Australian Red Cross
BLOOD SERVICE

PEPFAR CAMBODIA BLOOD SAFETY PROGRAM 2013-2018

FINAL PROJECT REPORT

This report provides the final status update, conclusions and recommendations moving forward for the Cambodia Blood Safety program.

February 2018


M&E 2013 focus – VNRBD & TTIs

TABLE OF CONTENTS

INTRODUCTION 4

CAMBODIA BACKGROUND 5

COUNTRY OVERVIEW 5

NATIONAL BLOOD TRANSFUSION SERVICE (NBTC) OVERVIEW 8

PROJECT OVERVIEW 9

WORKING IN CAMBODIA 9

PROJECT RISK MITIGATION 10

PARTNERSHIPS AND INTEGRATION 11

PROJECT IMPLEMENTATION 12

OVERVIEW 12

PEPFAR II TASK ORDER 13

2014 CHANGE TO PROJECT PRIORITIES 14

COMPLEMENTARY PROJECTS 15

PROJECT TIMELINE 15

MIDTERM REVIEW 16

PROJECT RESULTS 17

INTRODUCTION 17

PILLAR 1: NATIONAL POLICY & LEGISLATION 18

PILLAR 2: HOSPITAL & PATIENT BLOOD MANAGEMENT 22

PILLAR 3: COMMUNITY & DONOR MOTIVATION 25

PILLAR 4: NATIONALLY COORDINATED BLOOD SERVICE 32

PROJECT INSIGHTS 55

KEY LOCAL LEARNINGS 55

PROJECT SUCCESS FACTORS 59

OPPORTUNITIES FOR FUTURE PROJECTS 61

SUSTAINABILITY AND TRANSITION PLANNING 62

SUMMARY OF RECOMMENDATIONS 62

PROJECT ACTIVITY TRANSITION PLAN 64

PROJECT TEAM 74

GLOSSARY 77

APPENDIX 1 – TECHNICAL TRAINING SUMMARY 79

APPENDIX 2: DEVELOPED DOCUMENT SUMMARY 83

APPENDIX 3: JANUARY 2018 ACCREDITATION ASSESSMENT REPORTS 88

INTRODUCTION

Since 2011, the Australian Red Cross and Blood Service have worked closely with project partners to deliver the core activities of the US President's Emergency Program for AIDS Relief (PEFPAR) Cambodian Blood Safety Project and promote coordination amongst funding and technical assistance partners to help achieve the common goal of safe and sufficient blood for all patients in Cambodia Key partners included the Cambodian National Blood Transfusion Service (NBTC), US Centers for Disease Control and Prevention (US CDC), AABB, American International Health Alliance (AIHA), World Health Organization (WHO), The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), US Pacific Command (PACOM) and the US Army Corps of Engineers (USACE).

The project has delivered strong results in capacity building, critical infrastructure, equipment and human resources, with the direct results being improved blood safety in the country. In 2017 over 70,000 units were collected nationally, an increase of 22,000 units from 2012. In 2012, 8% of donated blood tested positive for a transfusion transmissible infection (TTI) - HIV, HBV, HVC or syphilis; in 2017 the TTI rate had decreased to 5.9%. Cambodian hospitals were also primarily only transfusing whole blood in 2012 due to the limited availability of specific components for directed therapy. In 2017, 74% of the blood supplied by the National Blood Centre in Phnom Penh was components (FFP, red cells and platelets), contributing to better therapeutic outcomes for patients.

Dr Anthony Keller, Ms Emily Tonks and Dr Sally Thomas with staff from Kampong Cham Provincial Blood Centre in 2011

CAMBODIA BACKGROUND

COUNTRY OVERVIEW

Cambodia covers an area of 181,035 km^2 and has an estimated population of 15.96 million people[1]. It is located in Southeast Asia on the Indochinese peninsula, bordered to the north by Laos, northwest by Thailand, Vietnam to the south east and by the gulf of Thailand to the southwest. The country's flat interior, known as the Mekong Lowlands, spreads around the Tonle Sap Basin and is bordered by mountain ranges to the southwest (Cardamom Mountains and Elephant Ranges) and north (Dangrek Mountains).

