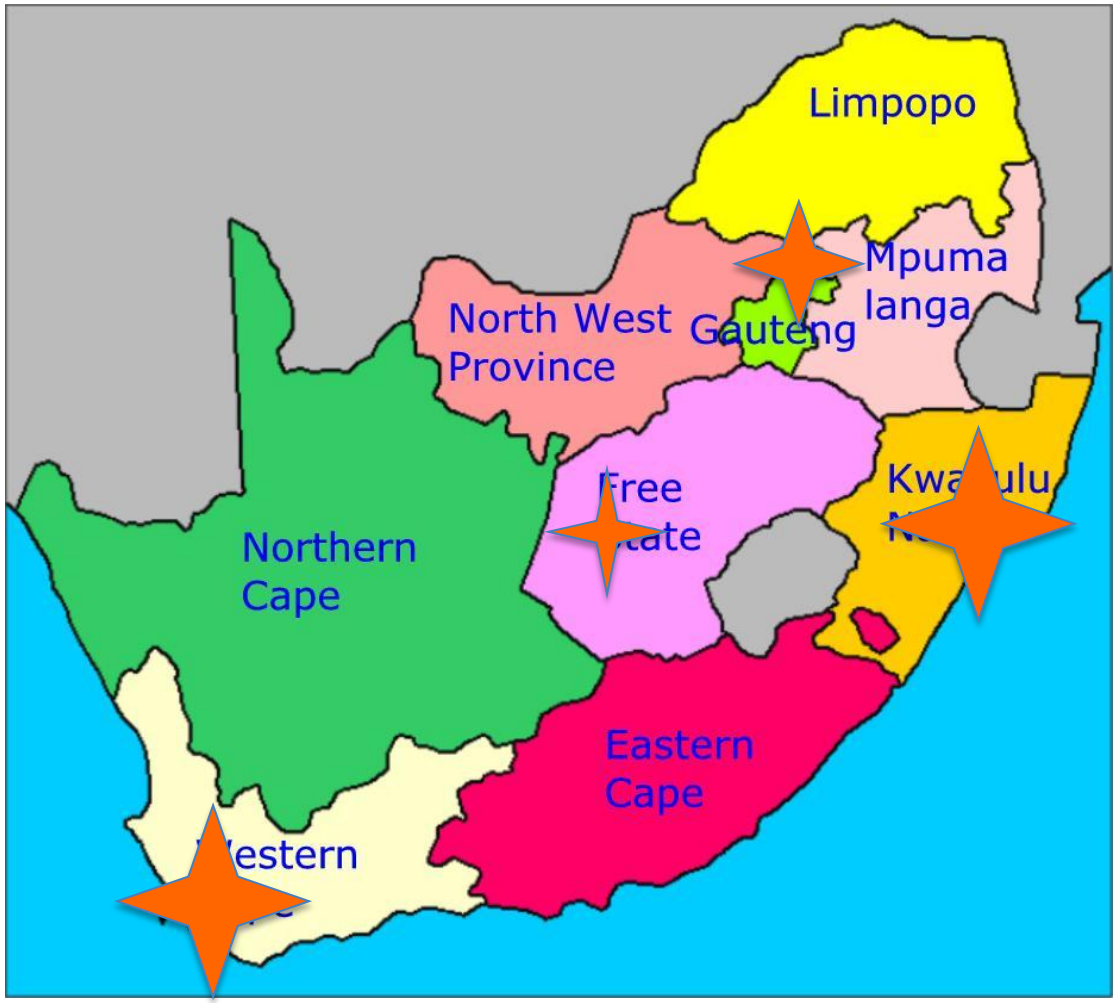
Graft processing across Africa: What is available?

