# A decade and a half of haemovigilance in South Africa

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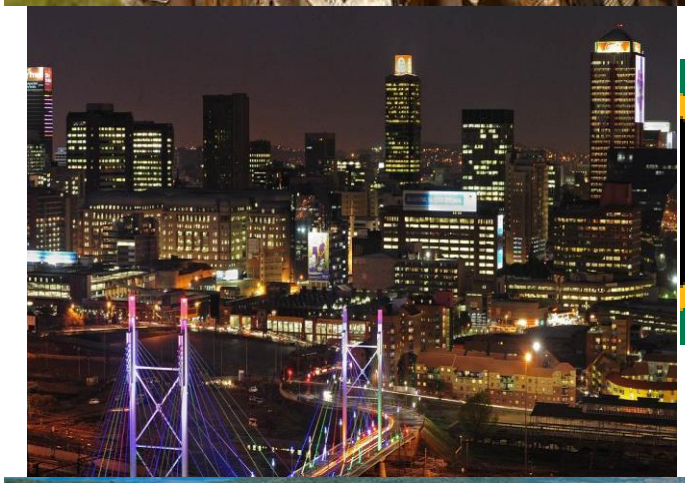



Platform A
Platform B

# Presentation overview

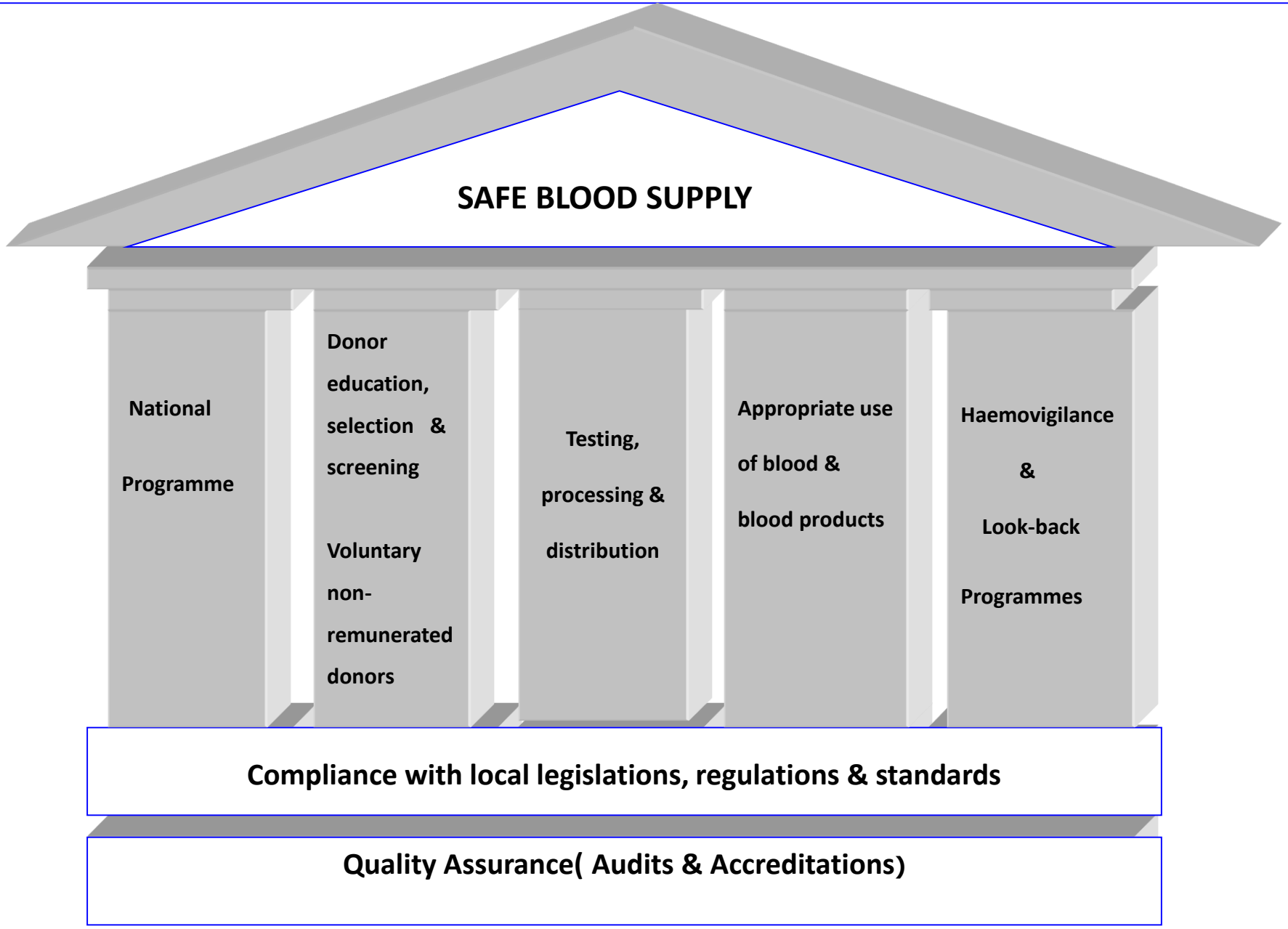
- Introduction - general country information
- Blood Transfusion Systems in the country
- S.A Haemovigilance (HV) system
- Challenges and constraints
- Future goals

