jembi health systems NPC

BSIS
BLOOD SAFETY INFORMATION SYSTEM

BSIS | Blood Safety Information System

Product Overview

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Overview | What is BSIS?

The Blood Safety Information System (BSIS) is an electronic information management system developed by Jembi Health Systems NPC (Jembi) as part of a larger CDC-funded Blood Safety Strengthening Programme (BSSP). The programme's over-arching goal is to improve the safety and availability of the blood supply and to minimise the risk to the health of patients receiving blood transfusions. Our aims are to:

- Improve the accessibility of safe whole blood and blood components;
- Improve the ability to effectively track blood donations from collection through the testing, processing, labelling and distribution stages to the point of dispatch;
- Generate high quality, standardised labelling of whole blood and blood components at National Blood Services;
- Provide timely, accurate and complete information related to donors and blood donations to support quality assurance practices and management decision-making.

Three of the most important requirements of a blood safety information system are *traceability*, *auditability* and *confidentiality*. Therefore, the key objectives of BSIS are:

- To provide full traceability of donors and donations throughout the collection, component processing, testing, labelling, inventory management and distribution processes;
- To ensure strict access control to confidential data;
- To provide full auditability including the ability to identify the individual(s) responsible for performing key steps throughout the processes;
- To allow the provision and extraction of information necessary for the management of a Blood Service;
- To support the process of certification and accreditation of Blood Services in Africa by the Africa Society for Blood Transfusion (AfSBT) under the PEPFAR programme by providing key information that is accurate, timely and complete;
- To support linkage of TTI-positive donors to further testing, care and treatment;
- To support haemovigilance programmes by recording transfusion data where available;

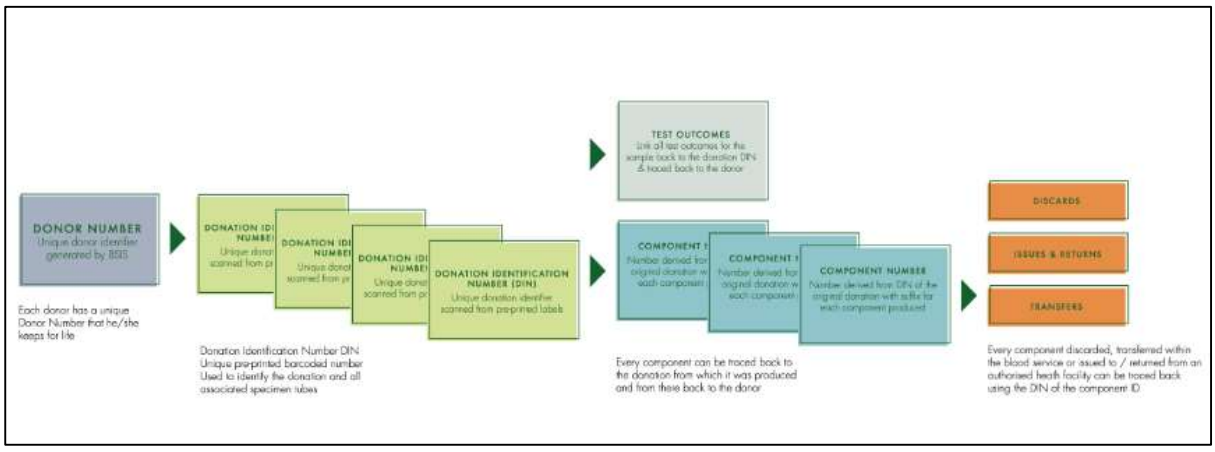

Figure 1: Traceability in BSIS

What are the benefits of using BSIS?

- Traceability via uniquely identifiable donors, donations and components;
- Management of the donor's eligibility to donate;
- Automated blocking of donors according to defined deferral criteria;
- Automated blocking of unsafe donations;
- Automated flagging of donors for post-donation counselling;
- The use of barcodes for donor and donation identification to streamline data entry and reduce data entry errors;
- Pre-defined management reports available within the system;
- Comprehensive role-based access & audit logging;
- Configurable via system-administrator defined parameters;
- Standardised labelling of blood and blood components;
- BSIS supports the African Society for Blood Transfusion (AfSBT) step-wise certification and accreditation process and recommended best practice. See the FAQ section for more details.

What does BSIS do?

