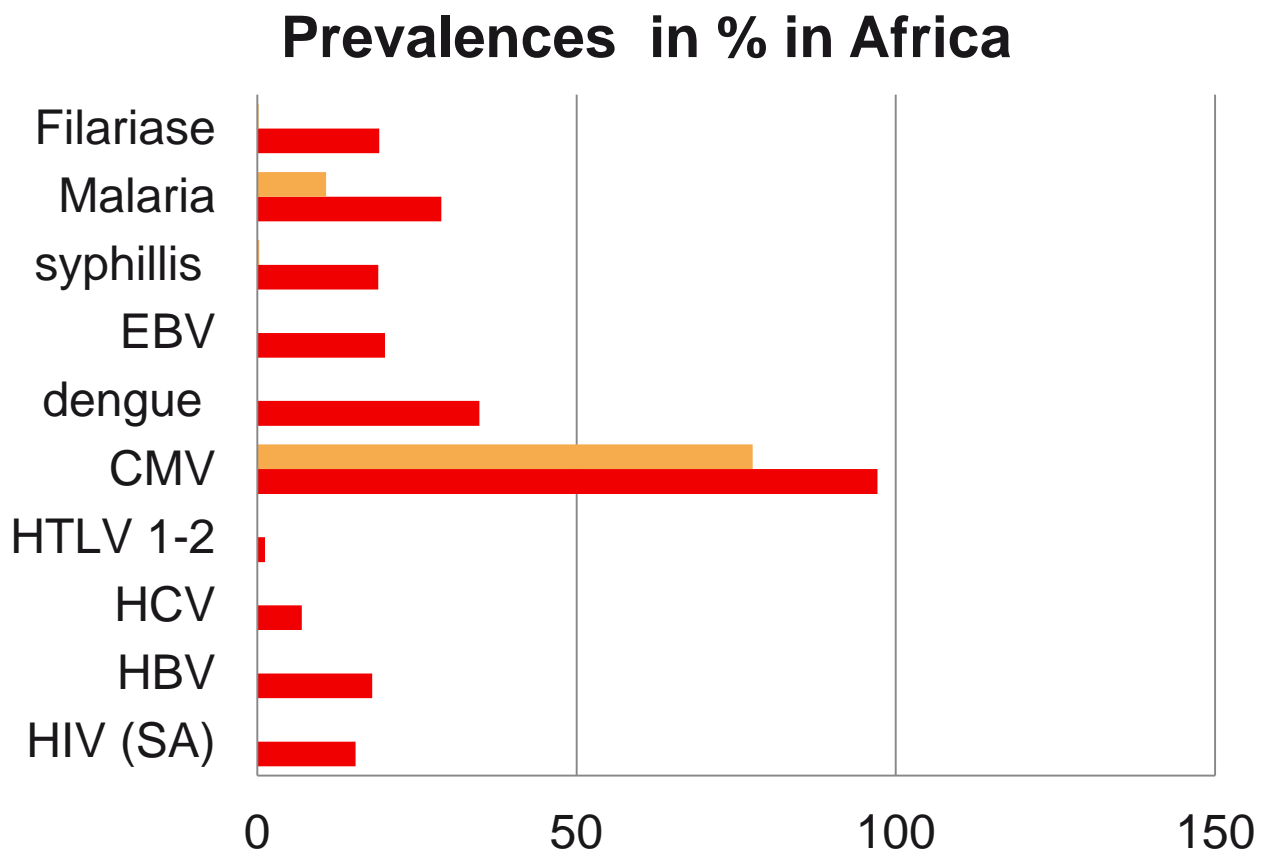
Denmark (patients transfused: 53 834)