# General country information

- SA population- 54 million
- 9 provinces
- 12 official languages
- Democratic since 1994

# Blood Transfusion Systems in the country

- 7 independent blood transfusion services merged in 2001
- 2 Blood Transfusion Services in South Africa :
  - South African National Blood Service (SANBS)
  - Western Province Blood Transfusion Service (WPBTS)
- Licensed by the National Department of Health
- ± 1 million units collected annually by both services (100% VNRD)
  - Fixed Centres 107
  - Mobiles 97
- ± 1,1 million units issued annually
  - Blood banks 93
  - Emergency fridges 500
  - Healthcare facilities 749 (public ± 80%, Private ± 20%)


SAFE BLOOD SUPPLY
National Programme
Donor education, selection & screening
Voluntary non-remunerated donors
Testing, processing & distribution
Appropriate use of blood & blood products
Haemovigilance & Look-back Programmes
Compliance with local legislations, regulations & standards
Quality Assurance( Audits & Accreditations)

# SA Haemovigilance system

# Milestones

- **Human Tissue Act 1983** (No 65 of 1983) and the Regulations Relating to Blood and Blood Products No R. 1935 of 17 August 1990
- The programme was initiated by collating historical information gathered by means of a **questionnaire**(Jan--Dec 2000)

**2000**

HV established

Modeled on:

United Kingdom's Serious Hazards of Transfusion (SHOT) system

**2010**

- Joined the International Haemovigilance Network system(IHN)