BSIS is designed as a fit-for-purpose information system for use specifically in resource-constrained blood services. The BSIS solution captures, tracks and reports information across the core business areas of a blood service organisation, namely:

- Donor registration activities;
- Donor clinics incorporating donor assessment and blood donations;
- Donor counselling services;
- Testing for Transfusion Transmissible Infections (TTIs), serology and blood grouping;
- Blood component production including pack labelling; and
- Inventory management and distribution of whole blood and blood components.

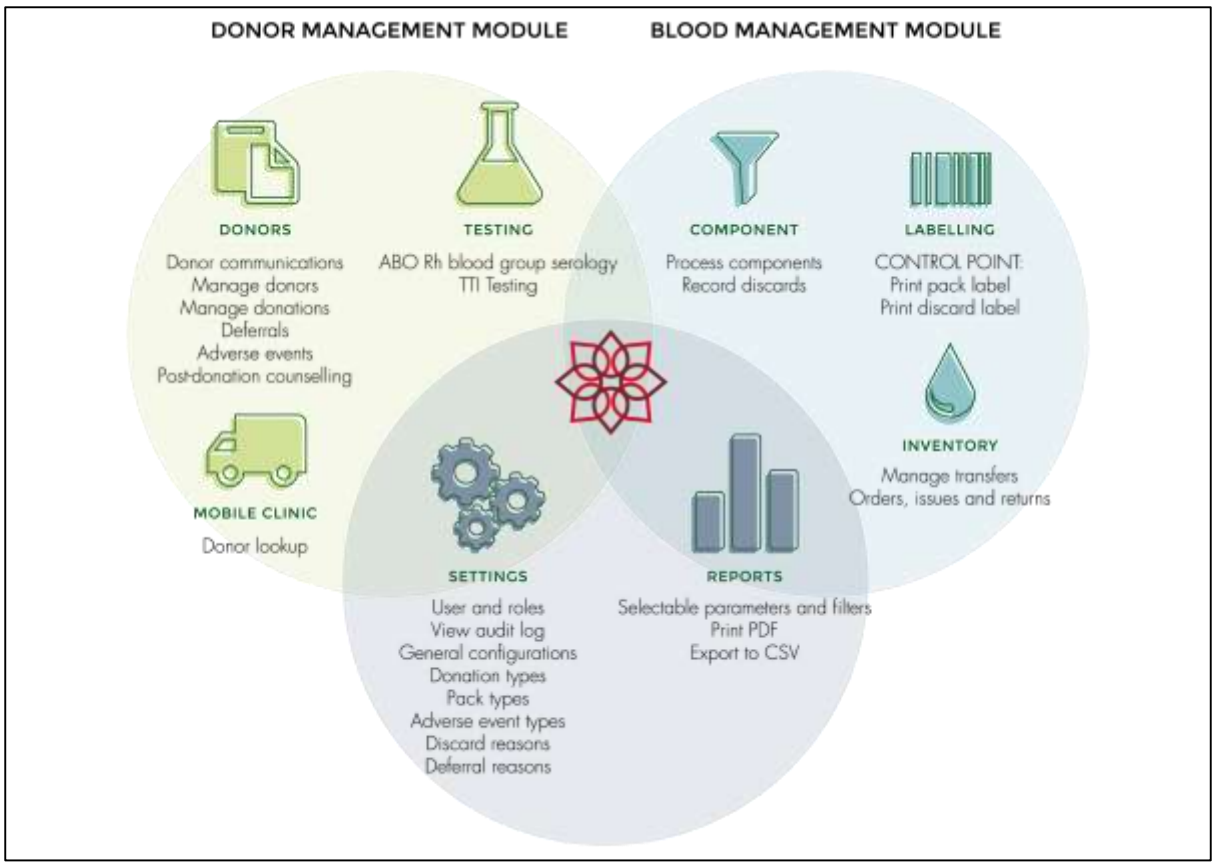

Figure 2: Major functions in BSIS

BSIS functions and features

The donor management function is aimed curating a safe pool of blood donors. This is done by managing accurate and timely information about the blood service's donors and recording key data about the donations collected from them with the aim of ensuring the safety of the donors and the blood supply and improving the recruitment and retention of repeat Voluntary Non-Remunerated Donors (VNRBD) and conversion of Family Replacement Donors (FRD) to repeat VNRBDs. Another objective is to make it easier to identify and contact TTI positive donors and refer them to further testing, care and treatment.