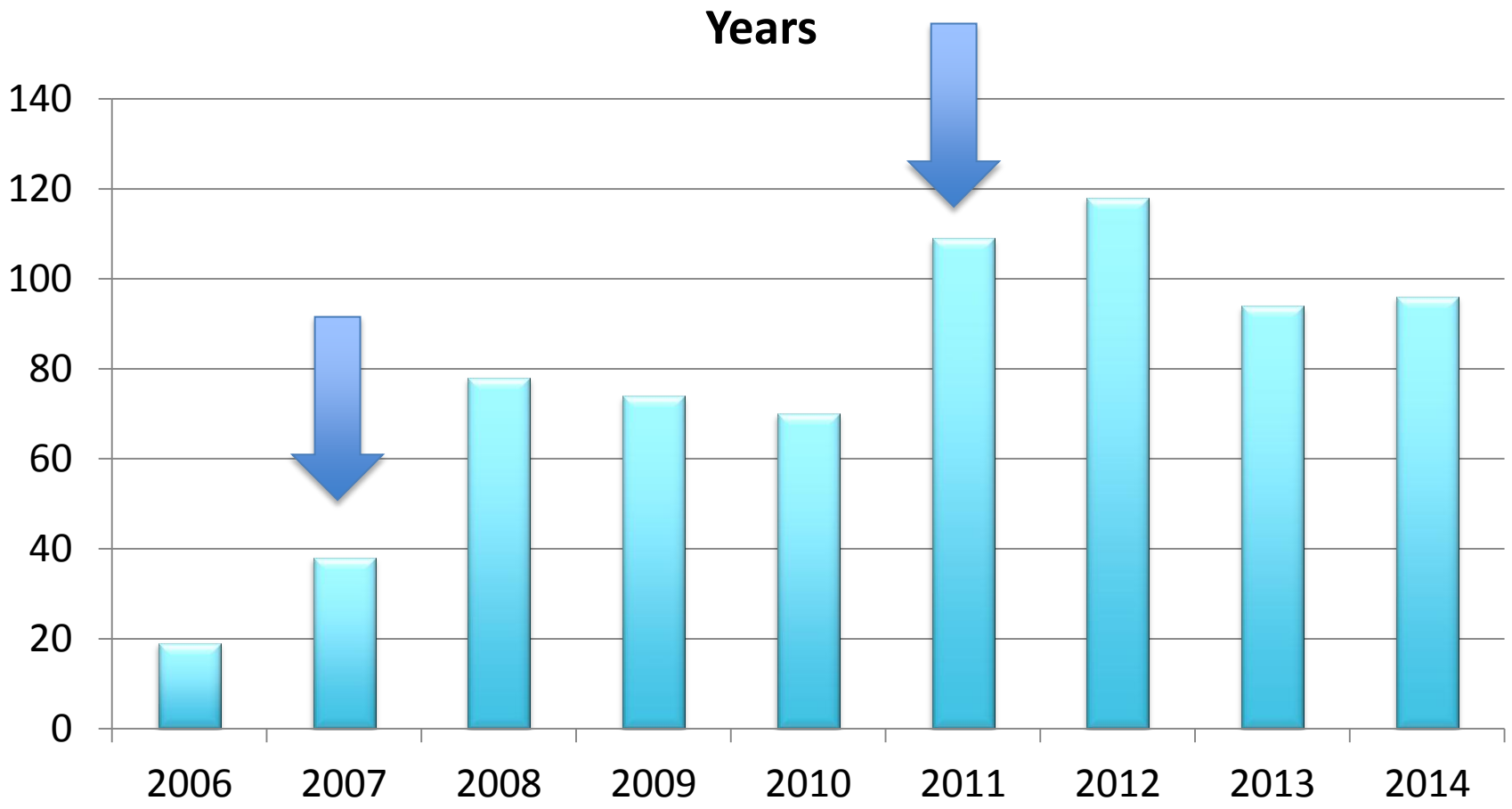
Jackie Thomson
Alberts cellular therapy
Pretoria

