BSIS | Blood Safety Information System

Product Overview

Version 1.2

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Overview | What is BSIS?

The Blood Safety Information System (BSIS) is an electronic information management system being developed by Jembi Health Systems NPC (Jembi) as part of a larger CDC-funded Blood Safety Strengthening Programme (BSSP) with the overall goal to improve the health of patients receiving blood transfusions. Our aims are to:

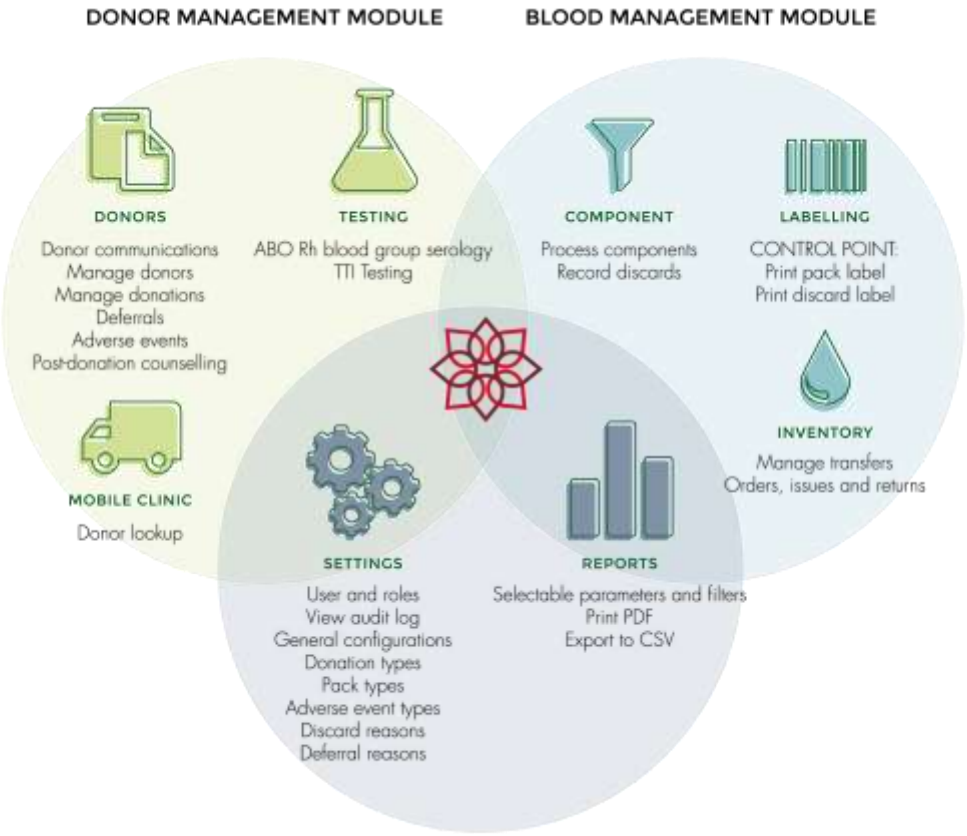
- Improve accessibility of safe blood components;
- Increase the appropriate usage of safe blood components;
- Improve the ability to effectively track blood donations through collection, testing, processing and release stages; and
- Provide a means to generate high quality, standardised labelling of blood components at National Blood Services or in Hospital Blood Banks.

What does BSIS do?

BSIS is designed as a fit-for-purpose BECS (Blood Establishment Computer 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:

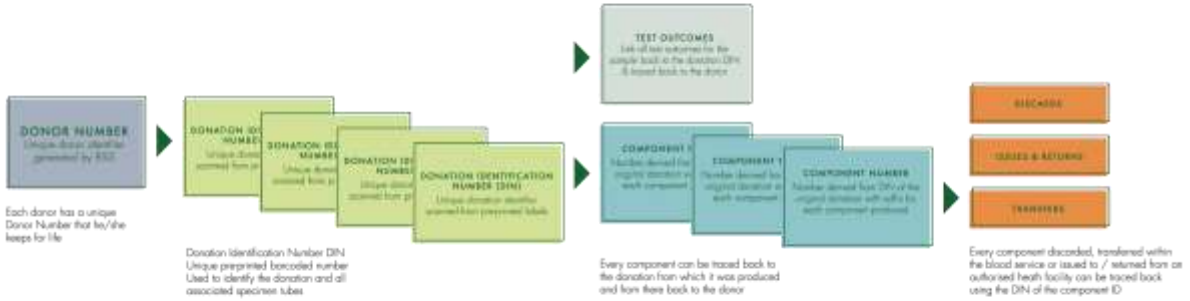
- Donor recruitment activities;
- Donor counselling services;
- Donor clinics incorporating donor registration, donor assessment and collections;
- Testing for Transfusion Transmissible Infections (TTIs), serology and blood grouping;

