



Blood Safety Strengthening Programme (BSSP)

Implementation Plan

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Physical Address Unit D11, Westlake Square, Westlake Drive, Westlake, Cape Town
Postal Postnet Suite 280, Private Bag X26, Tokai 7966, South Africa
Tel +27 (0)21 701 0939 **Fax** +27 (0)21 701 1979
E-mail info@jembi.org **Website** www.jembi.org

Jembi Health Systems NPC
(Reg#: 2009/018985/08) a not-for-profit company registered in South Africa
(NPO#: 054-906-NPO) (PBO#: 930034124) (VAT#: 4480259243)
Directors: S Reid (Chair), D Moodley (Vice-Chair), CJ Seebregts (CEO), A Gray, G Loots, N Gasa, D Morkel



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Introduction

The Blood Safety Strengthening Programme (BSSP) refers to the selection of services offered by Jembi Health Systems NPC (Jembi) around the implementation and maintenance of the Blood Safety Information System (BSIS) software tool. BSIS is an open-source health information system that is designed to manage donors and blood-safety information from the point of donation, through to testing, component processing, transfers between distribution sites within the blood service and issues to, and returns from, hospitals and clinics. BSIS is developed specifically for resources-limited settings and offers blood services a configurable Blood Establishment Computer System (BECS) offering the core functionality that are necessary for good blood donor and donation management.

The BSSP looks at the implementation of the BSIS software as more than the simple deployment of BSIS at sites, but takes a whole-system approach that acknowledges the interconnection between policy, practice and technology, and looks at:

- Environment (**where** will the system be used?)
- Process (**how** will the system be used?)
- Technology (**what** hardware/software will be used?)
- Capacity building (**who** will use the system?)
- Sustainability (**how** much will it cost and who will pay?)

The aim of the BSSP is to implement the BSIS tool in an effective and sustainable way that help blood services better manage blood donors and donations. In this way the BSSP will make strong contribution of the improvement of blood safety in resource-limited countries. The BSSP is funded by PEPFAR through a cooperative agreement with the Centers for Disease Control and Prevention (CDC). The programme forms part of their broader strategy to improve quality management in resource-limited blood services. The comprehensive approach that Jembi is taking with the BSSP requires us to work closely with blood services and their technical assistance (TA) partners to ensure that the implementation of BSIS is accompanied by strengthening in other areas of the blood service, i.e. clinical/laboratory skills and standard operating procedures (SOPs).

The purpose of this document is to detail how Jembi plans to implement BSIS through the BSSP. This document outlines the implementation process as a series of steps to be undertaken by blood services, Jembi and other TA partners as part of the implementation process. The result will be a BSIS implementation that is positioned to be effective and sustainable within the blood service.

BSSP (BSIS) Country Application Process

The country application process is designed to identify countries interested in implementing BSIS as well as select countries where the implementation of BSIS can be funded using PEPFAR funds through our cooperative agreement with CDC. In this way, it is a means of prioritising country implementations for Jembi. This does not mean that countries that are not PEPFAR priority countries are not eligible for implementing BSIS, but rather that this process will help us identify where additional support is required for these countries and initiate discussions as to how we can go about supporting them to identify and access funding/support in order to implement BSIS.