The blood management function is aimed at managing accurate and timely information about whole blood and blood components produced by the blood service, from the separation processes to labelling, discard and inventory management and distribution. The goal is to ensure the safety of the blood supply and transfusion recipients.

Key features include:

Security, confidentiality and auditability

- Comprehensive role-based access: User roles can be configured with a detailed set of associated permissions that govern whether a user can view, add, edit and void specific sets of data. Users are then allocated one or more roles that will define what he or she is able to do within BSIS. At initial setup users are required to create their own unique password: this may be reset if the user forgets their

password. System Administrators set up and maintain the user accounts and can also block access for a user or provide temporary access if needed.

- BSIS log all changes to records by date, time and user and these can be viewed via the audit log.

Donor Recruitment

- BSIS provides the ability to generate a report of donors eligible to donate at the date of the planned clinic, selectable by donor's venue (place of usual donation) and blood group. This reports lists the donor's identifying demographic data and their mobile phone number and can be printed to PDF or exported to Excel.

Donor and Clinic Management

- Unique identification of donors through the use of a BSIS-system-generated number that is printed as bar-code label. The default format is 6 digits and this number is configurable ;
- Unique identification of donations through the use of a pre-printed bar-coded Donation Identification Number (DIN). The format of this DIN is configurable;
- Confidential traceability by linking DINs to donor numbers and to TTI and serological test outcomes;
- Donor lookup, with a forced search facility to minimise the creation of duplicate donor records. Donors can be searched for using their Donor Number, or First Name and/or Last Name, or by the DIN of any of their donations;
- Check for the donor's eligibility to donate according to:
    - minimum and maximum age
    - time since last donation
    - deferral status
- Automated blocking of donor if TTI test results of any previous donations are positive, preventing the collection of a donation from the permanently deferred donor;
- Record key data from the pre-donation clinical assessment: Haemoglobin, blood pressure, weight and pulse;
- Record deferrals using a configurable list of deferral reasons with associated deferral periods. BSIS is pre-configured with the standard list of deferral reasons but these can also be configured to meet the unique needs of the blood service;
- Record donations collected as part of a donation batch during a donor clinic enabling traceability to the venue and date of collection;
- Record any donor adverse events, whether these occur during the donation process or are reported afterwards. BSIS is pre-configured with the standard list of deferral reasons but these can also be configured to meet the unique needs of the blood service;
- Donor merging function whereby an authorised user can choose to merge donor records that appear to be duplicates, using a wizard that allows the user to select which data elements to retain or remove in the merged record.
- Whilst the current versions of BSIS do not provide for data synchronisation to and from laptops to enable the use of BSIS at mobile donor clinic sites, this feature is planned for release in 2017. In the interim, BSIS provides the following:

- to support the look-up of donors to check eligibility to donate and to support counselling of repeat donors, BSIS provides a printout of eligible donors and two CSV exports that can be uploaded into Excel on a laptop and utilised at mobile sites.

Donor Counselling

- The donor counselling feature provides a printable report that lists all donors flagged for counselling due to a positive TTI test outcome, selectable by venue and date range. The outcome and notes of the counselling session can be recorded by the donor counsellors.

TTI and Serology Testing

- Ability to set-up TTI and serology tests and configure a set of testing rules, for example: the blood service can configure whether or not a donor should be automatically deferred if the initial TTI screening test is positive (initially reactive) but all repeat tests are subsequently negative (non-reactive).
- Ability to configure new tests e.g. set up a test for malaria.
- Record ABO Rh serology test outcomes using an algorithm that ensures a repeat test is recorded for a first time donor and an automated check is done against a repeat donor's previous donation. Discrepancies are highlighted and must be resolved before the test sample can be released.
- Record TTI test outcomes using an algorithm that ensures two repeat tests are recorded if the initial TTI screening test is positive/reactive. If one or both of the repeat tests are positive/reactive then a confirmatory test may be recorded.
- Test samples may be released when all the initial screening test outcomes for a sample and any required pending repeat or confirmatory tests have been captured, and all ABO Rh and serology tests have been recorded and any discrepancies resolved.
- Any test sample with an initial screening test outcome that is positive is automatically set to unsafe and the associated donation is flagged for discard, thereby blocking the unit's release to labelling and inventory. The donor is also automatically flagged to receive counselling.
- Configure BSIS to enforce the double entry of test outcomes to minimise the risk of data entry errors.
- Generate exception reports listing samples with pending tests, positive TTIs or unresolved ABO Rh discrepancies.