- Blood component production including pack labelling; and
- Blood component inventory management



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

- To provide access to donor, donation and blood component data on a real-time basis where the infrastructure allows and to enable offline access where internet connectivity is intermittent;
- To provide full traceability of donations throughout the collection, component processing, testing, labelling, inventory management and distribution processes;
- To allow the flexible extraction of information necessary for the management of a Blood Service;
- 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; and
- 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.



What are the benefits of using BSIS?

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

BSIS modules

BSIS is designed as two core modules: (i) the donor management module, which is able to operate as a stand-alone module and manage information about donors, donations and the TTI, blood grouping and serology testing processes; and (ii) the blood management module that extends the system to incorporate blood component processing, pack labelling, inventory management and distribution. BSIS can be implemented either by implementing the donor management module first followed by the blood management module or as the full blood safety application, according to the needs and preferences of the blood service.

The Donor Management Module

The donor management module is aimed curating a safe donor pool. This is done by managing accurate and timely information about the blood service's donors, recording key data about the donor and the donations collected (including TTI and serological test outcomes) 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.

Key features of the donor management module include:

- Donor Recruitment
  - Report of donors eligible to donate at the date of the planned clinic, selectable by venue and blood group, and listing the donor's identifying demographic data and their mobile phone number. This can be printed to PDF or exported to Excel.
- Donor and Clinic Management
  - Unique identification of donors through the use of a BSIS-generated number and 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);
  - Confidential traceability by linking DINs to donor numbers and test outcomes;
  - Donor lookup, with a forced search facility to minimise 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 age, test results of any previous donations, time since last donation and deferral status;
  - Record key data from the pre-donation clinical assessment: Haemoglobin, blood pressure, weight, medication, 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 according to the AfSBT standards;
  - 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 according to the AfSBT standards 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.
- Donor Counselling
  - 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 of the counselling session can be recorded by the 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).
- 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 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 have been captured and any required pending repeat or confirmatory tests 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 flagged for discard, thereby blocking the associated component's release to labelling and inventory. The donor is also flagged to receive counselling.
- Ability to configure BSIS to support the double entry of test outcomes by two users to minimise the risk of data entry errors
- Generation of exception reports listing samples with pending tests, positive TTIs or unresolved ABO Rh discrepancies.

o Security, confidentiality and auditability
  - Comprehensive role-based access: 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 if needed.
  - BSIS log all changes to records by date, time and user and these can be viewed via the audit log

The Blood Management Module

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

Additional features planned for inclusion are:

- Synchronisation of data between laptops and the central database for use in mobile clinics; and
- Integration of BSIS with automated laboratory testing machines.

The key features of the blood management module are:

- Processing and labelling components:
  - Manage 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 component;
  - Record the collection bleed times and weight of the donation pack, blocking any packs that do not meet the required standards for weight range;
  - Record the weight of the processed components and block any that do not meet the required standard for weight range;
  - 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 final pack label. The labelling process is a control point that determines if a pack is safe for use and can be released to inventory or if it must be discarded. The labelling algorithm looks at the following factors:
    - TTI and serology testing are complete with no tests outstanding;
    - TTI outcomes are negative;
    - ABO Rh blood groups are determined and confirmed;
    - If the bleed time was exceeded for specific components;
    - If the donor should have been deferred at the time of the donation;
    - If the pack has expired; and
    - If the pack should be discarded.
  - The Final Pack Label incorporates standardised information about the contents, with eye-readable barcodes printed as well where the information is a date or an identifier:
    - Donation Identification Number (DIN);
    - ABO Rh blood group;
    - Collection date;
    - Contents code;
    - Expiry Date (and time where relevant);
    - Storage and transport conditions; and
    - Name, number and address of the blood service.

    This information is the same as that required by ISBT128 although BSIS currently does not conform to the ISBT128 coding standards.

