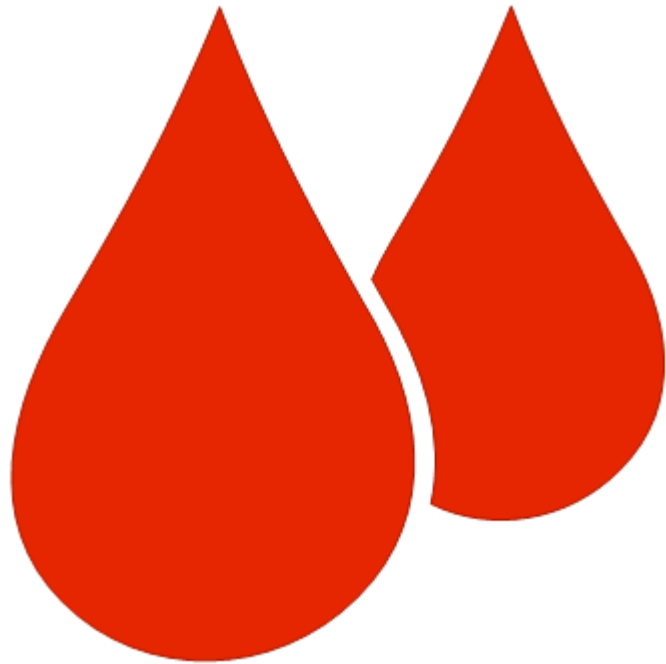


# PROPOSALS TO MITIGATE THE RISK OF DELIBERATE CONTAMINATION OF BLOOD TRANSFUSION COMPONENTS IN TUNISIA



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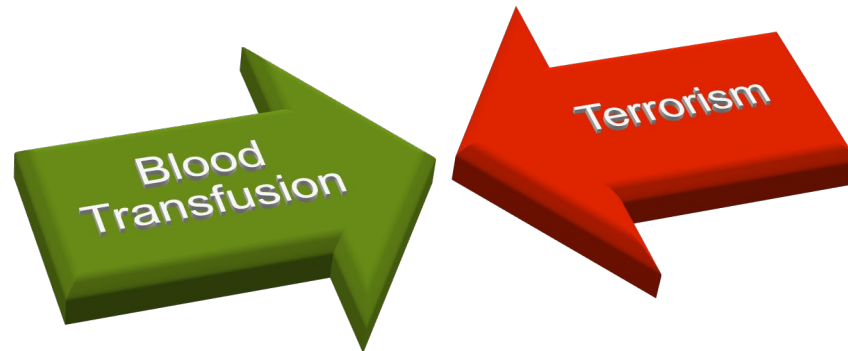
ABSA International 62<sup>nd</sup> Annual Biosafety and Biosecurity Conference  
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# Introduction

**Blood transfusion:** life-saving intervention that has an essential role in patient management within health care systems

Over 220,000 units of blood donations are collected each year in Tunisia (110 millions worldwide)

Many **terrorist organizations** have expressed an interest acquiring biological weapons



# Preparation of blood components from whole blood



Centrifugations and separations of blood components

**Test for:**  
HIV  
Hepatitis B  
Hepatitis C  
Syphilis  
ABO + RhD  
Other phenotypes

Special processes

Patient



# How a terrorist may proceed



# Could deliberate contamination be attractive to terrorists?

|                    | Classical bioterrorism diagram | Blood transfusion attack |
|--------------------|--------------------------------|--------------------------|
| Agent acquisition  | Difficult                      | Very simple              |
| Agent production   | Difficult                      | -                        |
| Weapons Production | Difficult                      | Very simple              |
| Storage            | Difficult                      | -                        |
| Dissemination      | Difficult                      | -                        |