The country is divided into 24 administrative provinces, and one municipality - the capital Phnom Penh. The majority of the population (around 80 %) live outside the capital, in rural areas with 70% dependent primarily on agriculture (largely rice and livestock) for their livelihoods[2].

Approximately 90-95% of the population are Khmer ethnic. The remaining 5-10% includes Chinese-Khmers, Khmer Islam (also known as Chams), ethnic hill-tribe people (also known as the Khmer Loeu) and Vietnamese[3]. The official language of Cambodia is Khmer which is spoken by 90% of the

[1] https://www.cia.gov/library/publications/the-world-factbook/geos/cb.html accessed 27 July 2017
WHO Global Health Observatory website (http://apps.who.int/ghodata/) accessed Jan 2012.
[2] World Bank website (http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/EASTASIAPACIFICEXT/CAMBODIAEXTN/0,,menuPK:293861~pagePK:141159~piPK:141110~theSitePK:293856,00.html) accessed Jan 2012.
[3] Cambodia Census Survey 2008. National Institute of Statistics, Ministry of Planning (Accessed via National Institute of Statistics of Cambodia website http://www.nis.gov.kh/ accessed Jan 2012.

population, although in recent years the use of English has grown in the major cities and tourist centres. Overall, 70.5% of women and 84.5% of men are literate[4].

Theravada Buddhism is practiced by 95% of the population; however Islam, Christianity, Daoism and Confucism are also practiced among minorities. Adherence to Buddhist principles is generally considered intrinsic to the country's ethnic and cultural identity. As a collective society, Cambodia values altruism and actions for the common good.

Almost half of the population are younger than 24 years old and the female to male ratio in the over 65 age bracket is almost 2 to 1.[5] This population profile is a legacy of three decades of conflict but also a reflection of the success of National Health Programs, which in more recent years have focused on maternal and child health, as part of Cambodia's Millennium Development Goals (CMDG) (now the Sustainable Development Goals). National Health Programs such as these in Cambodia have contributed to a substantial increase in life expectancy, which is currently 60 years for males and 64 years for females, a major improvement since 1999 when the average life expectancy was 52 and 56 years respectively[6].

The climate is tropical with relatively high mean temperatures and high humidity year round. There are two distinct seasons; the dry season and the monsoon season. The dry season runs from November to April averaging temperatures from 28.0 °C (82.4 °F) to 38 °C (100.4 °F). The monsoon lasts from May to October and brings up to 80% of Cambodia's annual rainfall with the heaviest falls in elevated areas.

Health Services in Cambodia, including blood services are devolved and are the responsibility of each Provincial Health Department. The National Blood Transfusion Centre in Phnom Penh is responsible for providing technical training and support to blood centres at a national level.

The current regulatory framework for health is still developing and is further challenged by a fractured legal infrastructure. Many areas in health are regulated by Prakas issued directly by the Minister for Health on specific health activities. As a result, the health framework contains pockets of detailed regulation within systems which are less regulated.

The health infrastructure challenges along with limited availability of skilled health care workers has hampered Cambodia's efforts to reconstruct and improve the national

A patient receives an injection in Battambang Province, 2011

[4] CIA World Factbook https://www.cia.gov/library/publications/the-world-factbook/geos/cb.html accessed 28/02/2018
[5] CIA World Factbook https://www.cia.gov/library/publications/the-world-factbook/geos/cb.html accessed 22/02/2018
[6] World Health Organization, Cambodia Country Profile. WHO, 2011. (Available at: http://www.wpro.who.int/countries/cam/2011/CAM.htm, accessed Jan 2012)

health care system.

