



Step-Wise Accreditation of blood transfusion services in Africa

L'Accréditation par étapes des services du sang en Afrique

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INTRODUCTION

The Africa Society for Blood Transfusion (AfSBT) advocates for access to safe blood and blood products in Africa. The Step-Wise Accreditation Programme (SWAP) is a tool for achieving this. Individual countries decide whether to be certified at basic level at Step 1 or intermediate level at Step 2, or to undergo full accreditation at an international level at Step 3. The specific requirements for each step are detailed in the AfSBT Compliance Chart. Twenty countries on the continent are currently engaged in the programme.

THE ACCREDITATION PROCESS

Accreditation is performed against the AfSBT Standards which were developed in conjunction with the American Association of Blood Banks (AABB) and endorsed by a panel of international experts in the field of blood transfusion. A process is underway to obtain accreditation of the AfSBT Standards by the International System for Quality Accreditation (ISQua).

The AfSBT accreditation process in African countries begins with training on the requirements of the AfSBT Standards. Thereafter a baseline assessment is carried out to perform a gap analysis and to develop a work plan. When the facility has addressed the identified gaps, a progress assessment is performed and any remaining corrective actions are identified. Finally, a formal certification or accreditation assessment is performed by an independent AfSBT team. A surveillance audit is performed eighteen months after accreditation/ certification is achieved and a full re-assessment is carried out after three years.

The AfSBT currently has a management office of ten part-time employees working from virtual offices around Africa. In addition, the Society has trained a panel of over thirty educators and assessors to support the accreditation programme. The educators perform training as well as the baseline and progress assessments while the assessors perform the formal accreditation/certification assessments. In this way, a separation is established between education and accreditation activities.

The AfSBT accreditation programme has been made possible by funding obtained, over three years, from the Centers for Disease

Control and Prevention (CDC) in Atlanta. The CDC has sponsored assessments in specific countries supported by the President's Emergency Plan for AIDS Relief (PEPFAR). For other countries, alternate funding has been sourced from a commercial company or assessments are being self-funded. Non-financial support for accreditation-related activities has been provided by the International Society of Blood Transfusion (ISBT) and the AABB.

THE PACE OF PROGRESS

In developing countries in Africa significant progress has been made towards accreditation in a relatively short time compared with more developed countries, like South Africa. Blood transfusion facilities in South Africa have been in existence for eighty years and a national accreditation programme has been in place for the past sixteen years. The quality system currently in place has been developed and improved steadily over many years. In comparison, the establishment of national blood transfusion services and the implementation of quality systems is a recent development in many other African countries. To mention specific examples, national blood transfusion services were only established in Malawi in 2002 and in Tanzania in 2004.

COUNTRIES ENGAGED IN AFSBT SWAP

Table 1 shows the current status of progress towards accreditation in the twenty countries engaged in the SWAP (as of December 2018). In some countries all regional branches have undergone assessment whereas in others a start has been made by first assessing the main branch or headquarters. To date, two countries have achieved accreditation at Step 3 and one country is about to be certified at Step 2. Baseline assessments, together with training on the AfSBT Standards, have been conducted in nineteen countries, progress assessments in six countries and formal assessments in another five countries.

BENEFITS OF AFSBT SWAP

Namibia

The Namibia Blood Transfusion Service (NAMBTS) became the first blood establishment to achieve Step 3 accreditation in 2012. In an article written for the AfSBT newsletter, the Technical Division Manager, Mr Israel Chipare, states that accreditation has facilitated continuous improvement in the quality and safety of collect-

Table 1: State of progress in 20 countries engaged in the SWAP (as of December 2018)

| Country | Baseline Assessment | Progress Assessment | Formal Assessment | Achievement |
|---------------|---------------------|---------------------|-------------------|----------------|
| Benin | Complete | | | |
| Burkina Faso | Complete | | | |
| Cameroon | Complete | | | |
| Côte D'Ivoire | Complete | Complete | | |
| Ethiopia | Complete | | | |
| Eritrea | Complete | | | |
| Ghana | Complete | | | |
| Kenya | Complete | Complete | | |
| Lesotho | Complete | Not required | Complete | |
| Malawi | Complete | Complete | Complete | |
| Mali | Complete | | | |
| Mauritius | Complete | | | |
| Mozambique | Complete | | | |
| Namibia | Complete | Not required | Complete | Step 3 |
| Nigeria | Complete | | | |
| Rwanda | Complete | Complete | Complete | Step 3 |
| Tanzania | Complete | Complete | Complete | Step 2 pending |
| Uganda | Complete | Complete | Due Nov 18 | |
| Zambia | Complete | | | |
| Zimbabwe | Due 2019 | | | |

ting, processing, testing, transfusing and distribution of blood and blood products.¹ A full quality system has been implemented, including regular reviews of the system, planned internal audits and validation of processes and equipment. Specific improvements have been made in the management of vendors and the handling of critical raw materials as well as in haemovigilance and clinical interface. Since AfSBT accreditation, a culture of quality has become core to the business. Testing for TTI has been successfully relocated from South Africa to Namibia and NAMBTS meets the requirements for supplying plasma for fractionation. The adequacy of blood supply has improved from 10 units (2012) to 15 units/1000 population (2017).