& ISTARE submissions

- Donor vigilance incorporated

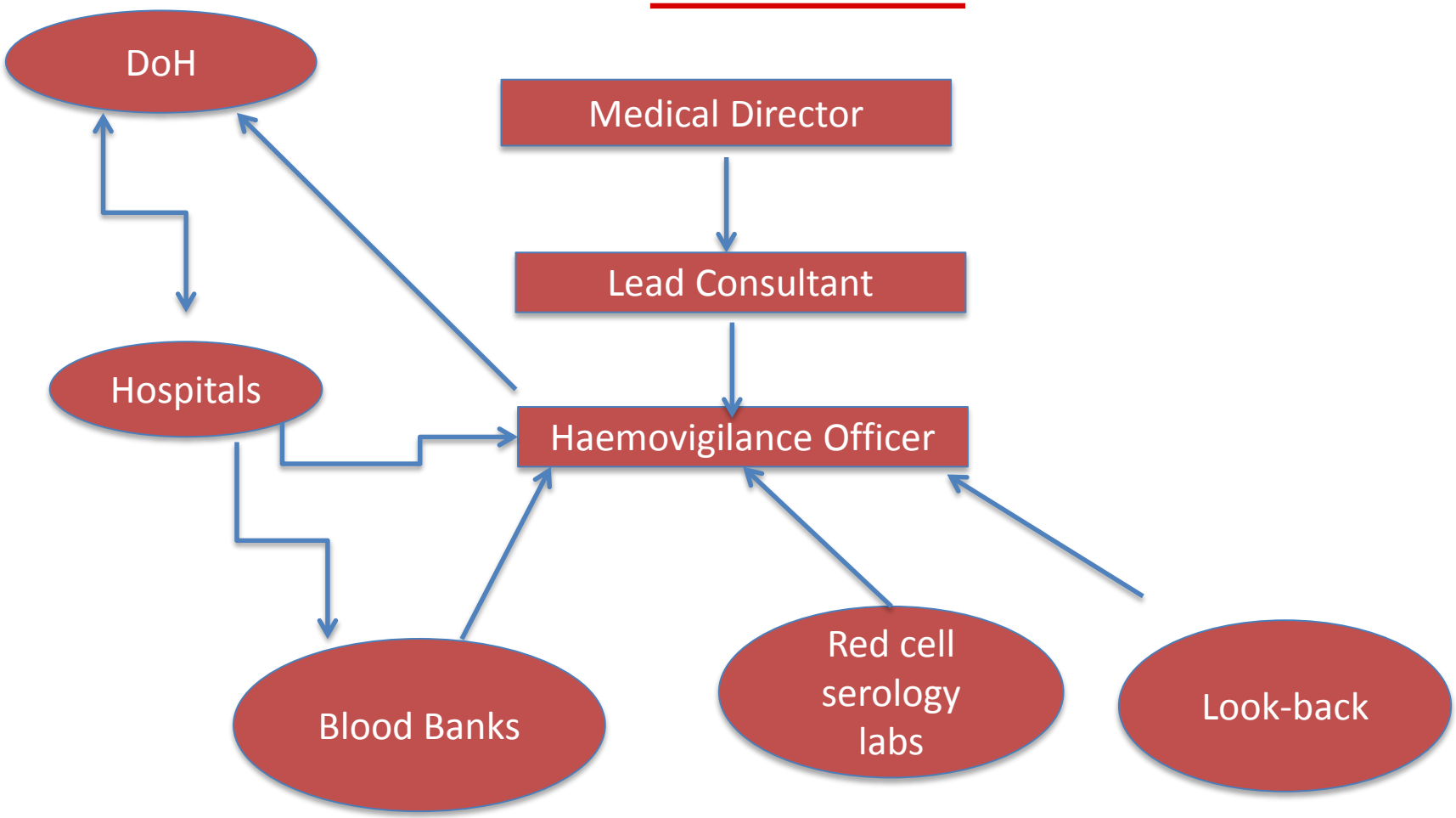
**2014**

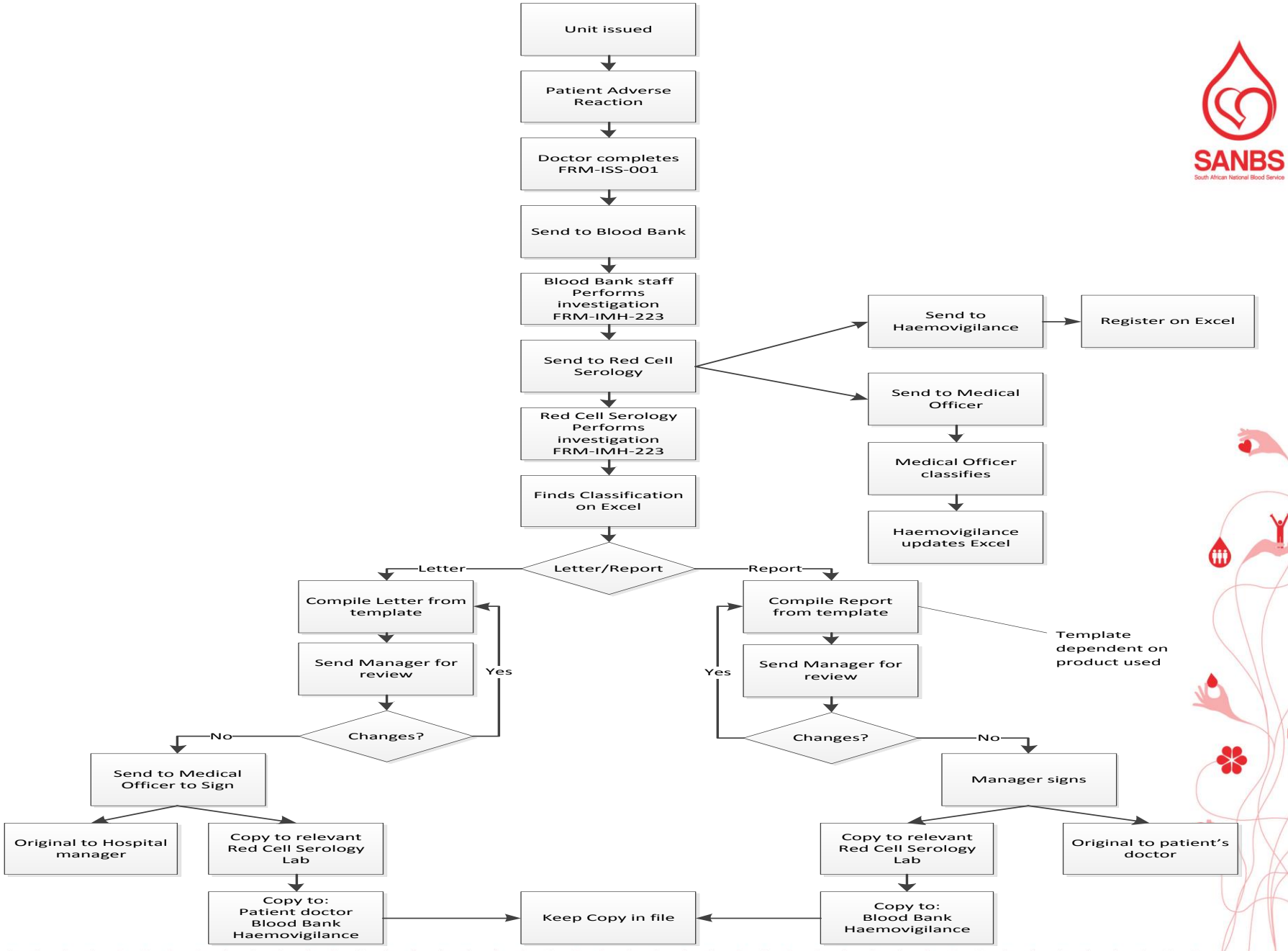
- MSM ban lifted
- Iron study conducted
- WHO guidelines draft committee participation
- Hosted HV session at AfSBT in Victoria falls with WHO