In terms of blood service delivery, the blood supply to rural areas is often challenged due to both geographic isolation and as a result of seasonal flooding which also brings outbreaks of malaria and dengue fever.

Malaria is a major cause of morbidity and mortality in all age groups in Cambodia and reduction of the incidence of malaria and other major diseases is identified in the new Sustainable Development Goals, and these are recognised as relevant for the Cambodian context[7].

Poor road conditions and the prevalence of land mines in some regions, compounded by the isolation of rural areas and their consequences also impacts on access to blood. This presents challenges in terms of servicing the health care needs of remote regions, including the safe and timely distribution of blood to remote areas and patient transfer from remote areas to provincial centres for transfusion.

Thalassemia and sickle cell anaemia occur in the highest frequency in developing countries like Cambodia where adequate services for their management, control and surveillance are not yet fully in place. Improved nutrition, sanitation and public health services in developed nations provide the right environment for early detection and treatment[8].

Many of the aspects of a functioning health system rely on stable and sustainable government health service financing. According to United Nations Development Program (UNDP) reports, approximately 20% of government spending occurs at the provincial and local levels, furthermore, grant disbursements to provinces are consistently late and routinely differ from initial budget amounts. The result is a burden on the individual to finance their own healthcare.

The Cambodian government is striving to improve health services, including blood supply, and this is reflected in the support for staff and consumables, new Prakas and the upgrade of blood depots in remote areas.

Cambodian Government and MoH:
Continuing commitment to the development of a strong national blood program to benefit Cambodian patients

- First Blood Policy - 2003
- First National Strategic Plan for Blood - 2008
- Commitment and support from Prime Minister H.E. Hun Sen – encouraging voluntary blood donation
- HSP3 2016 – Blood References

Cambodia—2017 Quick Stats

- Population = 16M
- # Whole Blood Collections / Annum = 76,511
- 79% blood supplies as components
- VNRBD = 26.5%
- Blood donor infectious disease rate = 5.9%

[7] HE Mr. Theng Pagnathun, Delegate of the Royal Government of Cambodia in Charge of Director General of Planning, Ministry of Planning, Kingdom of Cambodia. Second ECOSOC Forum of Financing for Development Follow-up. The 1st Session of the United National General Assembly, New York 22-25 May 2017. Accessed 26/02/2018 from http://www.un.org/esa/ffd/wp-content/uploads/sites/3/2017/05/2017FFDF_GeneralDebate_Cambodia.pdf

[8] Weatherall DJ. Thalassemia as a global health problem: recent progress toward its control in the developing countries. Ann N Y Acad Sci. 2010 Aug;1202:17-23.

NATIONAL BLOOD TRANSFUSION SERVICE (NBTC) OVERVIEW

The NBTC has the responsibility for organising and supervising the collection and supply of blood throughout the country. In 1994 by government decree, the Ministry of Health adopted a policy of promotion of voluntarily non-remunerated blood donation.

NBTC has 64 government staff (up from 38 staff in 2012), and two project contract staff (down from eight in 2012) who work in one of two main departments; the administration/finance department and the technical department. The administration department includes budgeting and planning, cashier, stock control, information service and reporting, and staff and administration. The Technical Office includes Laboratory Unit; Blood Component Preparation Unit; Blood Donor Services Unit; Quality Management and Assurance Unit and Clinical Transfusion Support Unit.

Mr Vong Yokly with NBTC laboratory staff in 2013

Ms Linda Nicolo and Mr Vong Yokly, NBTC Deputy Director review laboratory processes in 2013

There are currently 21 Provincial Blood Transfusion Centres across the country and four of these – Kampong Cham, Siem Reap, Battambang and Takeo are considered to be key regional centres. They have achieved this status for a variety of reasons including, geographic placement, volume of collections and level of support from their PHD.