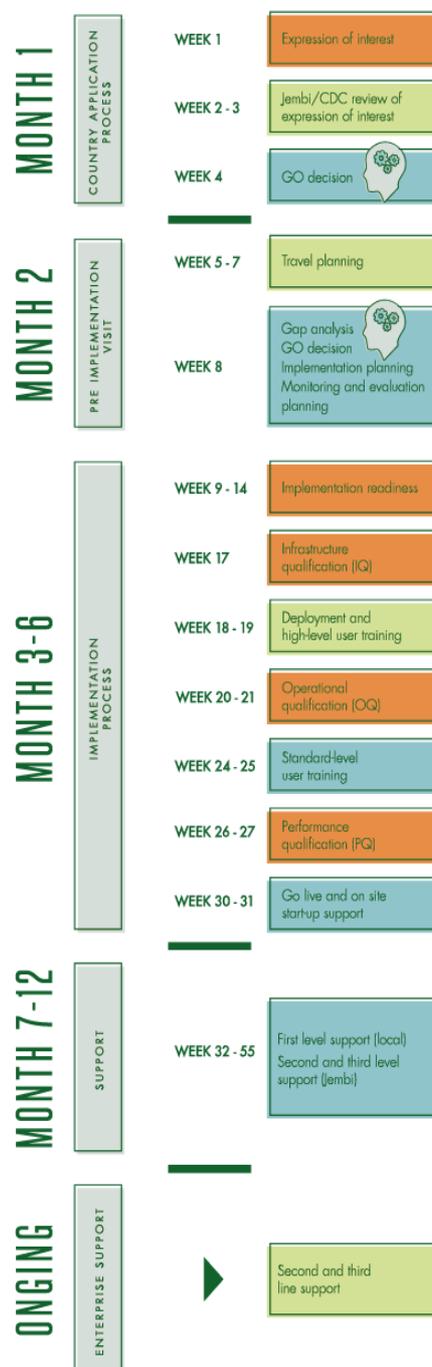
Step 1: Country Awareness

A blood service contacts Jembi or partners to request to be a BSIS and/or BSSP implementation site. This introduction to BSIS and BSSP can be made through a range of channels:

- Introduction by CDC team to the project
- Introduction by TA provider
- Conference or meeting attendance
- Online searches and browsing of website (including videos)
- Discussions with Jembi

As a blood service explores or is introduced to BSIS and the implementation strategies surrounding it, the interested blood service will be given an information pack and pointed to the online videos and a website demo URL to allow them to explore a demonstration version of the tool. A blood service could also ask for an initial discussion call with Jembi to find out more about unpack BSIS and the various engagement models.

BSIS Implementation



As part of the initial BSIS information pack blood services will be provided with the following documents:

- BSSP Implementation Overview
- BSSP Implementation Description
- BSIS Software Overview
- BSIS Software Description
- Country Expression of Interest Guide

After receiving the information pack and or having an option exploratory call with Jembi the blood service would move to the next step: Expression of Interest.

Step 2: Country Expression of Interest

After reviewing the information pack the blood service will be asked to complete the Expression of Interest document that forms part of the information pack described above. Once Jembi has received the completed Expression of Interest document this will be reviewed by the BSSP management team who will use this information to prepare for the discussion detailed in step 3.

The expression of interest will provide Jembi with information about the:

- Size and nature of the blood service wanting to implement BSIS
- Level of local Ministry of Health, PEPFAR/CDC or other donor support received by the blood service
- Blood service's relationship with blood safety TA providers
- Blood service's infrastructural readiness to implement BSIS

All this information will make it easier for Jembi to prepare for initial discussions with blood services about implementation of BSIS and inclusion in the BSSP. Blood services are encouraged to complete the expression of interest in as much detail as possible.

Step 3: Implementation Discussion

Once a blood service has completed the expression of interest and Jembi has had the opportunity to review it a discussion between Jembi, the blood service and other stakeholders (i.e. blood safety TA providers) will be held. The purpose of this discussion is to:

- Start to build a relationship between parties.

- Discuss whether the blood service is ready to implement BSIS or, if not ready, what steps need to be taken by the blood service in order to be ready to implement BSIS.
- Discuss whether the blood service is eligible to be a part of the PEPFAR/CDC funded BSSP or if the blood service will need to find external funding for the implementation of BSIS.

Once a way forward has been established the blood service will be provided with a more detailed pre-assessment questionnaire to complete prior to the Jembi team scheduling and undertaking, where required, an exploratory visit to the blood service to review the pre-assessment questionnaire and discuss the blood services requirements in light of the implementation of BSIS. The nature of the initial implementation visit is detailed below.

Initial Implementation Visit

The purpose of the initial implementation visit is to further solidify relationships between the partners, give the BSSP team an in-depth understanding of the nature of the blood service and complete the assess the readiness of the blood service to adopt BSIS. In more detail the desired outcomes of the initial implementation visit is to develop:

- Strong working relationships between stakeholders.
- Good understanding of the blood service structure/network and its health information systems requirements.
- Clear understanding of the local workflow and roles of user groups in donations clinics, including mobile clinics, testing laboratory, components processing laboratory, blood bank and donor recruitment/communications.
- Clear understanding of the process between the blood service and other facilities to which blood is supplied.
- Confirmation of the blood service's user requirements and identified areas where there are gaps or differences between these and BSIS functionalities and agreement for the process on how any gaps will be addressed.
- Clear understanding of the gaps between the local standard operating procedures (SOPs) and BSSP generic SOPs including the work required to bring them into line.
- Clear understanding of the existing local infrastructure, information architectures, existing electronic systems and identified upgrade and data migration requirements for implementing the system.
- Clear understanding of the level of computer literacy amongst the different user groups.
- Clear understanding of the level of technical IT skills available to provide local support and day to day administration of the system.

The three primary activities for the initial implementation visit are detailed in steps 4, 5 and 6 below.