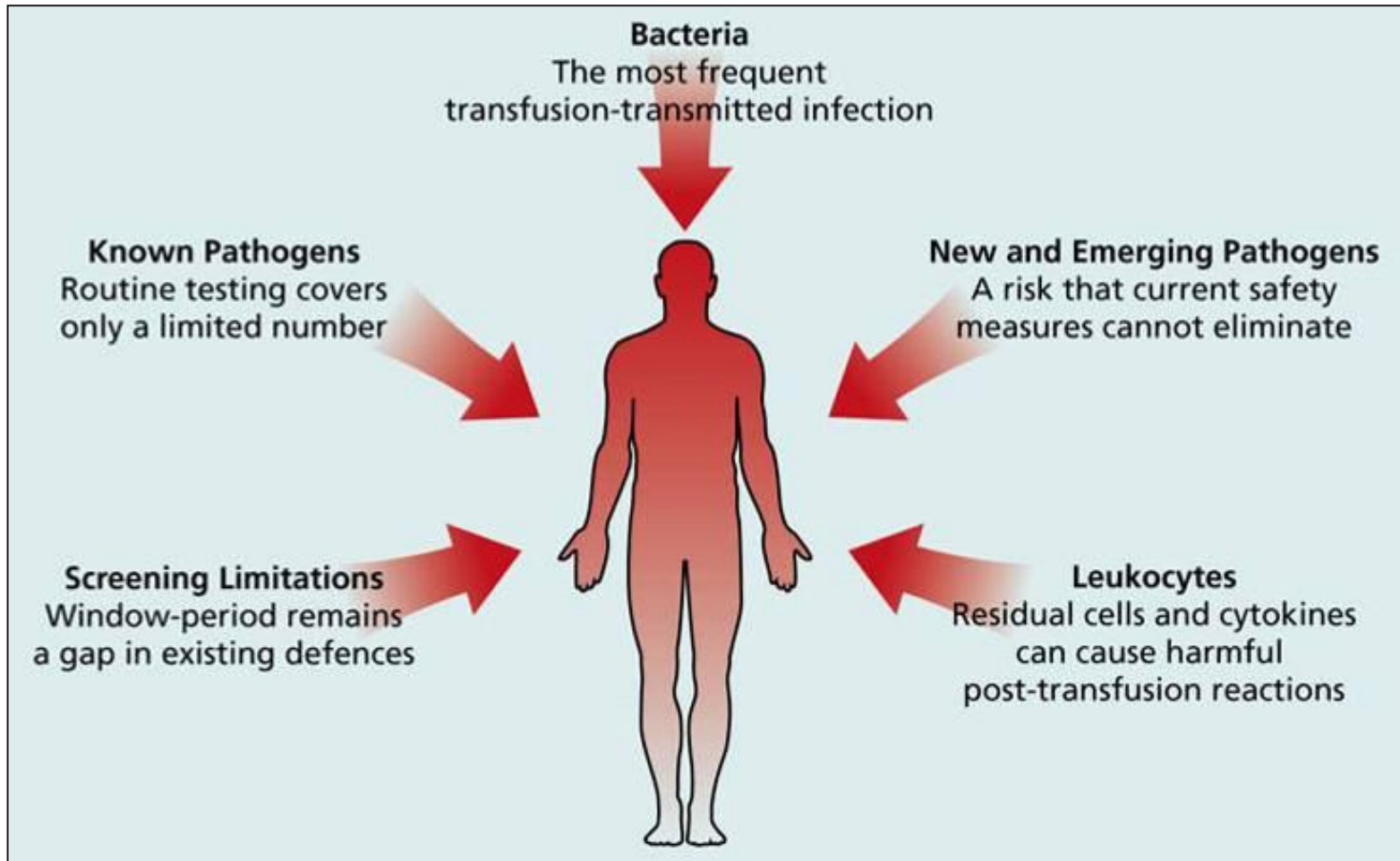
Benin (patients transfused: 55 459)