- 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 will generate a label that indicates that this is a bio-hazard and is unfit for use; and
  - It is also possible to record a discarded pack at any point in the process with an associated discard reason. Discard reasons are configurable according to local practice and AfSBT standards.
- Inventory and Distribution:
  - View stock levels by type and storage area/distribution site:
    - Labelled and available for issue or transfer; and
    - Components still under-going processing.
  - Generation of reports to indicate packs that have expired and packs that are due to expire;

- Record orders received from hospitals and record issues to hospitals and calculate any gaps;
- Record transfers to other facilities within the blood service or hospital group; and
- Record returns from hospitals or hospital wards

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. These include:
  - TTI prevalence report - including statistics by TTI type, venue, date range and gender; and
  - Blood Grouping report – including statistics by blood group, venue, date range and gender.
- WHO Global Database on Blood Safety (GDBS). The ability to generate an excel file that contains those indicators based on data collected by BSIS is a priority feature that is on our software development roadmap for this year. The excel file can then be used to enter this information into the WHO Global Database on Blood Safety (GDBS).

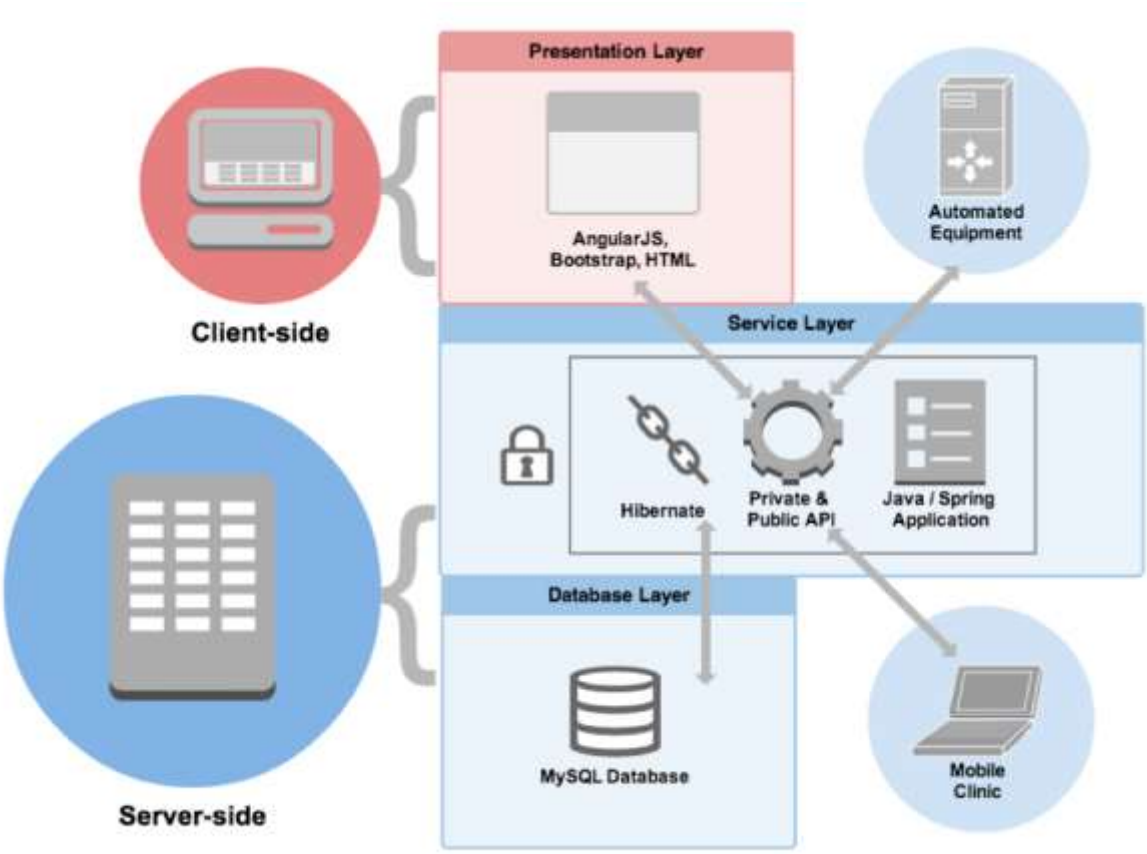
What's on our software roadmap?