Step 4: User Requirements and Gap Analysis

Reviewing country BECS user requirements, and through discussion establishing the gaps between these and the functionality available in BSIS, is critical to understanding if BSIS is a suitable option for implementation at the blood service and when it is best to schedule such an implementation given the current BSIS development roadmap. These discussions also allow countries to contribute requirements to the BSIS development roadmap and be an active part of the development of this open-source software solution.

Step 5: Implementation Planning and Scheduling

On the back of the information gathered in the expression of interest, pre-assessment questionnaire and during the initial implementation visit the Jembi, country and TA provider teams will collaboratively draft an implementation plan and schedule that will form the basis of the implementation agreement. The blood service will need to sign the implementation agreement that outlines the roles and responsibilities and expectations throughout the process as well as break clauses (such as the implementation not being able to proceed further due to external delays etc.).

Step 6: Monitoring and Evaluation Planning

As an organisation whose mission is to improve global health through the effective support of health information systems, the monitoring and evaluation (M&E) of the implementation of BSIS is critical to Jembi as it helps us measure and understand the real effects at blood services that result from the implementation of the BSIS software. As part of the development of Jembi's implementation plan we have developed a generic logical framework that will be used as the baseline for discussions with blood services about how to measure the effects of the implementation of BSIS. This logical framework is presented below:

OUTCOME - SHORT TERM	OUTCOME - MEDIUM TERM	OUTCOME - LONG TERM	IMPACT
Blood Service demonstrates an improvement in the quality of the labelling of blood components within the blood service	Blood Service demonstrates an improvement in the management of blood donations	BSIS has facilitated a higher level of AfSBT accreditation	Improved Blood Safety
Blood Service demonstrates an improvement in the tracability of blood components from point of donation to point of issue	Blood Service demonstrates an improvement in the management of blood donors	Reduction in cost of blood component production at the Blood Service	
Blood Service demonstrates an improvement in access to relevant information about blood donors and donations	Improved efficiency in managing donor and donation records within the Blood Service	BSIS is a sustainable information management solution at the Blood Service	

During the initial country visit the Jembi team will discuss how this logical framework can be applied in the M&E of the implementation of BSIS with the blood service and other stakeholders.

In addition countries who are selected for the implementation of BSIS under the PEPFAR/CDC supported BSSP will be required to work with Jembi to provide data to help PEPFAR/CDC to measure the effects of their Blood Safety Strengthening Initiatives more broadly. For information about the data required please view the BSSP M&E outline document.

Implementation Process

The implementation of BSIS requires a three-step user validation process that will be the responsibility of the blood service to carry out with support and mentorship from TA partners and Jembi. These three steps are installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) are all required to be signed-off by the blood service's senior management before the system can 'go live' at the blood service. The implementation of BSIS must follow the plans laid out in the following documents:

These are:

- Blood service must develop a master validation plan, including test cases and scenarios for all three areas of validation (IQ, OQ, PQ).

- Blood service, TA partners and Jembi must agree on the implementation plan and blood service must sign a BSIS Implementation Agreement detailing the roles and responsibilities of partners.
- Blood service, TA partners and Jembi must agree on an M&E plan for the implementation of BSIS at the blood service.

Step 7: Implementation Readiness

On the back of the information gathered in the expression of interest, pre-assessment questionnaire and the exploratory visit the Jembi, country and TA provider teams will collaboratively draft an implementation plan and schedule that will form the basis of the implementation agreement. The blood service will need to sign the implementation agreement that outlines the roles and responsibilities and expectations throughout the process as well as break clauses (such as the implementation not being able to proceed further due to external delays etc.). Upon agreement and full execution (signing of the agreement between Jembi and the country/blood service), the implementation schedule will begin. This will cover the configuration of BSIS for the implementation, the BSIS software deployment, installation qualification, operational qualification and performance qualification steps of the implementation as well as all associated training.

Step 8: Deployment and Pre-operational Qualification Training

Once the implementation agreement is signed and the configuration for BSIS for the blood service agreed the BSIS team will visit the blood service to deploy the BSIS software, ensure the configuration is as agreed and training the high level BSIS users who will make up the team undertaking the operational qualification (OQ).

As part of the deployment process Jembi will support the blood service as they carry out their installation qualification (IQ) of the BSIS software implementation at the blood service. This support includes the provision of templates and guidance on how to conduct an IQ as well as assistance with technical look-ups and other installation check activities on the server for blood services who don't have dedicated IT technical staff.

Jembi will also migrate any data from existing databases as agreed in the implementation agreement/plan and support blood services in the validation of this migration by providing them with templates and guidance on how to validate the migration of this data.