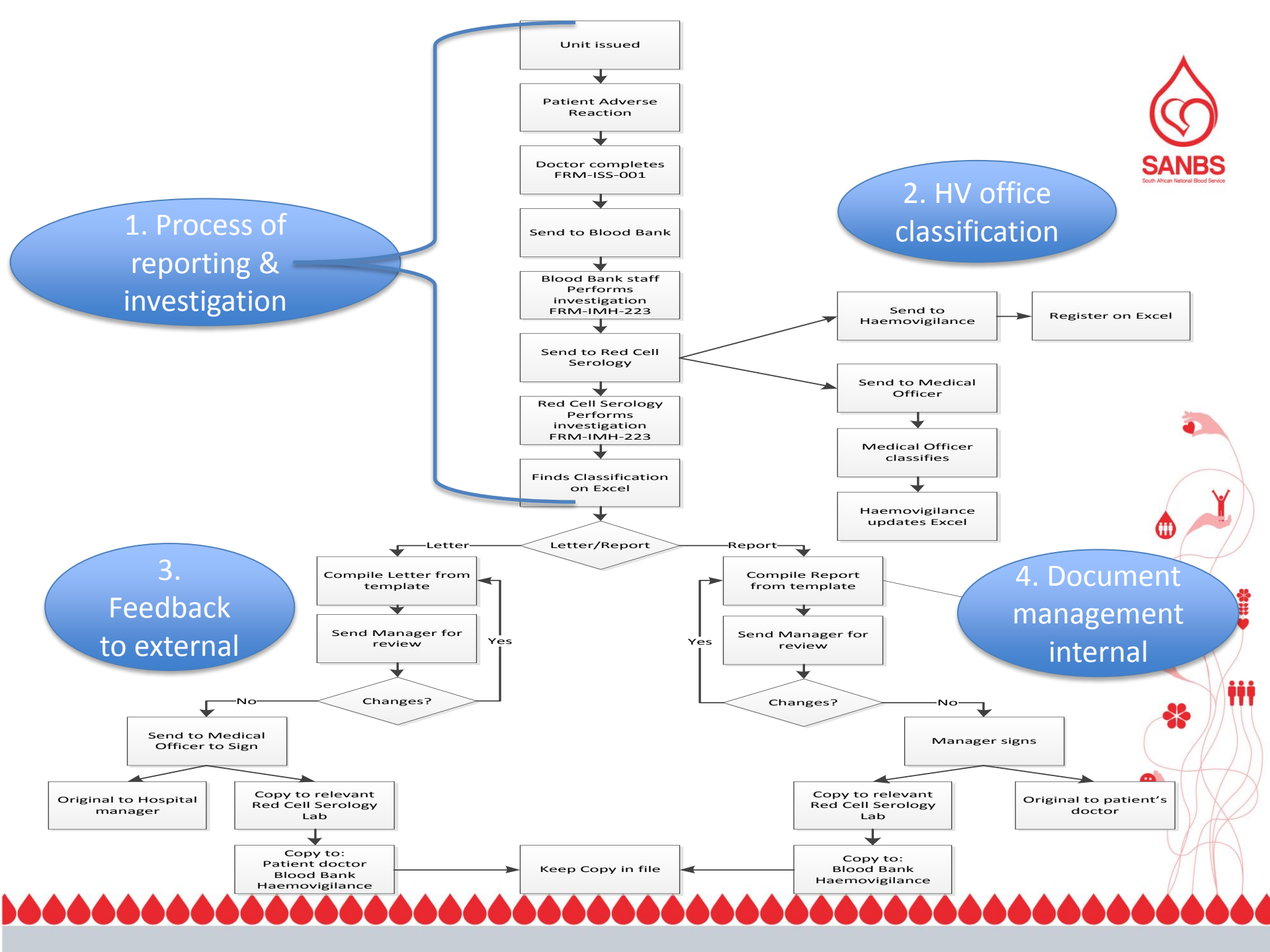
**2015**

- HV electronic system implemented
- Reviewed Transfusion reaction form
- Mentoring other African countries in HV (Botswana, Ethiopia)