Extremely challenging



Extremely simple

# Could deliberate contamination be attractive to terrorists?

## Consequences

Population impact

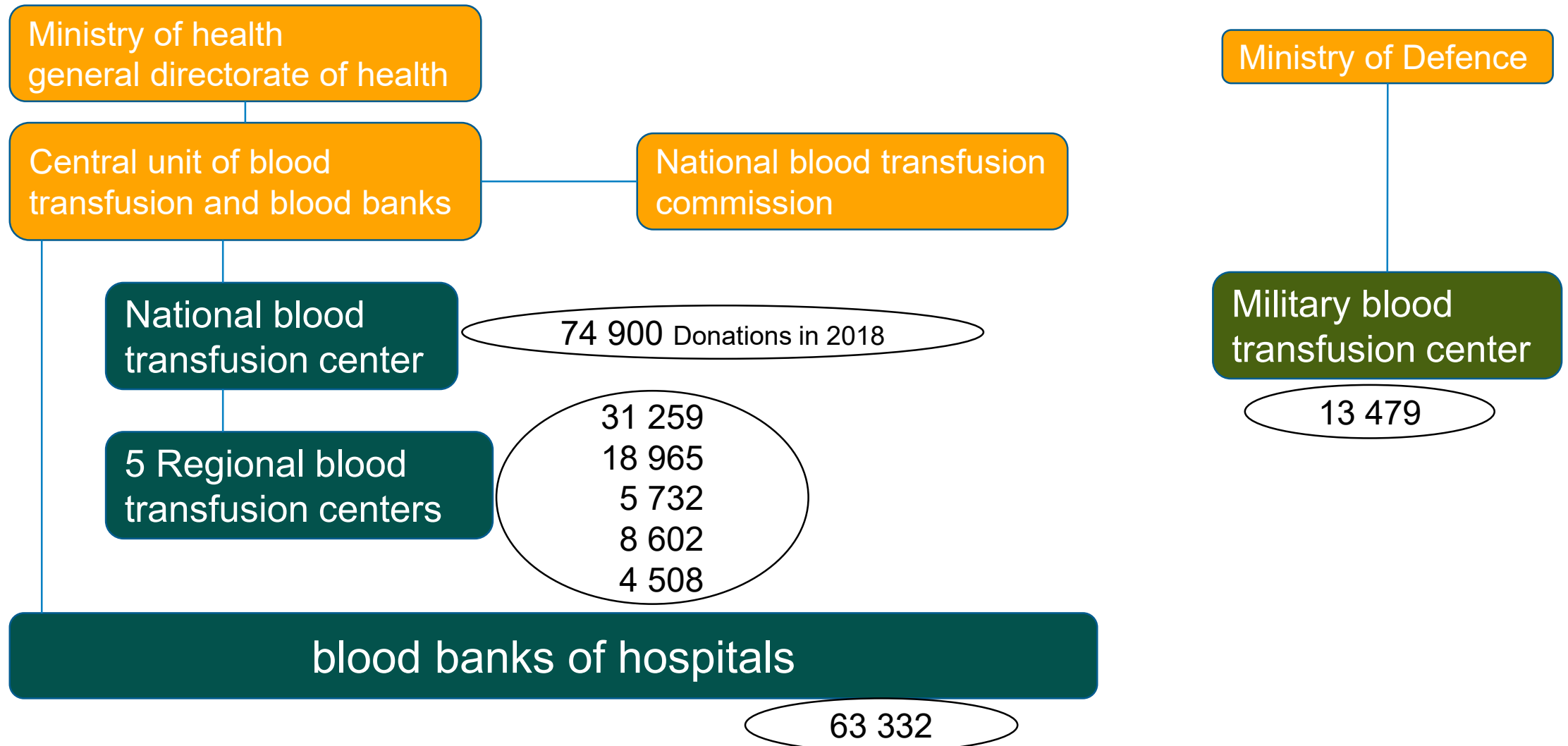
Healthcare impact

Political impact

Psychological impact

**Terrible**

# Blood centers in Tunisia





# Safety Safet ... Only Safety

The  
Clinical  
Use  
of  
Blood

Handbook

## ASSESSMENT CRITERIA FOR NATIONAL BLOOD REGULATORY SYSTEMS

## Screening Donated Blood for Transfusion- Transmissible Infections

Recommendations



World Health Organization

## Safe Blood Components

### AIDE-MÉMOIRE

for National Health Authorities

Safe blood may be used most effectively if it is divided into components prepared from whole blood donations or obtained by apheresis procedures. One unit of whole blood can be used to meet the needs of more than one patient and provide only that component that is required. In addition, the availability of blood components enables the provision of therapeutic support for patients with conditions such as disorders of haemoglobin, coagulation and bone marrow.

An effective blood component programme requires a sustainable national blood programme, including a well-organized, nationally coordinated blood transfusion service (BTS), a stable base of suitable, voluntary non-remunerated blood donors, accurate testing systems, quality systems and a suitable regulatory mechanism. For this, the commitment and support of national health authorities and additional human, financial and technological resources are needed.

Requirements for a blood component programme include:

- Effective strategies for the recruitment and retention of voluntary non-remunerated blood donors, including apheresis donors, where applicable, to ensure a safe, adequate and reliable source of blood for component preparation
- Centralization or regionalization of blood p... permit economies of scale and uniform sta...
- Systems and standardized procedures for d... collection, processing, testing, storage and tr... the consistent quality, safety and efficacy of...
- Training of BTS staff in all activities related blood components
- Training in appropriate blood component t... involved in the clinical transfusion process.

Consideration should be given to the use of surp... production of plasma-derived medicinal product... utilizing facilities either within or outside the coun...