Processing components

- Record the receiving of donations at the processing laboratory, marking the handover of donations from the donor staff to lab staff.
- Record the separation of whole blood donations into various components, according to a pre-configured set of processing rules that determine which components can be made from a particular starting pack;
- Automated calculation of expiry dates;
- Record the weight of the donation pack, flagging any packs that do not meet the required pre-configured range for pack weight as unsafe;
- Record the weight of the processed components; (V1.2)
- Record the collection bleed times

    - Flags any components where the allowed time since collection has been exceeded as unsafe; (V1.2)
    - Flags any components where the allowed time since collection has been exceeded as unsafe; (V1.2)
- Find whole blood and blood components and view their current status.

Labelling components

- Generate a report listing those components where the test outcomes have been recorded in the testing lab and are therefore cleared for labelling;
- Generate and print a pack label. The labelling process is a control point that performs a series of checks that determine whether a pack is safe for use and can be released to inventory or whether it is unsafe and must be discarded. The labelling algorithm looks at the following factors:
    - TTI and serology testing are complete with no pending tests outstanding;
    - All TTI outcomes are negative;
    - ABO Rh blood groups are determined and confirmed;
    - the deferral status of the donor ;
    - the expiry date of the whole blood or blood components;
    - Pack weight is within the range limits;
    - Donation bleed time and time since collection not exceeded. (V1.2)
- Label Verification feature (V1.2)
    - Once a pack label has been printed the system enforces a check to ensure that the label has been placed on the correct pack. This is done by scanning both the original DIN barcode and the DIN on the pack label to ensure that they match. A check is also done to ensure that the same DIN barcode has not been scanned in twice.
- The Pack Label (V1.2) incorporates the following standardised information about the contents, with eye-readable barcodes for dates or identifiers:
    - Donation Identification Number (DIN);
        - This includes a flag character and check digit used for label verification (V1.2)
    - ABO Rh blood group;
    - Collection date;
    - Component code and description;
    - Expiry date and time;
    - Volume
    - Storage and transport conditions; and
    - Name, number and address of the blood service.

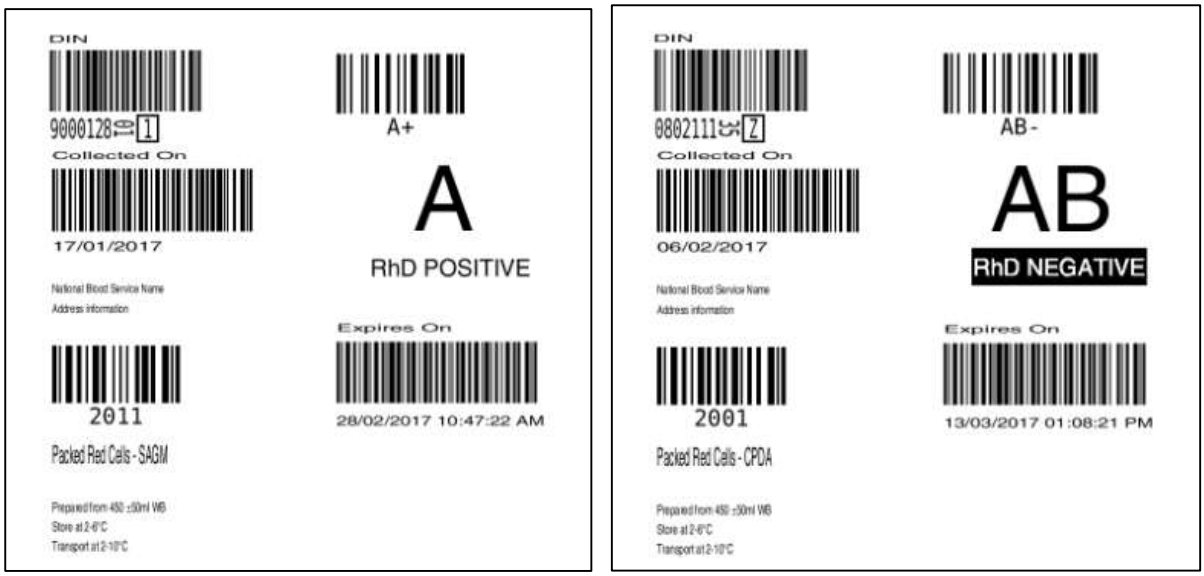

Figure 3: Sample BSIS Pack Labels

The label format includes the same information in the same layout, including eye-readable barcodes, as that required by ISBT128 but BSIS currently does not conform to the ISBT128 coding standards for the global identification of blood services and component types.