# Structure


DoH
Medical Director
Lead Consultant
Hospitals
Haemovigilance Officer
Blood Banks
Red cell serology labs
Look-back


Unit issued
Patient Adverse Reaction
Doctor completes FRM-ISS-001
Send to Blood Bank
Blood Bank staff Performs investigation FRM-IMH-223
Send to Red Cell Serology
Send to Haemovigilance
Register on Excel
Send to Medical Officer
Medical Officer classifies
Haemovigilance updates Excel
Red Cell Serology Performs investigation FRM-IMH-223
Finds Classification on Excel
Letter/Report
Letter
Report
Compile Letter from template
Send Manager for review
Changes?
Yes
No
Compile Report from template
Send Manager for review
Changes?
Yes
No
Template dependent on product used
Send to Medical Officer to Sign
Original to Hospital manager
Copy to relevant Red Cell Serology Lab
Copy to: Patient doctor Blood Bank Haemovigilance
Manager signs
Copy to relevant Red Cell Serology Lab
Original to patient's doctor
Copy to: Blood Bank Haemovigilance
Keep Copy in file


1. Process of reporting & investigation
2. HV office classification
3. Feedback to external
4. Document management internal
Unit issued
Patient Adverse Reaction
Doctor completes FRM-ISS-001
Send to Blood Bank
Blood Bank staff Performs investigation FRM-IMH-223
Send to Red Cell Serology
Red Cell Serology Performs investigation FRM-IMH-223
Finds Classification on Excel
Send to Haemovigilance
Register on Excel
Send to Medical Officer
Medical Officer classifies
Haemovigilance updates Excel
Letter/Report
Letter
Report
Compile Letter from template
Send Manager for review
Changes?
Yes
No
Send to Medical Officer to Sign
Original to Hospital manager
Copy to relevant Red Cell Serology Lab
Copy to: Patient doctor Blood Bank Haemovigilance
Compile Report from template
Send Manager for review
Changes?
Yes
No
Manager signs
Copy to relevant Red Cell Serology Lab
Original to patient's doctor
Copy to: Blood Bank Haemovigilance
Keep Copy in file
SANBS
South African National Blood Service

# Policies & procedures

- Transfusion reaction form (FRM-ISS-001)
- Blood bank investigation (FRM-IMH-223)
- Transfusion reaction SOP
- Meditech System (completed)
- Business Intelligence- Haemovigilance cube (in development)

ACCOUNT NUMBER | LAB NUMBER | HOSPITAL LABEL

## PATIENT INFORMATION

Name of patient: _____ Age: _____
Surname: _____ Gender: M ☐ F ☐
Hospital name: _____ Hospital number: _____
Diagnosis (before transfusion): _____
Indication for transfusion: _____
Products transfused: _____ Unit/Pack numbers: _____
Was the blood warmed? _____ How? _____
CATEGORY: ☐ Haematology ☐ Oncology ☐ Medical ☐ Obstetrics/Gyn/Perinatal ☐ Anaesthetics
☐ Trauma ☐ Surgical ☐ Paediatric ☐ Orthopaedics
Brief medical history: _____

## REACTION DETAILS

Date of transfusion: ___/___/___ Time: _____ Volume transfused: _____
**Onset of reaction:** ☐ Immediate ☐ < 1 hr ☐ 1-2 hrs ☐ < 6 hrs ☐ > 6 hrs ☐ > 24 hrs Date: ___/___/___

## CLINICAL SIGNS AND SYMPTOMS (Compulsory fields, please complete in full)

| Symptoms (Tick all that apply) | Pre-transfusion | Temp: °C | BP: | Pulse: | Hb: |
|---|---|---|---|---|---|
| | Post-transfusion | Temp: °C | BP: | Pulse: | Hb: |

| | | | |
|---|---|---|---|
| ☐ Urticaria (rash) | ☐ Joint/muscle pain | ☐ Dyspnoea (shortness of breath) | ☐ Pruritis (itching) |
| ☐ Back pain | ☐ Wheezing | ☐ Facial/tongue swelling | ☐ Chest pain |
| ☐ Hypertension | ☐ Fever | ☐ Dizziness | ☐ Hypotension (SBP drop ≤ 30mm Hg) |
| ☐ Headache | ☐ Jaundice | ☐ Tachycardia (Hr rise > 40bmp) | ☐ Rigors (involuntary shaking) |
| ☐ Oliguria | ☐ Flushing/sweating | ☐ Collapse | ☐ Cyanosis |
| ☐ Shock | ☐ Restlessness/anxiety | ☐ Nausea/vomiting | ☐ Decrease in oxygen saturation |
| ☐ Haematuria | Other relevant clinical information: | | |