Purpose of the talk

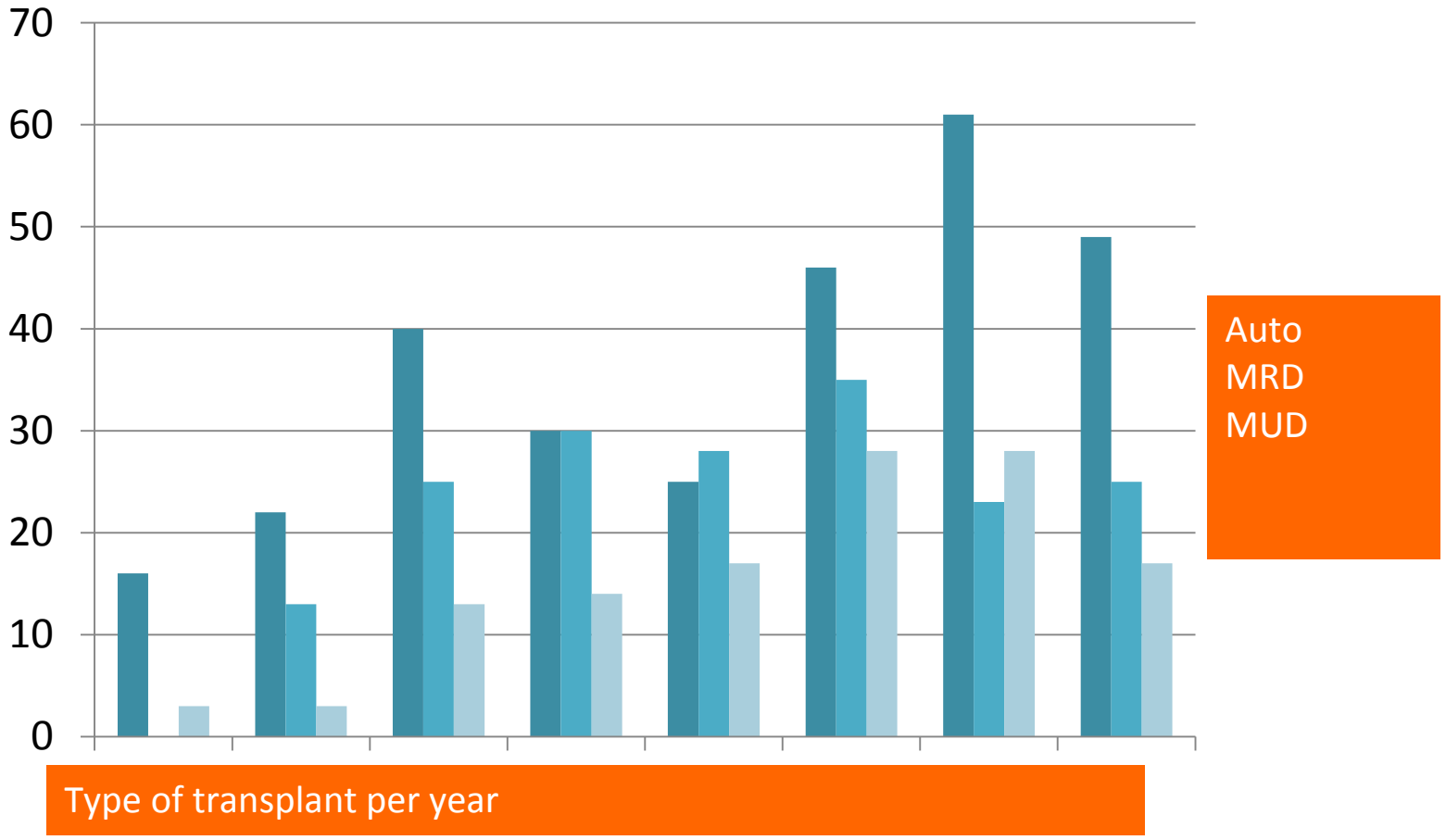
- range of activities, staffing, any problems you face both scientifically, logistically and financially?
- Following that, are you then able to give a snapshot of the rest of S Africa and if possible, any other regions across Africa