Prevalent Infectious diseases



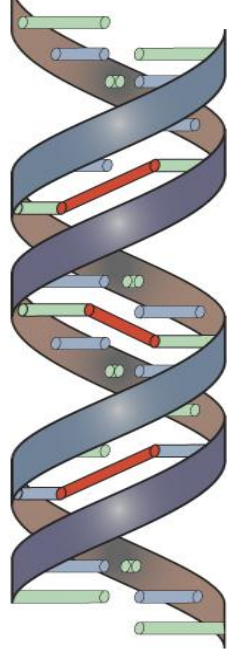
Prevention of transmission: Testing and Pathogen Inactivation



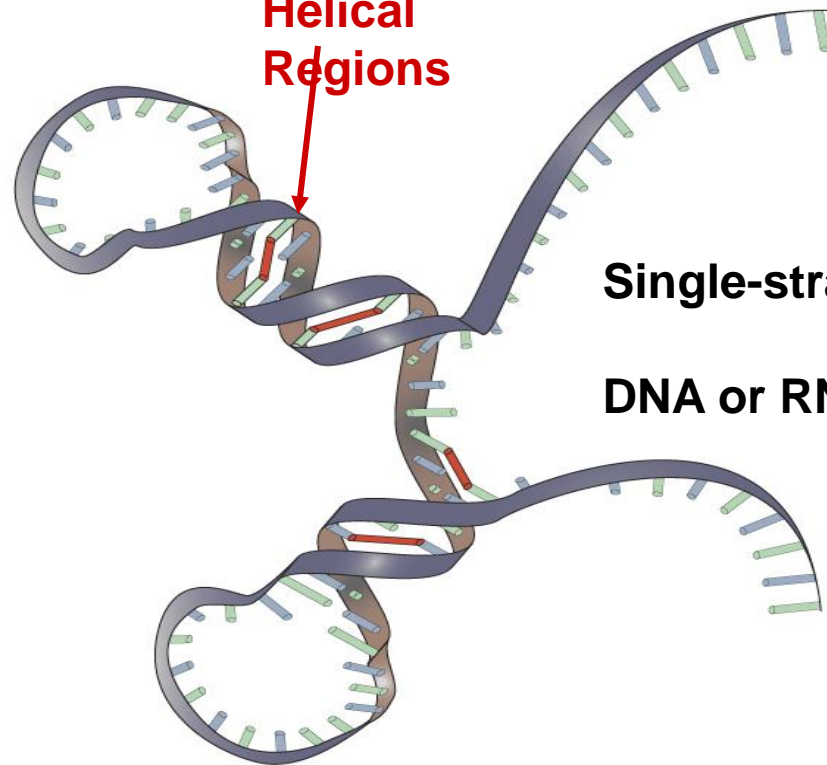
Pathogen Inactivation by the Intercept method (S303)

Double-stranded

DNA or RNA



**Helical
Regions**



Single-stranded

DNA or RNA

The PI technology inactivates parasites and viruses

Pathogen	Mean Log Reduction*
First generation system	
<i>Plasmodium falciparum</i>	>6.8
<i>Babesia microti</i> ,	>4.9
<i>Trypanosoma cruzi</i>	>5.3
West Nile virus	>6
Second generation system – tube study	
XMRV	>4

*n=1-3 RBC units or tubes

Pathogen	Mean Log Reduction**
<i>S. aureus</i>	5.1 ± 0.3
<i>S. marcescens</i>	5.1 ± 0.1
<i>Y. enterocolitica</i>	≥6.8 ± 0.2
<i>E. coli</i>	≥6.7 ± 0.1
HIV	>5.9 ± 0.1
Bovine viral diarrhea virus	>4.8 ± 0.1
Blue Tongue	≥5.0 ± 0.4
Adenovirus Type 5	>7.4 ± 0.2