Discard management

- If the donation fails to meet the requirements of the labelling process and is rejected as being unsafe for use then the system can generate a label that indicates that this is a bio-hazard and is unfit for use. The label includes the DIN, component code and blood service information.
- It is also possible to record a discarded pack with the reason for discard at any point in the process. BSIS is pre-configured with the standard list of discard reasons according to the AfSBT standards but these may be configured to meet the reporting needs of the blood service.

Figure 4: BSIS discard label

Inventory and Distribution:

- View stock levels by distribution site or across all distribution sites according to component type and blood group. User can choose to view a summary of:
    - In Stock – units that are labelled and available for issue or transfer;
    - Not in stock – unlabelled units that are currently under-going processing and/or testing.
- Search for units in inventory and generate lists for:
    - Units that have expired or that are due to expire on the selected date;
    - Specific components according to DIN and component code;
    - Units according to component type, blood group and distribution site.
- Record orders received from hospitals and record units issued to hospitals and calculate any gaps;
- Check that units match the order they are allocated to;
- Print dispatch notes;
- Record transfer of units to other facilities within the blood service; and
- Record returns from hospitals. Returns may be accepted back into inventory or may be discarded.

Management Reporting:

- In addition to the operational reports, including those listed above, BSIS provides a number of standard pre-defined aggregate reports for use by management for statistical analysis and decision making. All aggregate reports can be generated by the selected date range and are available in PDF or CSV format. BSIS terminology uses the term "venue" to indicate a collection site/ donation site/ donor panel. The reports are:
    - Blood Grouping report – Summary of donations collected according to venue and categorised by gender and blood group.
    - TTI prevalence report – Summary of donations tested, grouped according to venue and categorised by TTI type and gender; TTIs as a percentage of total donations.
    - Donation Types Report – Summary of donations collected by venue and categorised by donation type i.e. Voluntary, Family Replacement, Autologous or Other.
    - Donors Deferred Summary Report – Summary of donors deferred by venue and categorised by gender and reason for deferral.
    - Donors Adverse Events Summary Report – Summary of donors who suffered an adverse event according to averse event type and venue.
    - Discards Summary Report – Summary of units discarded according to component type and reason for discard.
    - Components Produced Report - Summary of whole blood and blood components produced by processing site and categorised by component type and blood group
    - Blood Units Issued Report – Summary of whole blood and blood components issued by component type compared to units ordered and showing any gap.

- Data Export – BSIS has a feature that allows the generation of a set of CSV files containing donor, donation, deferrals, post-donation counselling, test outcomes and component datasets. This raw data can be utilised for more complex and in-depth analysis by data analysts and researchers within the blood service. (V1.2)

What's on our software roadmap?

The BSIS Software roadmap that describes new features and enhancements that are planned with estimated release dates as well as software versions already available can be viewed online **here** at our BSIS wiki. This is updated regularly.

Major functional areas that are planned for development in future versions of BSIS are:

- Haemovigilance support: a new feature to record and a limited set of information about the recipient of any unit of blood issued by the blood service and to record any adverse transfusion events reported to the blood service. This feature is intended to support haemovigilance initiatives.
- Synchronisation of data between laptops and the central database for use in mobile clinics;
- Synchronisation of data between regional blood services;
- Internationalisation – a version that supports the translation of the user interface into other languages that use a western character set;
- Device interfacing with automated laboratory testing machines such as the Abbott Architect.

What does the technical architecture look like?

The BSIS technical architecture has evolved from a standalone Java/Spring/JSP web application into the current architecture, which consists of a stripped down Java/Spring backend on the server side, and an AngularJS/Bootstrap single web page application on the client side.