Depending on the implementation requirements/plan agreed upon during and post the initial country visit the Jembi team can deliver the following additional training during the deployment and high level user training visit:

- Train-the-trainer training for the OQ team, should they be responsible for the training of other staff members at the blood service.
- Tailored basic computer literacy training for blood service staff who have never used a computer before but will be required to use BSIS.

Step 9: Operational Qualification

The operational qualification (OQ) of the BSIS software at the blood service must be carried out by the blood service. The purpose of the OQ is to test the functionality of the software using a risk-based approach to ensure that the system works as intended. A collection of test cases based on the functional specification must be used to verify the proper functioning of a system. OQ activities should follow the blood service's master validation plan which will include test plans and test cases based on the blood service's user requirements specification (URS). These test plans should test:

- Control functions of BSIS to ensure the result is a product that meets all defined and agreed user requirements.
- That BSIS will make decisions correctly and allow the Blood Service to comply with regulations.
- Worst-case scenarios (those that could kill or severely injure a patient receiving blood products).

The blood service must record all errors/non-conformance issues and submitted using the formal Change Control Process.

Jembi and other TA partners will provide guidance throughout this process in the form of templates, written guidance and answering support queries. Once the operational qualification document has been completed it must be signed-off by hospital an authorised staff member of the blood service management and shared with Jembi for our records.

Step 10: Pre-performance Qualification Training

Following the blood service sign-off of the OQ the remaining staff within the blood service who will be using BSIS as part of their work will need to be trained as standard users of the system. This training will either be carried out by Jembi, the blood service or a combination of both (with a focus on building capacity of local trainers through experiential learning as

well as the training of additional staff). Once the staff have been trained they can take part of the final phase of the BSIS validation, the PQ.

Step 11: Performance Qualification

The performance qualification (PQ) of the BSIS software at the blood service must be carried out by the blood service. The PQ uses a collection of test cases to verify that the system performs as expected under simulated real-world conditions where the system is used by the blood service staff who have been trained as standard level users.

As part of the PQ the blood service will be required to review their standard operating procedures (SOPs) in light of changes resulting from the implementation of BSIS. Jembi will provide guidance on the BSIS aspects of the review while blood services and their blood safety technical assistance providers will be responsible for ensuring that revised SOPs meet blood safety best practices.

Once the PQ and revised SOPs have been signed-off by the blood services senior management BSIS will be ready to move onto the final 'go live' step at the blood service.

Step 12: 'Go Live' and Initial Post Implementation Support

With the PQ and revised SOPs signed-off by an authorised staff member of the blood service management BSIS will be ready to 'go live'. This means that the BSIS installation can be switched over to the production version which will contain a fresh set of migrated data and can be used actively in the day to day operations of the blood service. As part of the preparation for the 'go live' blood service will be required, with support from Jembi, to certify competence of their staff to use BSIS. Only after a staff member has been certified as competent by the blood service should that staff member be allowed to use the 'live' BSIS.

Following completion of the PQ for the particular module(s) that have been implemented, the blood service will move to an official 'go live' state and move into the six-month support period associated with the implementation. At the end of the six months implementation support the blood service can move to a community support model (i.e. leveraging the open-source community for support of the project and do self-upgrades and extensions), or the blood service may choose to move to an enterprise support model

Step 13: Expansion/Roll-out Planning Support

Once the implementation of BSIS has been completed at the initial blood service facility the Jembi team can work with the blood service to assist them in the development of a roll-out plan for taking BSIS to other facilities in the country. These plans will include an evaluation of existing skills within the blood service that are required to carry out further implementations independently, design discussion for expanded implementation and support with train the trainer training and access to training materials.

Enterprise Support

Should a country want to engage in the enterprise support model to continue supporting the implementation post 'go live' support and maintenance the implementation country/site the blood service can engage with Jembi to sign a 12-month service level agreement (SLA) to continue the support of the project. The costs of the SLA are dependent on the extent of the implementation. Countries may apply for their SLAs to be considered and presented to donors for external funding by CDC and should be done through discussion with Jembi.

BSIS Academy

The BSIS Academy is being developed to help facilitate country ownership of BSIS by providing training/capacity building for blood service and Ministry of Health personnel that will enable them to implement, support and manage BSIS locally. The BSIS Academy will combine distance learning with mentorship during practical implementation and support activities at the blood service, undertaken while Jembi implementation staff are in country. For more information about the BSIS Academy please visit <http://bsis.jembi.org> or email bsis@jembi.org.