Limpopo
Mpuma
langa
North West
Province
Gauteng
Northern
Cape
Eastern
Cape

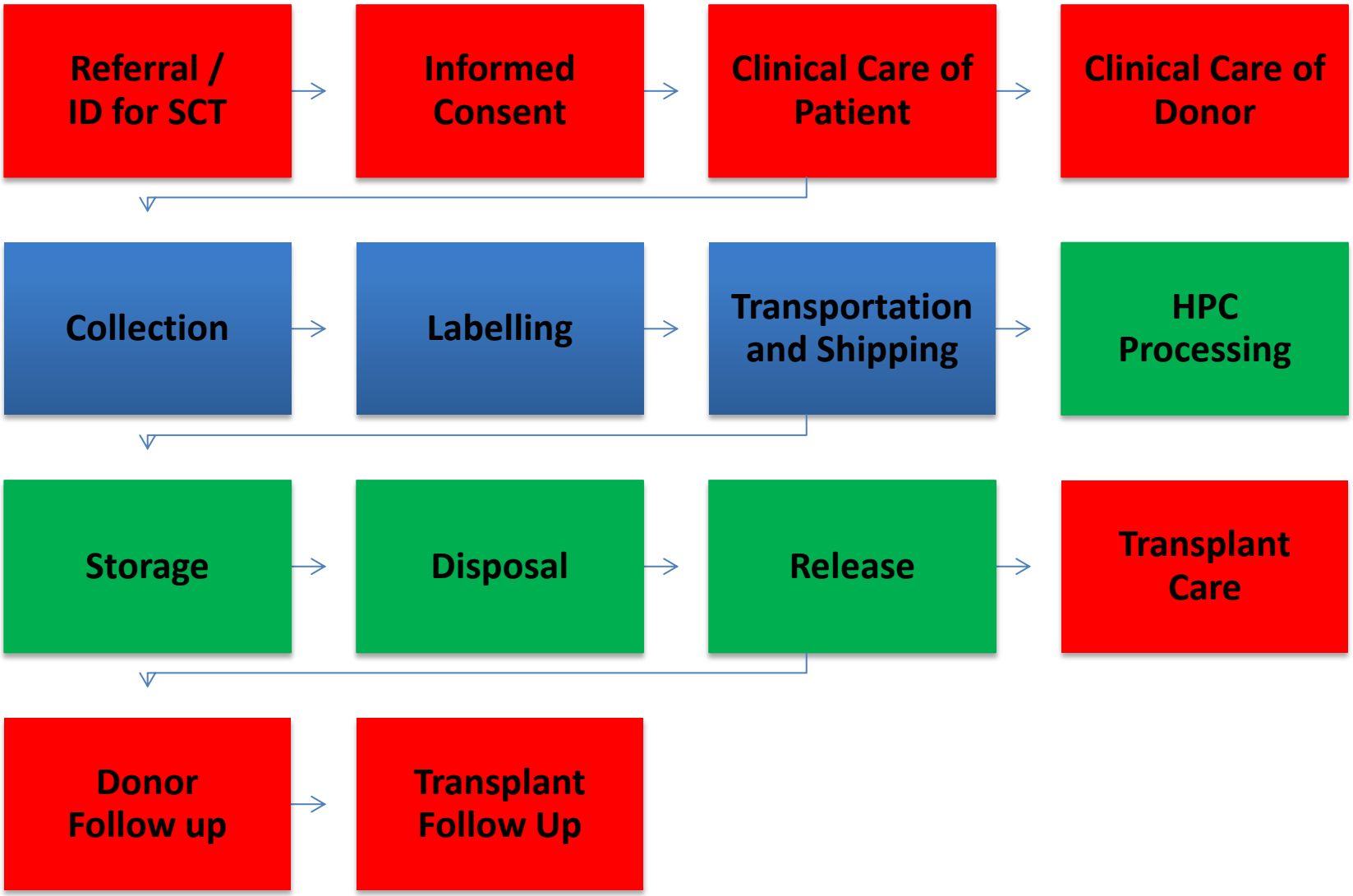
ACT


Years
140
120
100
80
60
40
20
0
2006
2007
2008
2009
2010
2011
2012
2013
2014

Type of transplant



Macro SCT Process



ACT processing facility

Time line:

2009 – Laboratory CD 34 enumeration

2010 – Processing of Stem cells

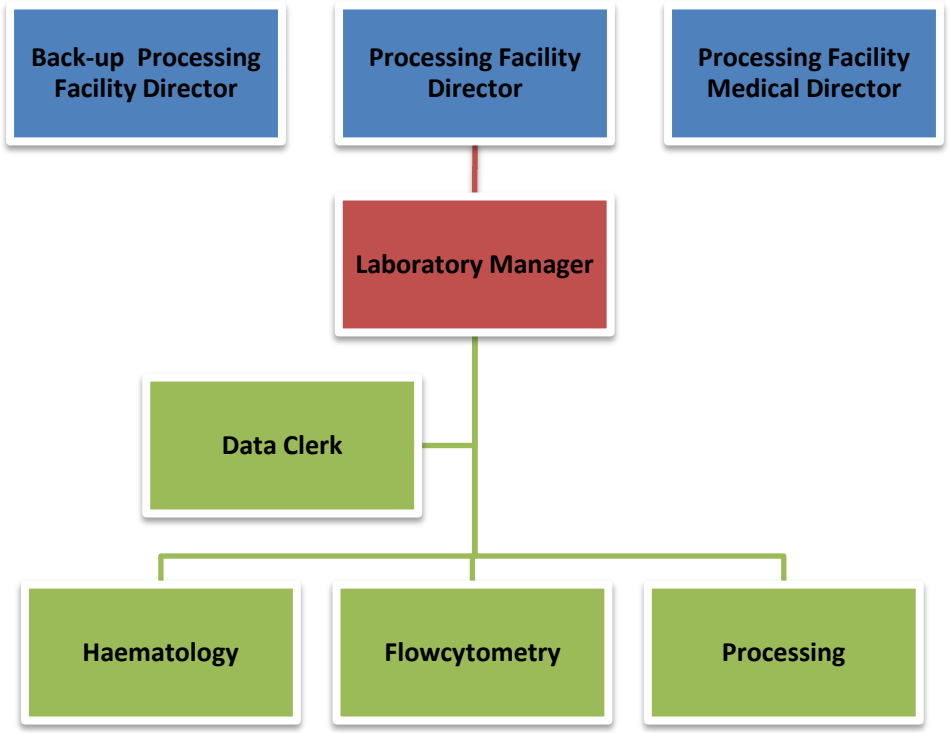
2012- Application JACIE

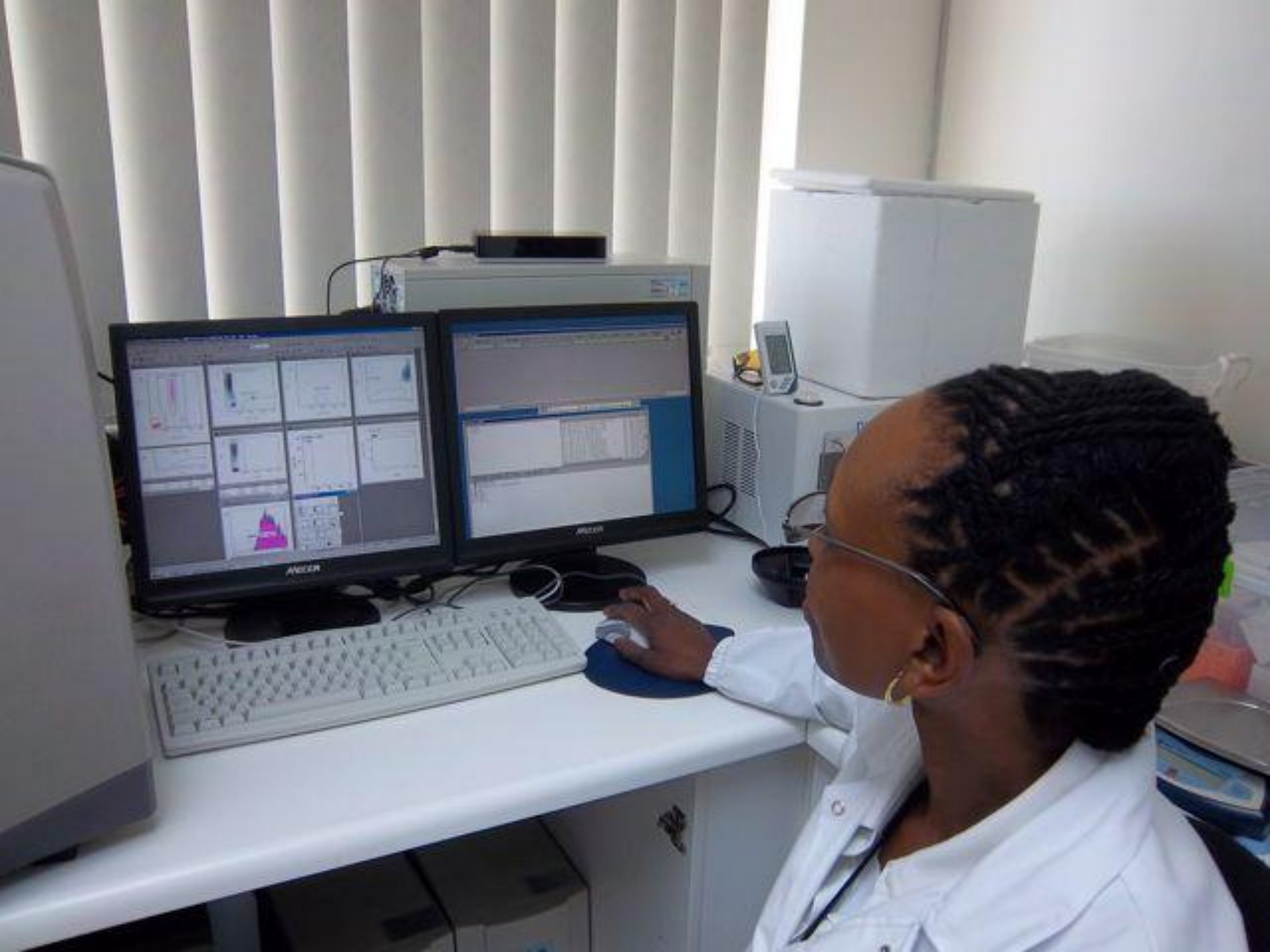
2013 - Inspection

2014 - Acredditation

ACT Laboratory

- Organization and personnel
- Laboratory layout (structure) and equipment
- Critical procedures
- Validation
- Quality management system
- Maintenance and continuous improvement


Back-up Processing Facility Director
Processing Facility Director
Processing Facility Medical Director
Laboratory Manager
Data Clerk
Haematology
Flowcytometry
Processing




Vessel 2


MVE

Defining critical procedures

Parameters

- Cryopreservation:Viability /Recovery / Potency/ Engraftment
- Red Cell Depletion:Pre and post RBC CD34Viability
- Volume reduction: Pre and Post CD34 Viability
- Transport & Distribution
- Temp. logger
- ShipsLog temp logger
- Storage to clinical (cryopreserved)
- Labelling

Defining Critical Procedures

- Bone Marrow Collection
- Volume
- CD34
- Sterility
- Cell viability
- Engraftment
- Apheresis Collection
- Volume
- CD34
- Sterility
- Cell viability
- Engraftment
- Efficiency

What about quality?

- Documents policies and procedures
- Validation, equipment, procedures, clinical and potency
- Audits
- Adverse event, incidents
- Review
- Improvement and training

Clinical Indication

- **Processing Facility Indicators**
- CD34+ Enumeration - External QC
- Number of bags contaminated< 4%
- Number of damaged bag < 3.5%
- CD34 Viability in % post thawing of cells >90%
- CD34 Viability in % Fresh Cells post process>90%

Clinical indicators

- Engraftment
- DLI
- ECP

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opportunity for new life

Obstacles

- Global Isolation
- Staffing
- Training
- Financial

Other facilities

- SANBS
- Cape Town: UCT academic and Private
- Constantiaberg Mediclinic

- Guidelines for SA!!

Bone Marrow Transplantation

Technical Report