NBTS staff attend the annual review in 2013

PROJECT OVERVIEW

WORKING IN CAMBODIA

The Australian Red Cross Blood Service technical project design has reflected the current best practice in technical program delivery. It incorporated three key overlapping areas (The Project, Human Capacity Building, and The local System) for a considered, quality approach which aimed to maximise sustainable outcomes across the areas of delivery whilst maintaining an awareness of project challenges and taking into consideration the wider Cambodia context of People, Patients and Country.

The People:
DISC personality—Dominance, Influence, **Steadiness**, Conscientiousness

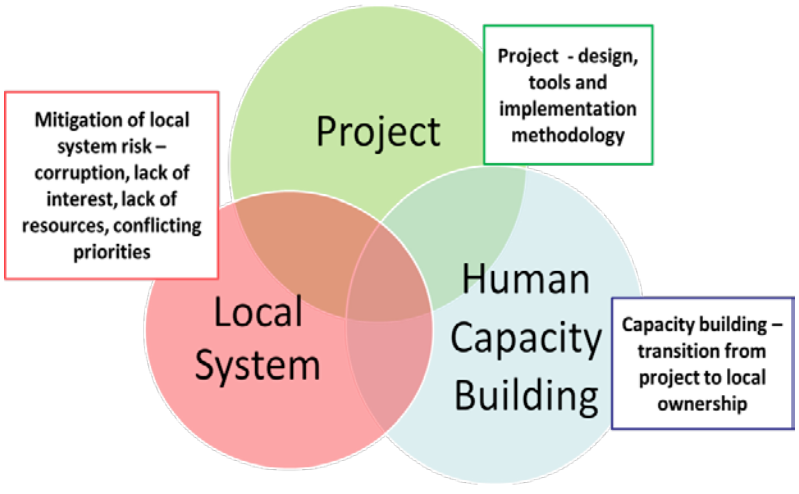
The Patients:
Transfusion indicators, staff training, facilities & resources

The Country
Legacy of the Khmer Rouge—Devastated infrastructure (universities, hospitals, etc), Loss of institutional memory

The "Project" – is the technical work plan and support provided by the Blood Service, including training, development of draft SOPs, training and technical advice, and has **project outputs.**

"**Human Capacity Building"** acknowledges that everything the project does (for example development of draft SOPs) needs to be transitioned from a project context to the local context – i.e. locally owned and managed. This is key in building sustainability. Local understanding and ownership positively impacts the beneficiary, for example resulting in a decrease in TTI rates, or an increase in VNRBD. This area has **local outcomes.**

The "Local System" acknowledges that there can be factors outside the project's control (or indeed that of the local blood service) that can impact on the success and sustainability of the project, for example corruption or lack of interest or resources at a government level. The project design mitigates these as much as possible.



PROJECT RISK MITIGATION

Throughout the project, the project team has made consistent efforts to identify and mitigate project risks, including risks around implementation, duplication of activities and sustainability. The following strategies have been employed to help facilitate this:

- Collaborative project planning, including broad-based dialogue with leadership & technical staff,
- Clear project and delivery objectives,
- Education of project and local stakeholders,
- Resource mobilization with government and other external donors to diversify funding sources,
- Country dialogue to support the establishment of national policies related to blood service management,
- Collaborative relationships between external technical consultants and partner staff at all levels,
- Technical design supports active transition of project outputs to locally owned activities and processes,
- Training programs, including train-the-trainer courses, tailored to specific needs at the national and provincial levels,
- Project plan alignment with organizational change capacity and staff well-being,
- Ongoing monitoring and evaluation (M&E) of project and local outcomes.

Dr Sally Thomas (above) and Ms Emily Tonks (left) both ARCBS review project plans and documents with key provincial stakeholders

PARTNERSHIPS AND INTEGRATION

The US-PACOM support to the Cambodian Blood Service has been crucial in improving the standard and capacity of facilities of the country's blood system. In collaboration with the US Army Corps of Engineers (USACE), they have financially supported the oversight and construction of three new state-of-the-art blood banks to date, Phnom Penh, Siem Reap and Kampong Cham. Two more facilities in Battambang and Takeo are currently under construction and due for completion in mid-2018. PACOM has also provided critical equipment for the blood service, and have conducted a range of training modules with their time in country. They remain key contributors in continued education for transfusion staff, providing one blood-related workshop per year covering an identified topic of interest or priority.