Rwanda

The Rwanda National Blood Transfusion Centre was the second facility to achieve Step 3 accreditation in 2016, after first obtaining Step 2 certification in 2014. In a presentation at the AfSBT congress in Arusha in June 2018, the head of the blood service, Dr Swaibu Gatere, stated that prior to accreditation the service had no written policies, processes or procedures, there was no factual approach to decision-making and efficiency was generally low. There was no haemovigilance, no customer focus and no quality culture. Implementation of a quality management system on their path to accreditation focused on the following steps:

- Development of policies, processes and procedures in order to implement the AfSBT Standards
- Training of staff in accordance with needs analysis
- Competency assessments and remedial action where necessary
- Managerial staff assigned responsibility for motivating staff, creating customer focus and cultivating a quality culture
- Improvement of the clinical interface with reporting on blood utilisation, supervision and mentorship.
- Further actions included:
 - Implementing an External Quality Assurance (EQA) programme for both blood grouping antibody screening and serology testing (HIV, HCV, HBV and Syphilis). Since implementation the score achieved has always been 100 %.
 - Reagent internal quality control done on a daily basis with no test being allowed to run if the QC failed. This encompasses antisera used in blood grouping, as well as reagents for automated blood grouping and the serology system
 - Introduction of monthly QC on blood products. For platelets, volume, pH and platelet count are determined. For red blood cells, percentage haemolysis, Hb, volume and haematocrit are determined.
 - Percentage of repeat donors was increased from 63 % in 2017 to 75 % in 2018.

- Blood supply orders were monitored against distribution and currently 96 % of orders are being met
- Forms were introduced to obtain feedback from both blood donors and health facilities. Donor satisfaction increased to 96% in 2017.

In conclusion, Dr Gatere stated that AfSBT Step-Wise accreditation has led to the establishment of a quality culture throughout the organisation, improved planning skills and an improvement in clinical interface. In addition, all staff are trained and certified competent to all SOPs.

Tanzania

The Tanzania National Blood Transfusion Service (TNBTS) was established in 2004. In 2014, the Service began working towards accreditation with the implementation of a quality management system. Policies, guidelines and procedures were standardised at the zonal, satellite and collection team levels. At the AfSBT congress, the Head of Quality Assurance, Mr Dunstan Haule, outlined the challenges faced during the AfSBT SWAP process. These included high staff turnover leading to repeated training of new staff, negative attitude of some staff towards quality, and inadequate funding for procurement of critical equipment such as cold chain equipment and an alarm system for continuous temperature monitoring.

During preparation for accreditation, the AfSBT provided technical assistance to TNBTS through training on the following topics:

- Overview of the blood transfusion chain including blood donor services and laboratory services
- Donor recruitment strategies
- Patient blood management
- Quality Management System and Good Manufacturing Practice (GMP)
- Cold chain management
- Management and supervision skills
- Handling of non-conformances
- Training on mapping of processes
- Training on providing mentorship
- Developing financial sustainability through cost sharing
- Monitoring and evaluation, including measurement of quality indicators
- Risk management

AfSBT facilitated support, with the aid of consultants, for the development of a blood group serology EQA programme which has been rolled out to over a hundred sites. Assistance was provided with the implementation of the eDelphyn computer software system and the establishment of a central database. Significant progress has been made in Tanzania since 2014 and the Service is about to be awarded Step 2 certification at six of its eight zonal centres. The TNBTS intends to continue working towards full accreditation at Step 3 for all its zonal centres.

Other countries

In all those countries working towards achieving AfSBT accreditation, the most significant improvement has been seen in the implementation of an effective quality management system. At the beginning of the process, documentation is often lacking and needs to be developed and approved. This includes policies, SOPs, forms, testing algorithms, job descriptions, organograms, personnel records and safety procedures. Many facilities have limited resources and this task is onerous but the benefits gained in implementing a robust documentation system have proved to be worth the effort enabling progress in the SWAP.

FUTURE CHALLENGES

Enormous strides are being made in improving blood safety in Africa but countries are often unable to progress at the rate they would like. Many countries have limited human resources (especially with regard to trained and skilled personnel), poor infrastructure and logistics, lack of essential equipment and regular supplies, and inadequate government support.² There is a need to engage with governmental organisations to garner support and facilitate the development of a national regulatory framework. There is also an extensive need for training in quality principles, laboratory techniques and management practices.

AfSBT is a not-for-profit organisation operating with a small core of part-time staff and therefore has limited capacity to provide countries with the assistance they require. The CDC cooperative agreement with AfSBT will be ending in March 2019. Alternate funding needs to be sourced. For the accreditation programme to be sustainable countries will have to cover the costs of their own assessments in future. This will need to be done through government support, which often presents difficulties, or through donor funding.

Despite the challenges being faced AfSBT remains committed to improving blood safety in Africa. Countries engaged in the programme are determined to progress to more advanced levels and it is hoped that the Step-Wise Accreditation Programme will grow to include more countries.

REFERENCES

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2. L Bust. *The Challenges of Quality Management in Resource-limited Countries*. Transfusion Today Number 114, March 2018.