**Treating doctor information**

Name: _____ Contact no.: _____ Date: _____
Ward no.: _____ Signature: _____

## INCIDENT (For SANBS staff only)

☐ Patient misidentification ☐ Product related ☐ Near miss event ☐ Other (specify): _____

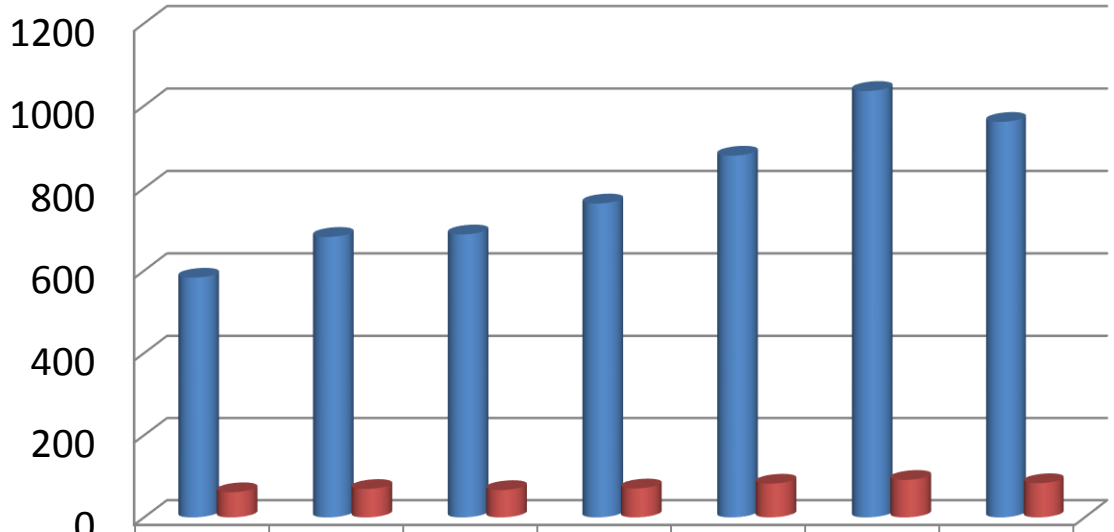
| | | | | |
|---|---|---|---|---|
| **Transfusion Reaction** | ☐ FNHTR | ☐ Minor allergic | ☐ Severe allergic | ☐ Anaphylactic shock |
| **Incompatible transfusion** | ☐ Acute haemolytic reaction | ☐ Delayed haemolytic reaction | | |
| | Cause: | | | |
| **Delayed Serological Transfusion Reaction:** | Specify new all antibody(ies) within 28 days of transfusion | | | |
| *Specify:* | | | | |
| ☐ TACO | ☐ TAD | ☐ Hypotensive reaction | ☐ PTP | ☐ TA-GVHD |
| **Bacterial Contamination** | ☐ Positive culture product | Organism (specify): | | |
| | ☐ Positive culture recipient | Organism (specify): | | |
| **TRALI** | ☐ Possible TRALI risk factors: | | | |
| | ☐ Unknown | ☐ Other (specify): | | |

## RELATIONSHIP AND GRADING (HAEMOVIGILANCE – OFFICE ONLY)

| | | | | | | |
|---|---|---|---|---|---|---|
| **Relationship of reaction to transfusion** | ☐ Definite | ☐ Probable | ☐ Possible | ☐ Doubtful | ☐ Ruled out | ☐ Not determined |
| **Severity (Grade)** | ☐ 1. (non-severe) | ☐ 2. (severe) | ☐ 3. (life-threatening) | | ☐ 4. Death | ☐ Not determined |