### Words of advice

- Assess the clinical demand for blood compo... of a component preparation programme
- Develop a programme that complies with reg... and is appropriate to the level of the health c... the diagnostic and medical services available
- Allocate adequate human and financial resou... sustainability of the programme
- Build a stable base of regular, voluntary non... donors to meet collection targets for blood co...
- Consolidate blood processing and testing wit...
- Strengthen the interaction between the BTS... promote appropriate blood component the...

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### Checklist

- Organizational requirements**
- Nationally-coordinated BTS with centralized/regionalized processing and testing
  - Assessment of clinical demand and feasibility of blood component programme
  - Adequate, sustainable finances
  - Suitable premises, working environment and waste management system
  - Appropriate infrastructure
  - Suitable regulatory mechanism
  - Sufficient number of trained staff
  - Appropriate technology, equipment and materials for blood collection, testing and processing
  - Effective quality systems, including standardized procedures and good manufacturing practices
  - Documentation of all processes and accurate labelling
- Blood donors and blood collection**
- Panel of regular voluntary blood donors
  - National criteria for donor selection and

## Protecting the Blood Supply During Infectious Disease Outbreaks

© World Health Organization  
WHO Technical Report Series, No. 961, 2011

### Annex 4 WHO guidelines on good manufacturing practices for blood establishments

1. Introduction
2. Glossary and abbreviations
3. Quality management
  - 3.1 Principles
  - 3.2 Quality assurance
    - 3.2.1 Good manufacturing practice in blood establishments
    - 3.2.2 Quality control
  - 3.3 Product quality review
  - 3.4 Quality risk management
  - 3.5 Change control
  - 3.6 Deviation evaluation and reporting
  - 3.7 Corrective and preventive actions
  - 3.8 Internal audits
  - 3.9 Complaints and product recall
    - 3.9.1 Complaints
    - 3.9.2 Recalls
  - 3.10 Process improvement
  - 3.11 Look-back
4. Personnel
  - 4.1 Organization and responsibilities
  - 4.2 Training
    - 4.2.1 Initial training
    - 4.2.2 Continuous training
    - 4.2.3 Competency
  - 4.3 Personal hygiene
5. Documentation
  - 5.1 Standard operating procedures and records
    - 5.1.1 Standard operating procedures
    - 5.1.2 Records
  - 5.2 Document control
    - 5.2.1 Document management
    - 5.2.2 Record retention and archiving
6. Premises and equipment
  - 6.1 Premises

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## Universal Access to Safe Blood Transfusion



National

World  
Organ

2016

## Global Status Report on Blood Safety and Availability



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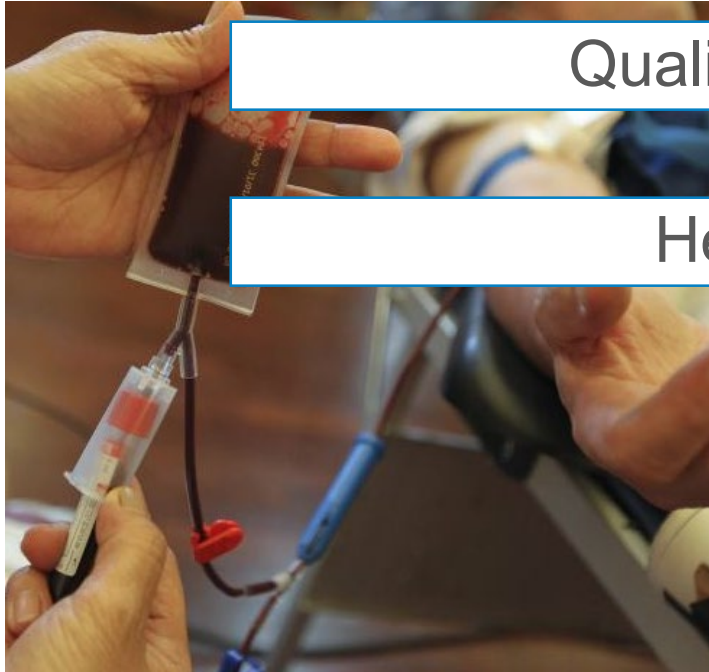


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# But you might say...

Donor screening for ~~infectious agents~~



Quality management ~~management~~

Hemovigilance ~~vigilance~~



# Proposals of mitigation measures

Outside threat  
Investigations

**Contribution**

1

Physical security  
preventing  
unauthorized access to  
the facilities that  
process and store the  
blood components

**Limits**

Cost  
Implementation  
Time

# Proposals of mitigation measures

Allow the detection of contaminations

**Contribution**

2

Strengthen quality management by including elements that take into account the risk of deliberate contamination.

