ACCESS TO SAFE AND EFFECTIVE BLOOD TRANSFUSION INCLUDING BLOOD COMPONENT THERAPY

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Introduction

 Blood transfusion services (BTS) play a vital role in clinical transplantation programs through provision of blood and components for transfusion support to transplant patients.



 A well-organized BTS with an effective blood component programme and quality systems in all areas is a prerequisite for safe and effective use of blood including component therapy.



Transplantation & BTS in Africa

Country	Scope of Transplantation services	Type of blood service	Blood Component	% Vol. donations GBDS WHO 2012	Total 2012 Health Expend.
South Africa	HSCT Solid organ	NCBTS • SANBS • WPBTS	RBC,FFP,CRYO,PC	100%	8.8
Tunisia	HSCT Solid organ	NCBTS National Blood Transfusion centre of Tunisia	RBC,FFP,CRYO,PC	32%	7.0
Algeria	HSCT	NCBTS Agence National du Sang	RBC,FFP,CRYO	60%	5.2
Egypt	HSCT Solid organ	NCBTS Egyptian National Blood Transfusion Service	RBC,FFP,CRYO,PC	64%	5.0
Morocco	HSCT	NCBTS Centre National de Transfusion Sanguine, Morocco	RBC,FFP,CRYO,	63%	6.4
Libya	Kidney	NCBTS Libyan Blood Transfusion Service	No data	No data	3.9
Nigeria	HSCT Kidney*	NCBTS & others NBTSN (3% collections)	No data	97% (NBTSN only 17 centres)	6.1
Ghana	Kidney (2008)	NCBTS NBSG	RBC,FFP,CRYO, PC	45%	5.2

- Nationally coordinated BTS with centralization or regionalization of blood processing and testing
 - economies of scale (resources & technology)
 - uniform standards of performance
 - improved quality and safety
- Assessment of clinical demands and feasibility of blood component programme.
 - clinical demand for blood and components
 - available medical and diagnostic services
 - capacity of BTS
 - may consider apheresis programme if demand cannot be met from components prepared from WB





- Advocate for adequate and sustainable financial resources
 - adequate finances to meet additional cost of component preparation
 - suitable premises that comply with cGMP
 - sufficient number of trained staff
 - appropriate technology, specialized equipment for blood collection, processing, testing, storage and transportation and a preventive maintenance system
 - reliable supply of blood collection bags, leukodelpletion filters, reagents etc.





- Appropriate infrastructure
 - suitable working environment for donor selection, blood collection, processing, testing and storage
 - appropriate technology, equipment and materials
 - reliable transportation system
 - reliable water and power supplies with back-up systems





- effective planning and communication system
 - set and evaluate targets for donor recruitment, blood collection and component preparation
 - collaboration with clinical staff for appropriate components for transfusion support
- waste management system



- Effective quality system
 - specifications for blood components, equipment and materials
 - validation of processes, procedures, equipment and materials
 - regular maintenance and calibration of equipment to ensure quality and minimize down-time
 - standardized procedures
 - hygiene and safety of environment, equipment, blood donors and staff
 - documentation of all processes and accurate labelling to ensure traceability
 - ongoing training of staff
 - monitoring of all activities to ensure continuous quality improvement



Suitable regulatory framework



OCUS

Blood Donors and Blood Collection

- A reliable base of regular VNRBD a prerequisite for safe and effective blood component programme to meet transfusion requirements.
- Effective donor education, recruitment, motivation, call-up and retention strategies to promote regular donations by suitable donors



- panel of regular VNRBD
- national donor selection and deferral criteria, including criteria specific for component preparation to transplant patients.
- mechanism for setting blood collection targets to meet component preparation targets and clinical demand



Blood Donors and Blood Collection

- Effective blood collection
 - systematic planning and preparation for fixed and mobile sessions



- planning of number and type of collections per session from whole blood/apheresis donors
- appropriately trained and adequate staff
- appropriate equipment
- suitable blood collection bags



Component Preparation, Testing & Distribution

- Preparation of components only from WB or apheresis donors who meet standard selection criteria
 - Prevalence of blood groups and alloantibodies





- Testing of all donated units and discard of all blood and components reactive for any TTI
 - mandatory tests- HIV 1&2,HBV,HCV,Syphilis
 - additional tests CMV, malaria, rare blood groups, HLA-matching
 - alloantibodies



Component Preparation, Testing & Distribution

- Quality system and cGMP for all aspects of component preparation and distribution.
 - use of efficient/closed system
 - RBC, PC, FFP, cryoprecipitate



 Compliance with specifications for components, equipment e.g. irradiators and materials

- Labelling system for untested, quarantined and available stock
- Mechanism for quarantine and release



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Component Preparation, Testing & Distribution

Provide special blood components

- irradiated components
- leucodepleted components
- CMV-negative components
- HLA-matched components
- rare RBC units, stem cell processing
- System for recall of defective components
- Cleaning and maintenance of all areas and equipment to minimize risk of contamination of components
- Quality monitoring of components, including statistical process control







Storage and Transportation

- Correct storage and transportation of blood bags, donor specimens, collected units, blood components, reagents and material
 - to processing centres and testing laboratories within prescribed temperature and time limits
- Separate storage areas for untested, quarantined and available units



 Suitable areas and equipment for storage and transportation that meet specifications





Storage and Transportation

 Monitoring and recording of temperatures in all cold chain equipment





 Corrective and preventive action in case of deviation from specified temperature ranges and time limits



Blood Component Stock Management

- Efficient stock management system are needed in the BTS and hospitals
 - formal agreement and ongoing communication between BTS and hospitals on optimum stocks, order and supply
 - ensure stock level optimum at all times in right mix.
 - monitoring and evaluation of component availability and utilization, including shortfalls and outdating





Blood Component Therapy

- Optimum use of blood as a scarce national resource requires
 - national and hospital guidelines on use of blood and blood products and alternatives to transfusion
 - HTC to develop local policies and guidelines and monitor component utilization
 - training of clinical staff involved in the prescription administration and monitoring of components
 - accurate transfusion records to ensure traceability of blood and efficacy of component usage



- Haemovigilance system for monitoring, investigation and reporting of adverse transfusion events
- ongoing assessment of current and future clinical needs for components and special products





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Constraints

- Inadequate Infrastructure
 - appropriate equipment
 - standard reagents & consumables
 - reliable utilities & transportation
- Lack of political will
- Lack of support and commitment from health authorities
- Inadequate resources
 - human
 - financial
 - technological
- Lack of coordination of BTS
- Unstable voluntary blood donor base
- Lack of specific training for BTS and clinical staff



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