**Conclusion** (Based on IHN definitions) _____

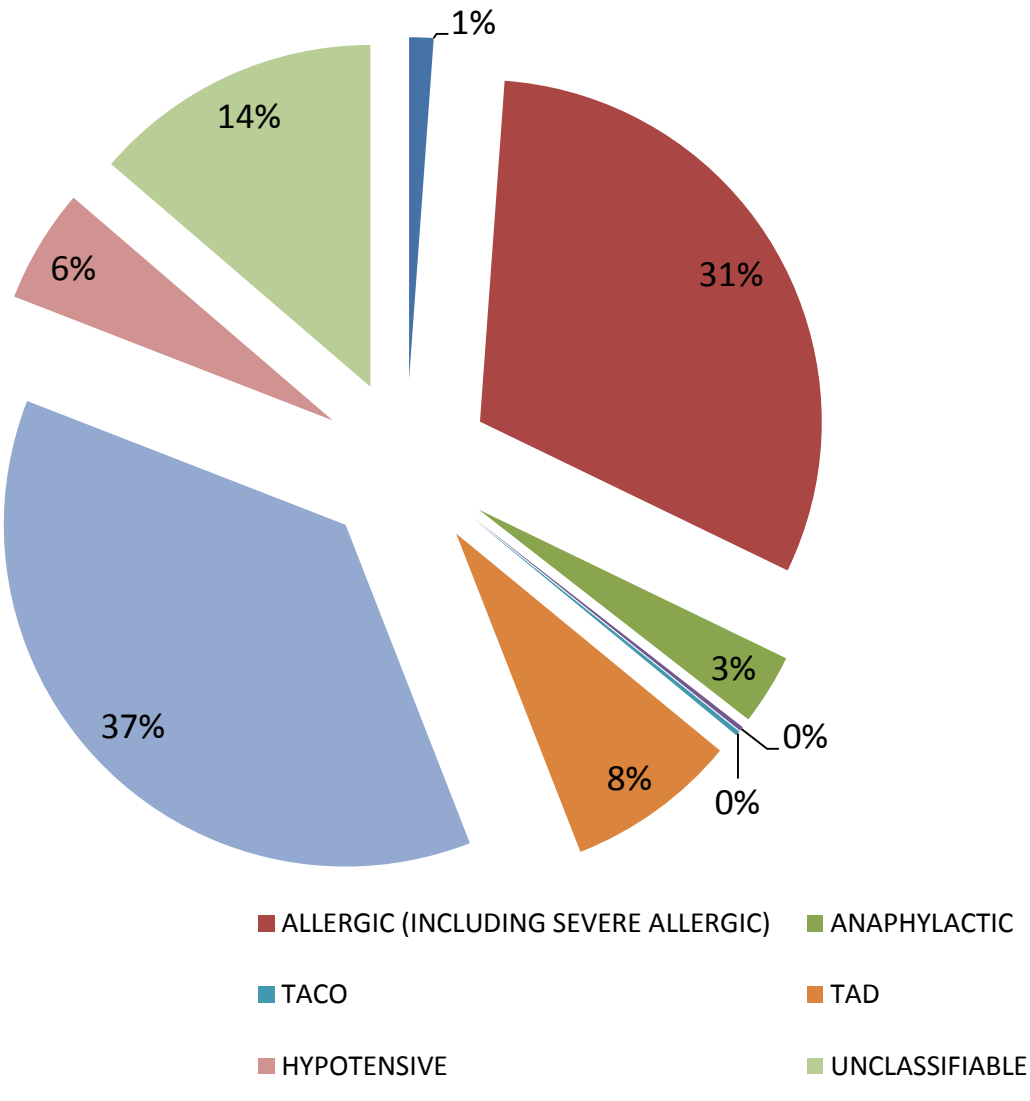
# Rates of Transfusion Adverse Events




| | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|---|
| adverse reactions | 583 | 682 | 688 | 763 | 879 | 1036 | 961 |
| rates per 100 000 issues | 61,3 | 69,3 | 66,6 | 70,5 | 82,2 | 91,4 | 83,4 |

| Acute reactions: | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Totals |
|---|---|---|---|---|---|---|---|---|
| AHTR | 13 | 15 | 15 | 1 | 4 | 4 | 10 | **62** |
| ALLERGIC (INCLUDING SEVERE ALLERGIC) | 177 | 222 | 231 | 221 | 274 | 297 | 251 | **1 673** |
| ANAPHYLACTIC | 11 | 5 | 6 | 16 | 26 | 64 | 53 | **181** |
| TRALI | 0 | 4 | 1 | 1 | 2 | 1 | 2 | **11** |
| TACO | 0 | 3 | 5 | 1 | 0 | 0 | 3 | **12** |
| TAD | 64 | 36 | 47 | 71 | 64 | 76 | 80 | **438** |
| FNHTR | 150 | 229 | 257 | 255 | 360 | 388 | 347 | **1 986** |
| HYPOTENSIVE | 25 | 12 | 51 | 54 | 40 | 52 | 57 | **291** |
| UNCLASSIFIABLE | 126 | 116 | 97 | 117 | 72 | 112 | 99 | **739** |
| Totals | **566** | **642** | **710** | **737** | **842** | **994** | **902** | **5 393** |