**Limits**

Difficult Training

# Proposals of mitigation measures

Detection of various biological contaminations

## Contribution

3

development and use of molecular diagnostic tests that enable testing of a variety of contaminants

## Limits

Difficult to include in the process  
Time  
Cost

# Proposals of mitigation measures

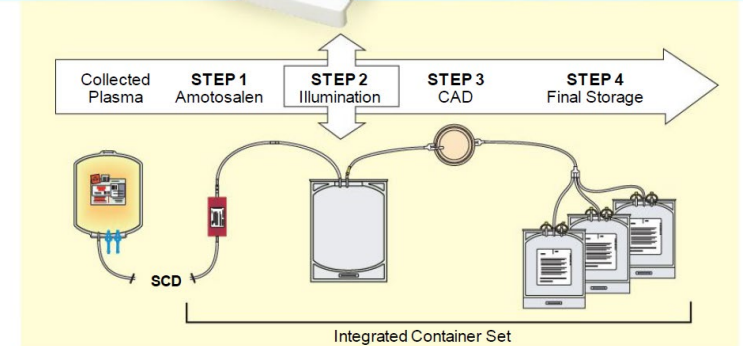
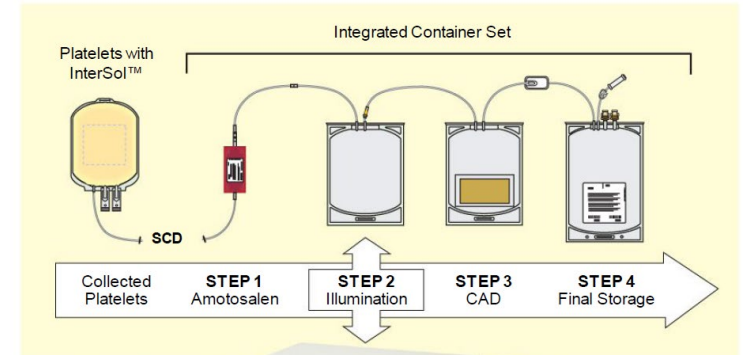
Excellent safety net  
Mitigate the risk associated with the earlier stages of

Contribution

4

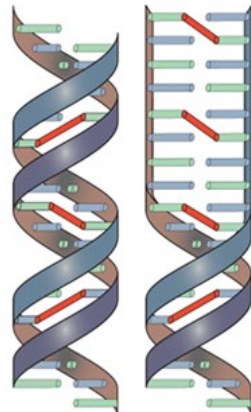
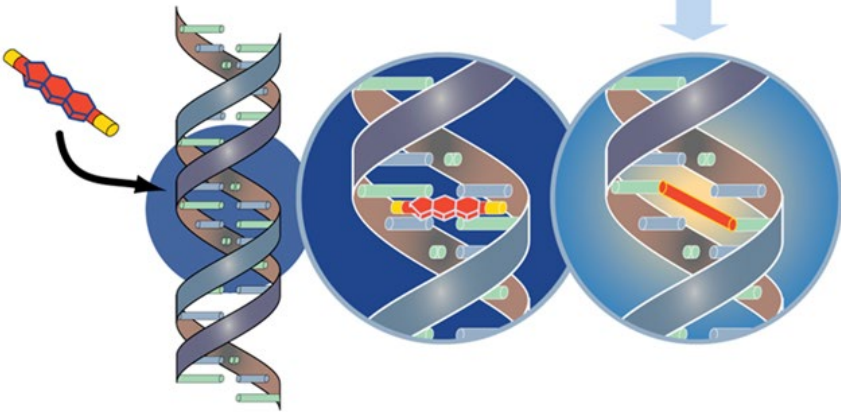
Pathogen inactivation technologies

Li



Amotosalen (S-59)

UVA Illumination



DNA or RNA

Reversible bond

Irreversible bond

Blocking of replication



# Proposals of mitigation measures

Insider threat  
Culture of responsibility

**Contribution**

5

conducting  
background checks of  
all employees in blood  
banks

**Limits**

Ressources  
Regulations  
Time  
Limited effectiveness

# Proposals of mitigation measures

Protection of sensitive information

**Contribution**

6

Cybersecurity of computer systems involved in testing, processing, and maintaining inventory and access logs of the blood

**Limits**

Cost  
Training  
Time

# Proposals of mitigation measures

Confirmation that institution invest time and effort

**Contribution**

7

Audit and inspections of facilities that collect, test, process, and supply the blood

**Limits**

Security standards  
Time

# Conclusion

Blood banks: potential  
bioweapons labs

Mitigation measures : in  
combination, difficult to implement



Risk communication ?

Biosecurity professionals:  
major role

Goal : safe and  
**SECURE** blood for all