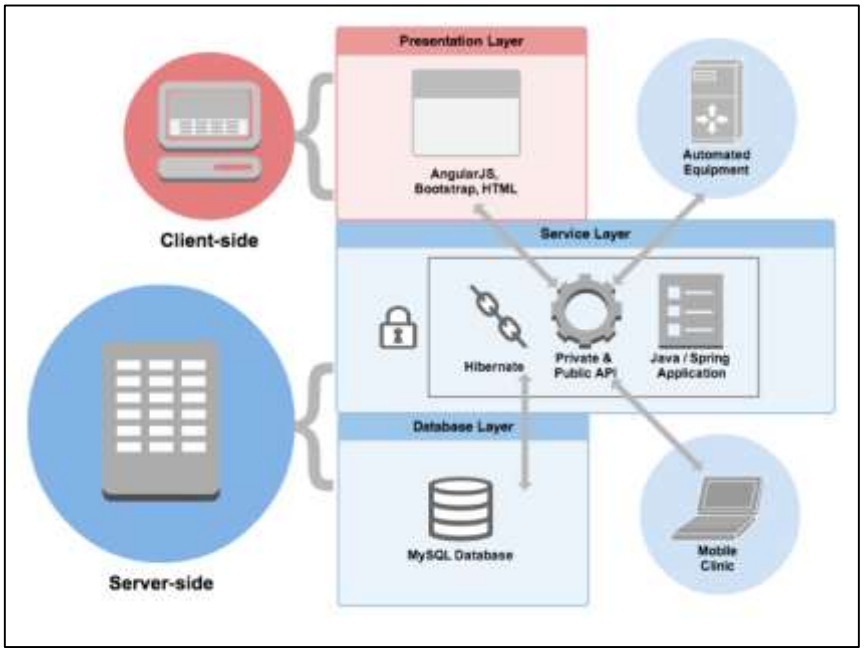

Figure 5: BSIS Technical Architecture

Server Side Technology Stack	Client Side Technology Stack
• Complete Spring application	• Single page web application
• MySQL database	• AngularJS
• Spring Security	• Twitter Bootstrap
• Spring REST API	• Responsive Web design
• Spring Data JPA and Bean validation	• HTML5
• Liquibase database updates	• Yeoman development workflow:
• Maven configuration for building, testing and running the application	• Bower and grunt for managing libraries, build, optimization and live reload
• Hibernate	

What hardware is needed for a BSIS implementation?

BSIS is designed to operate using a client-server architecture, making use of a dedicated production level server to host the BSIS application in a local or wide area network. The system makes use of a MySQL database and requires MySQL to be installed on the server. The recommended setup is to use an open-source Ubuntu server to host the application. BSIS is designed to be accessed via a Windows 7 machine using the free Google Chrome browser.

This design allows for simpler deployment and updates, adaptability to mobile access, and broader access than desktop applications, but with strict access control mechanisms to provide role-based access as required. With this model, the hardware requirements necessitate high-spec server(s) that are able to manage the client request loads; this will vary according to the needs of each implementation and expected transactional loads. Jembi will provide advice and work with the NBS's IT teams and Technical Service Provider to ensure a correct match and hardware configuration is made.

The application requires the use of barcode printers and scanners and Zebra pack label printers. Pre-printed Donation Identification Numbers DIN labels are also a pre-requisite, as are blank labels for printing Donor Numbers. Materials used must be suitable for use in a blood safety environment and label sizes and number formats should be confirmed with Jembi before ordering from suppliers.