Bone Marrow Transplantation , (16 June 2014) | doi:10.1038/bmt.2014.104

Essential requirements for setting up a stem cell processing laboratory

T Leemhuis, D Padley, C Keever-Taylor, D Niederwieser, T Teshima, F Lanza, C Chabannon, P Szabolcs, A Bazarbachi, M B C Koh and on behalf of the Graft Processing Subcommittee of the Worldwide Network for Blood and Bone Marrow Transplantation (WBMT)

The Graft Processing subcommittee of the Worldwide Network for Blood and Marrow Transplantation wrote this guideline to assist physicians and laboratory technologists with the setting up of a cell processing laboratory (CPL) to support a hematopoietic stem cell transplant program, thereby facilitating the start-up of a transplant program in a new location and improving patient access to transplantation worldwide. This guideline describes the minimal essential features of designing such a laboratory and provides a list of equipment and supply needs and staffing recommendations. It describes the typical scope of services that a CPL is expected to perform, including product testing services, and discusses the basic principles behind the most frequent procedures. Quality management (QM) principles specific to a CPL are also discussed. References to additional guidance documents that are available

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POST PROCESSING

- Perform the finger daps first before you clean.
- Close the TSA and SAB culture plates and perform the finger daps left and right hands
- Put all the used consumables in the red plastic bag to count consumables then after discard.
- Clean the LF and the floor.
- Change the tacky-mate from the processing room and the second room.
- Send the blood culture bottles and plates to AMPATH.
- Analyze the FBCP on Sysmex machine.
- Store the cells cryocytes bags in the racks and record the storage position of the bags and cryovials.
- Update the HPC database.