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

- Internationalisation – a version that supports French and that can be translated to other languages;
- Donor communication feature whereby donors can be communicated with via SMS;
- Mobile phone app to provide the ability to check a donor's eligibility to donate at a mobile clinic;
- Transfusion Management Module: to manage information about the recipient of the blood and record any adverse transfusion events in order to support haemovigilance and look -back.

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.



Server Side Technology Stack

- Complete Spring application
- MySQL database
- Spring Security
- Spring REST API
- Spring Data JPA and Bean validation
- Liquibase database updates
- Maven configuration for building, testing and running the application
- Hibernate

Client Side Technology Stack

- Single page web application
- AngularJS
- Twitter Bootstrap
- Responsive Web design
- HTML5
- Yeoman development workflow:
- Bower and grunt for managing libraries, build, optimization and live reload

What hardware is needed?

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.

The application is also designed to be used with additional hardware that requires 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 must be confirmed with Jembi before ordering from suppliers.

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 Technical Service Provider to ensure a correct match and configuration is made.

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		
BACKUP SERVER	Must mirror server specs	
TRAINING AND	Recommended for use in training staff and for performing	

TESTING SERVER/S	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 is configurable in BSIS
Blank labels (100mm x 100mm)	For printing Pack Labels and Discard Labels. Must be labels suitable for use in a blood safety environment Estimated 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

STATIC DONOR CLINICS

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- Barcode scanner
- Barcode label printer

COUNSELLING WORKSTATIONS

- Desktop Workstation (PC + Monitor + keyboard & mouse)

DONOR RECRUITMENT AND COMMUNICATIONS WORKSTATIONS

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- (LAN access to) A standard printer

COMPONENT PROCESSING WORKSTATIONS

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- Barcode scanner
- Pack Label Printer

DISCARD MANAGEMENT WORKSTATION

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- Barcode scanner
- Pack Label Printer

TTI AND SEROLOGY TESTING WORKSTATIONS

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- Barcode scanner

INVENTORY WORKSTATION

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- Barcode scanner
- (LAN access to) A standard printer

ADMINISTRATION AND MANAGEMENT WORKSTATIONS

- Desktop Workstation (PC + Monitor + keyboard & mouse)
- (LAN access to) A standard printer

Frequently Asked Questions

General

1. Is BSIS an open-source system?

The Blood Safety Information System (BSIS) is an open source project that will carry an OSI (https://opensource.org/) open source license. It is built using an open source technology stack, including Java, Spring, AngularJS, and a MySQL database. Jembi is in the process of applying the appropriate OSI license to the code bases.

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 and Safe Blood for Africa) towards the goal 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);
- 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. 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 validation from the quality management perspective, there will be no automatic updates to software.

New versions of the software that includes bug fixes, improvements to the existing functionality and new features will be released on a periodic basis. The new version will be accompanied by a set of release notes that describe the fixes, new features and changes since the last version. The paid support service that Jembi offers will provide access to the Jembi support team who can assist blood service staff with implementing the updates, validating those updates and providing additional information and training if needed. The support package is renewable on an annual basis to enable provision of support for as long as the blood service feels it is needed.

4. Is BSIS up and running in any African Country?

BSIS Donor Management module is currently live in the Lesotho National Blood Service with the BSIS Blood Management module scheduled to be implemented later in 2016.

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

5. **What about legacy data?**
   There is a function that will import selected, verified data such as donor information into BSIS from existing systems. As part of the implementation process, Jembi will discuss the options and pros and cons of each option regarding the migration of data from existing systems.

6. **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.

Costs

7. **What does BSIS costs?**
   The first 6 months are free. After 6 months, there is an option to extend on an annually renewable basis for the life span of the software. The software carries no license cost however the NBS may choose to enter into an enterprise support agreement that would include access and support to the Jembi help desk.

   There are no forced costs after 6 months. As we are building an open source tool the local NBS is able to curate it themselves if they have the necessary skills in-house and believe that they do not require any assistance. Jembi's support model is aimed at providing a business to business support package that provides active support via access to the Jembi help desk. This includes support for queries, troubleshooting, reporting of bugs or other issues and submission of new feature request that will be considered for inclusion in a future version.

8. **Who bears the cost of hardware?**
   The hardware costs of the implementation are carried by the NBS or Hospital Blood Bank.

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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