Recommended minimum hardware requirements

For a single instance of BSIS installed in a LAN or WAN

EQUIPMENT	**VOLUME OF BLOOD UNITS COLLECTED PER ANNUM**	
Recommended Minimum Specifications	**Up to 20 000 units**	**Up to 100 000 units**
SERVER AND MONITOR	Processor: i7 3.2 Ghz RAM: 16GB HDD: 500GB 2x1GB NIC Ubuntu version 14.04 LTS operating system (server edition) 18" LED Monitor	Processor: i7 3.2 Ghz RAM: 16GB HDD: 1000 GB 2x1GB NIC Ubuntu version 14.04 LTS operating system (server edition) 18" LED Monitor
UPS	Uninterruptable Power Supply	
BACKUP SERVER	Must mirror the production server specs	
TRAINING AND TESTING SERVER/S	Recommended for use in training staff and for performing Operational and Performance Qualification testing on new software releases and patches before implementing on the live system. • 500GB Hard drive • 16GB RAM • Desk desktop monitor, keyboard and mouse • Ubuntu version 14.04 operating system (server edition)	
NETWORK Recommended:	Ethernet 10/100/100 network switch / network cables	
Desktop Workstation (PC + Monitor + keyboard & mouse)	• Processor: : i5 • 3.3 Ghz • RAM: 8GB • HDD: 500 GB	
Workstation Operating System	• Windows operating system 7 or 10 with Google Chrome browser installed	
Barcode scanner	• Motorola LS 1203 USB Scanner • Motorola LS 2208 USB Scanner	
Barcode label printer Pack Label Printer	• Zebra ZT230high speed label printer • Zebra GC420 Compact Thermal Transfer Label Printer • Zebra GK420 Thermal Transfer Label Printer	
Standard A4 Printer	Used for printing reports and worksheets	

SUPPLIES	Number required is dependent on procurement policies and re-order times per supplier
Pre-printed Donation Identification Number (DIN)	Must be labels suitable for use in a blood safety environment Estimated number of piggyback labels needed for number of collections
Blank labels (15mm x 50mm) for printing Donor Number barcode labels	Number of Donor Number barcode labels to be printed per donor is configurable in BSIS
Blank labels (100mm x 100mm)	For printing Pack Labels and Discard Labels. These labels must be suitable for use in a blood safety environment. Estimate number required for number of components produced Estimated number required for number of discards, if discard labels are used.
Printer ribbons	Per printer according to re-order period

Workstations - Recommended set-up

The requirements for workstations will vary and is dependant on number of staff and physical layout and workflow within each blood service, but the following is a suggested set of workstations for a typical workflow.

WORKSTATION	HARDWARE REQUIREMENTS PER WORKSTATION
STATIC/FIXED SITE DONOR CLINICS	• Desktop Workstation (PC + Monitor + keyboard & mouse) • Barcode scanner • Barcode label printer
DONOR COUNSELLING	• Desktop Workstation (PC + Monitor + keyboard & mouse)
DONOR RECRUITMENT AND COMMUNICATIONS	• Desktop Workstation (PC + Monitor + keyboard & mouse) • (LAN access to) A standard printer
COMPONENT PROCESSING AND LABELLING	• Desktop Workstation (PC + Monitor + keyboard & mouse) • Barcode scanner • Pack Label Printer
DISCARD MANAGEMENT	• Desktop Workstation (PC + Monitor + keyboard & mouse) • Barcode scanner • Pack Label Printer
TTI AND SEROLOGY	• Desktop Workstation (PC + Monitor + keyboard & mouse)

TESTING	• Barcode scanner
INVENTORY	• Desktop Workstation (PC + Monitor + keyboard & mouse) • Barcode scanner • (LAN access to) A standard printer
ADMINISTRATION AND MANAGEMENT	• Desktop Workstation (PC + Monitor + keyboard & mouse) • (LAN access to) A standard printer
MOBILE CLINIC SITES	BSIS V1.1 and V1.2 does not currently provide a data synchronisation between laptop and server but this is a major feature scheduled for release in 2017. BSIS does provide two CSV exports for donor lookup and donor counselling at mobile sites that can be uploaded to Excel on a laptop and used on-site in the interim.

Who bears the cost of hardware?

The hardware costs of the implementation are carried by the National Blood Service. Jembi's Blood Safety Strengthening Programme is not able to fund the procurement of hardware, networking or infrastructure costs. Jembi can provide as to what hardware and networking needs are appropriate for operational use.

What about BSIS Support?

How are software updates and upgrades handled?

Due to the nature of the software as a system that supports good manufacturing practice and the requirement for formal validation of the hardware and software from the quality management perspective, there will be no automatic updates to software. New versions of the software that include bug fixes, improvements to the existing functionality and new features are released on a periodic basis. All patches and new versions are accompanied by a set of release notes that describe the fixes, new features and changes since the last version. User manuals are also provide for each software version. As part of the initial implementation local IT staff are trained to install, deploy and manage updates in-house.

What support does Jembi provide for implementations?

As part of the wider Blood Safety Strengthening Programme, Jembi has a number of options to provide consultancy, implementation support and training, and post-implementation software support, with the emphasis on building BSIS software support capacity in-house. These range from a fully managed implementation to a self-managed implementation with options for paid support on an annually renewable basis if required. These can be discussed in more detail with the Jembi team to ensure the best and most sustainable approach for the blood service.