**Second generation process, n=4 full RBC units

PI with Intercept

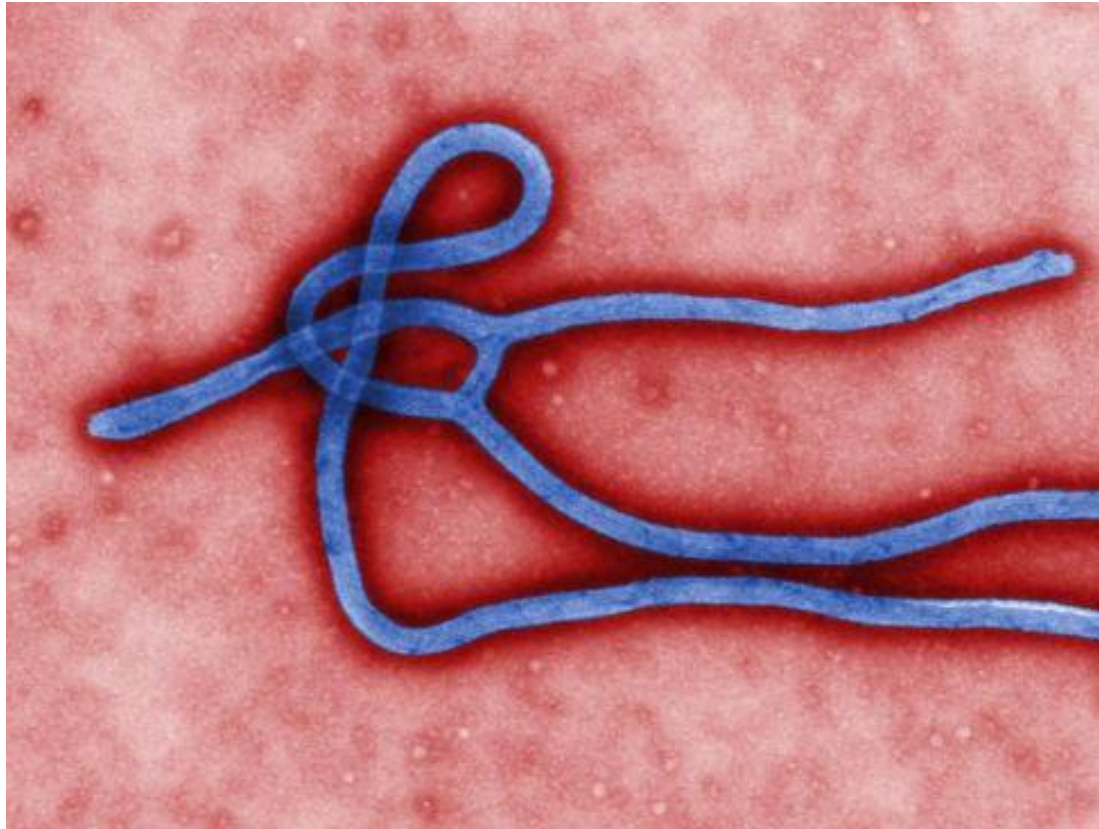
- Pathogen Inactivation (PI) is routinely used in Switzerland for **Platelets** (since 2012) and for **fresh frozen Plasma** (since 2014).
- **Red Cells:** 5 clinical trials with the first generation and two clinical studies with the second generation have been completed
- 3 clinical studies on Red Cells in Germany, Italy and France started 2012 on acute and chronic anaemia patients
- New project:

➤ **Transfer of the PI method on Whole Blood**

Reasons for Whole Blood

- More than 70% of the transfusions in Sub-Saharan Africa are Whole Blood Transfusions
- This technology is easy to use in rural contexts
 - No expensive aphaeresis machines
 - No expensive separation into RBC and Plasma
 - Easier to recruit and to train the staff
- We are addressing major challenges
 - Transfusion related maternal mortality in Sub-Saharan Africa, very often in rural areas with limited ressources
 - Prevalence of Malaria in Sub-Saharan Africa