CLEAN THE LAMINAR FLOW AND TRANSFER THE CONSUMABLES.

- Switch on the light of the Lamimar Flow cabinet.
- Spray the {LF} with cleaning reagent either A,B,or C leave for 2-3 min wipe it off with the wipes.
- Spray the LF with 70% sterile Isopropanol wipe off.
- Wipe all consumables, plasma and the cells with 70% sterile isopropanol then transfer them into the LF.
- Cryocytes bags 500ml freezing volume 55-100ml
- Cryocytes bags 250ml freezing volume 30-70ml
- Cryocytes bags 50ml freezing volume 10-30ml

PROCESSING IN THE CLEAN ROOM

- Lay out the pre contact plates on the LF, SAB and TSA are exposed for the duration of the process.
- Collect 4ml of the harvest for pre-processing blood culture bottles.
- Transfer required volume of plasma to the transfer bag then add requisite volume of DMSO through a DMSO resistant spike to make 10% and weigh the bag and record the volume, leave the cryoprotectant on ice packs for at least 10 min.
- Before adding the cryoprotectant to the cells the staff member should be available to start the CRF and collect the cells when processing is completed.
- Mix well, weigh and record the volume, label each bag.

PROCESSING IN THE CLEAN ROOM

Transfer equal volume of the cryoprotectant and cell product to the cryocytes storage bags by using a transfer set, remove excess air from each bag

Heat seal cryocytes storage bag, weigh and record the volume.

On the last bag take 4ml for two aerobic and anaerobic post processing blood culture bottles.

Take 0,5ml for three cryovials and EDTA (purple top) tube 1ml.

Transfer the bags with ice-pack through the hatch to be vacuum sealed with overwrap bag and load the bags into the freezing plates,cyrovials on the vial holder.

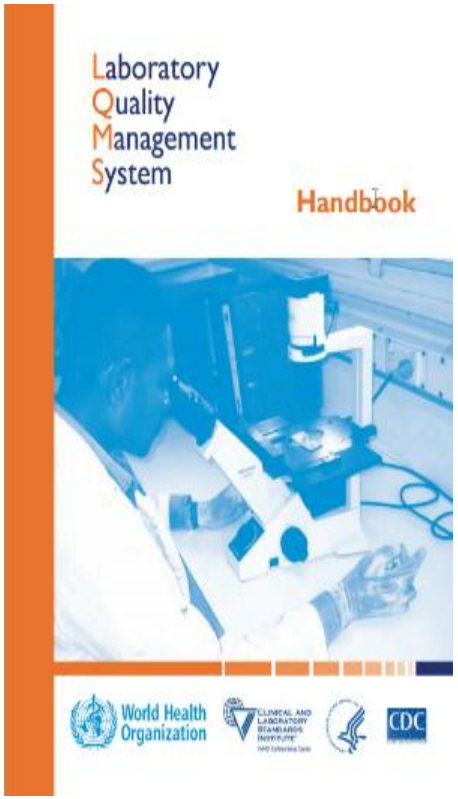
Vial holder and cryocyte bags are placed in the re-chargeable coolerbox and transported to the cryostarage room for freezing.

ASEPTIC ENTRY TECHNIQUE

- Spray the hands with 70% filtered Isopropanol
- Put on the non sterile gloves and the mask.
- Spray the door handle and wipe, then open the door to transfer the wiped coverralls,sterile gloves and sterile cover shoes to the second room.
- Put the non sterile cover shoes and step on the tacky mate and close the door with the elbow.
- In the second room, spray the door handle with 70% filtered Isopropanol and wipe.
- Dress with coverroll and put the sterile cover shoes and step on the tacky-mate , spray the hands put the sterile gloves.
- **Close the door with the elbow or use your feet.**
- **DO NOT TOUCH YOUR BOBY AT ALL !!**

Support Functions

Laboratory quality management system handbook



- Comprehensive reference on Laboratory quality management
- Covers topics that are essential for quality management of a public health or clinical laboratory.
- Based on both ISO 15189 and CLSI GP26-A3 documents

http://www.who.int/ihr/publications/lqms/en/#