How much does it cost?

The BSIS Software carries a zero cost license and is to be released under an open source license in the future.

Support costs are negotiated upon understanding the support requirements of the service. Jembi has a support team that is available during weekdays (Monday to Friday) from 9am to 5pm Central African Time (GMT + 2 hours). Our implementation approach is focused on building capacity in blood service staff to provide first line support in-house and so facilitate faster response times and reduce dependence on real-time support responses for countries in different time zones.

Hardware costs are not included in the implementation costs. The blood service must fund and procure hardware and networking.

Implementation costs vary widely depending on the implementation model selected. Jembi offers a "train the implementer" model to train local staff to implement as well as offers a fully managed implementation service. Attendance at a BSIS Implementer Academy is also an option. Costs range between $80'000 to $150'000 for a fully managed implementation service based on travel and required engagement models. The full implementation service includes support through the workflow review, system deployment, staff training, validation, SOP reviews and go-live process. The model is designed to promote safe, dependable and sustainable implementations of the BSIS software that is integrated into quality management practices.

An accurate implementation cost can be provided upon a detailed discussion with the Jembi team.

Frequently Asked Questions

1. Is BSIS an open-source system?

The Blood Safety Information System (BSIS) is developed under an open source project and the software carries an open source BSD license. It is built using an open source technology stack, including Java, Spring, AngularJS, and a MySQL database.

2. Does BSIS support the AfSBT certification and accreditation process?

Yes, BSIS is designed in consultation and in conjunction with blood safety experts and technical assistance partners (such as AABB (American Association of Blood Banks) and Safe Blood for Africa) with the aim of supporting the AfSBT step-wise certification and accreditation process through the provision of accurate and timely information to support the SOPs required to achieve certification or accreditation. For example:

- BSIS enables the keeping of records that are identifiable, legible, complete and retrievable ([1]ref. AfSBT standard 1.4.2);
- BSIS provides a system to protect the confidentiality of information (ref. AfSBT standard. 1.4.2.2);

[1] AfSBT Chart of Evidence of Compliance for Standards - 2014

- BSIS enables the traceability of blood and blood components from source to final disposition (ref AfSBT standard 1.4.2.3);
- BSIS ensures the unique identification of donors (ref. AfSBT standard 1.4.2.3.1); and
- BSIS can provide quality data indicators on a scheduled basis (ref. AfSBT standard 1.11.2).

3. **Is BSIS up and running in any African Country?**
   BSIS is currently in full production use in the Lesotho National Blood Service. The Zambian National Blood Transfusion Service, The Ethiopia National Blood Bank Service and the National Blood Service of Ghana are in the final stages of validation, with go-live planned for the first quarter of 2017.

4. **What about legacy data?**
   There is a data import function that imports selected, verified data such as donor information into BSIS from existing systems. As part of the implementation process, Jembi will discuss the various options and pros and cons regarding the migration of data from existing systems and agree the best approach for the blood service.

5. **Is BSIS interoperable?**
   One of Jembi Health Systems' core competencies is interoperability of health information systems and BSIS is designed to follow the same technical architectural principles: we support the use of open standards and open architectures. That does not mean that your system will be open. All integration or interoperation with other systems is always configurable on an as-needed basis and no automatic export of data is ever allowed. Integration with laboratory testing machines and potential interoperation with hospital or other systems will be via an API.

Acknowledgements

The BSIS software was initially developed under the Computing For Good (C4G) initiative in the Georgia Tech College of Computing in Atlanta, GA, under the name Vein-To-Vein (V2V). This was supported by a US Centers for Disease Control and Prevention (CDC) Blood Safety Team. From 2007, faculty and students from C4G led the research-and-development phase of the software, allowing the system to evolve in an academic environment where new ideas and technologies were tested and applied against the subject of blood safety. During this phase, Georgia Tech consulted frequently with end-users from a number of African countries, including Zambia, Cameroon, Namibia and Ghana, as well as with blood safety experts in South Africa. Following the decision in May 2013 to transition the software for use in production, Jembi Health Systems took over the software in order to develop a scalable, production-ready version of the system suitable for implementation in low-resource settings.

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