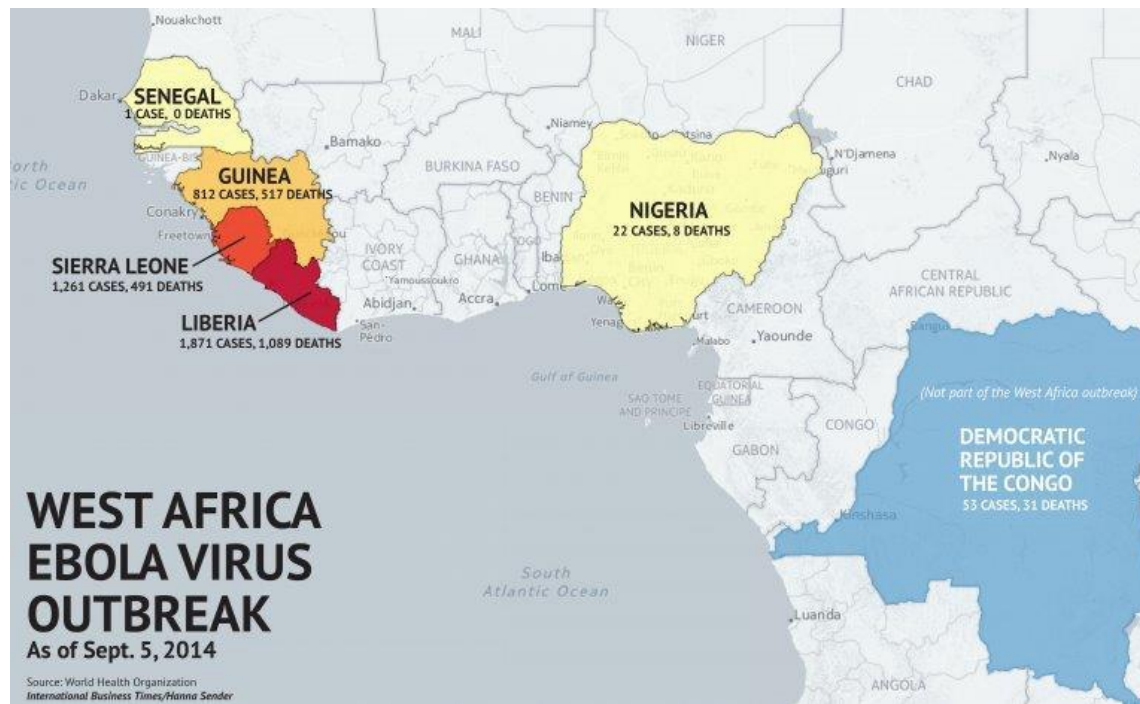
Ebola – Epidemic outbreak 2014



EBOLA RESPONSE ROADMAP SITUATION REPORT

WHO, 29 OCTOBER 2014

There have been 13 042 EVD cases, with 4 818 deaths, up to the end of 05 November.



Convalescent Plasma and Whole Blood (I)

- No proven treatment for Ebola Virus Disease (EVD) is currently available.
- However, blood collected from patients who have recovered from EVD may be an effective treatment, due to the contained high antibody titer.
- The WHO task force reached consensus that the use of experimental medicines and vaccines under the exceptional circumstances of the Ebola epidemic is ethically acceptable.

Convalescent Plasma and Whole Blood (II)

- The experts agreed to prioritize convalescent blood and plasma therapies for further investigation.
- Several studies from different groups starting in the near future in the affected countries, with
 - Convalescent Plasma
 - Pathogen Inactivated Convalescent Plasma (Intercept method)
- Difficulties to recruit enough trained medical and technical staff
- Limitations in the number of convalescent patients
- **Our project on PI Whole Blood is NOT ready for clinical trials yet**

Combination of Pathogen Inactivation and Convalescent Whole Blood (4 – 5 years to finish)

Phase 1 :
Feasibility
and toxicity
studies

Phase 2 :
Clinical Trials
in 3 African
centres

Phase 3 :
Post Clinical
Trial



Our goal

- To achieve a safe technology which can be rapidly used in large **and** small medical centers
- To eliminate the transmission of infections by blood
- To use this technology in combination with convalescent donors to treat patients during epidemic outbreaks like Ebola.

➤ **To give our patients a future**

Thank you!