# Common Adverse events

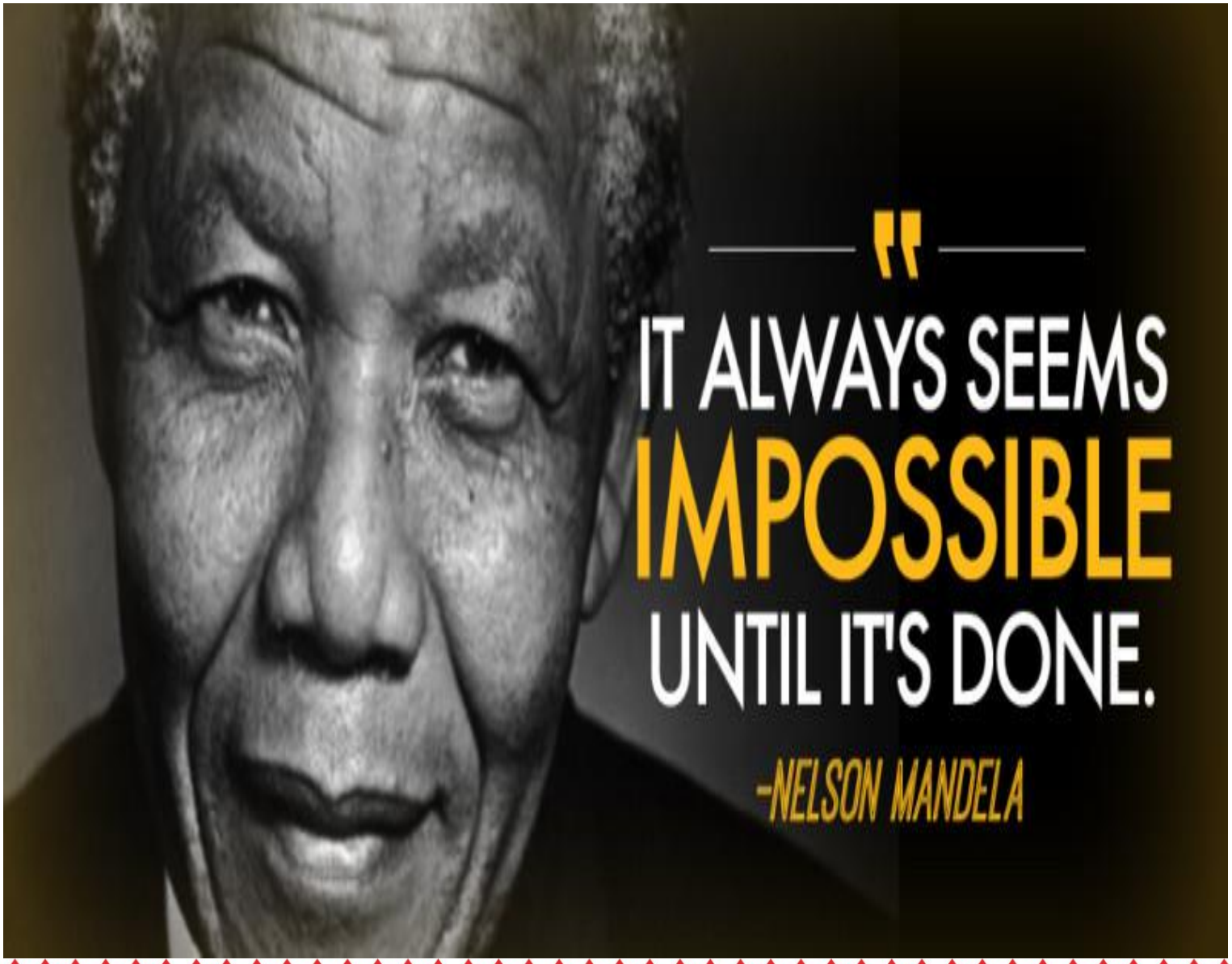


# Challenges & constraints

- Only 2 HV staff (Consultant & HV officer)
- Lack of education and training
  - HV staff
  - BBK staff
  - Doctors and other healthcare professionals
- Manual system of reporting (telephone, email & fax)
  - Some data might be missed/lost
  - High volumes of emails
- No single system between 2 BTSs; documents & templates not standardised
- Under-reporting of TAE

# Future goals

- Full electronic system
- Aligned templates for accuracy of data captured
- Increased staff capacity
- Education and training of all stakeholders
- Research in HV
- Continued collaborations within the continent & internationally


IT ALWAYS SEEMS
IMPOSSIBLE
UNTIL IT'S DONE.
-NELSON MANDELA


Thank you