(L-R) Dr Hok Kimcheng NBTC Director, Dr Rob Newman, CDC Country Director, Mr Ly Sovith Kampong Cham PBTC Chief, Mr Scott Olsen, USACE and Dr Ly Vanthy, US CDC attend the opening of the new Kampong Cham Provincial Blood Centre in 2016

Mr Scott Olsen from USACE links the success of the project to the collaboration and sharing of information with partners, the national blood service and the Cambodian government.

"From our perspective, the projects would not have been nearly as successful without all the various partnerships such as US-PACOM's commitment to the buildings, the staff training, & supplying many of the consumables necessary for a blood bank to operate properly, US-CDC, the Australian Red Cross Blood Service and the National Blood Service to help develop the most functional buildings possible."

Provision of the latest technology blood analysers and other equipment to provide a high quality blood service has also been a key consideration in increasing the safety of the Cambodian blood supply. The Australian Red Cross Blood Service has assisted the Cambodian Blood Service to manage its critical equipment needs between US-PACOM and Global Fund, providing advice on equipment requirements by site, and their specifications according to specific purpose and ensuring duplication is minimised.

This successful collaboration between partners can be largely attributed to open communication, the sharing of a common goal and strategic directive to identify where each could "fill the gaps" and provide the missing pieces for ongoing improvement.

"All relevant partners openly share, actively communicate and collectively drive to a common goal per the National Blood Transfusion Services Strategic Plan 2013-2017," said Dr Ly Vanthy, Deputy Director for the US CDC based in Phnom Penh. "The project has been successful through the implementation of international standard blood bank facilities equipped with the latest technology analysers."

PROJECT IMPLEMENTATION

OVERVIEW

A multidisciplinary technical assistance approach was used to build capacity and capability across the Cambodian blood banking sector. Through training and advice the technical team has supported the NBTS to:

- Improve blood service safety and delivery across the country,
- Improve clinical practice through training and clinical guideline development,
- Strengthen national policy and legislation for blood services and
- Ensure integration with the wider health system – for example with maternal health program, national HIV programs national education.

Additionally, the team focussed on program management, monitoring and evaluation (M&E), business, finance, communications, has developed tools and systems for blood service delivery and has promoted the effective use and management of other donor funding, e.g. Global Fund, through robust, integrated project work plans and partner coordination.

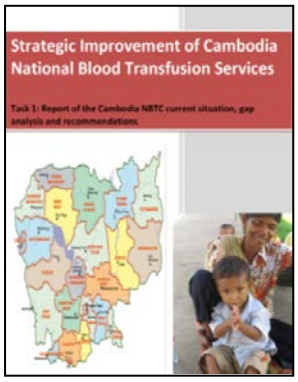
Dr Sally Thomas and Ms Laicey Colum, both ARCBS meet with Dr Laurent Ferradini and Dr Sek Mardy from the WHO Cambodia office

These efforts have been supported by the transparent sharing of information by the Cambodian National Blood Transfusion Centre and by the clear guidance and oversight received from the US CDC team in Cambodia. Specifically, technical consultants worked closely with the NBTS, MoH and partner organizations to foster:

- Dialogue and guidance to support the establishment of country policies related to blood service management,
- Collaborative relationships between external technical consultants and partner staff at all levels,
- Training programs, including train-the-trainer courses, tailored to specific needs at the national and provincial levels,
- Management development for leaders,
- Project plan alignment with organizational change capacity and staff well-being,
- Consideration of staff motivation requirements, and
- Monitoring of the impact that new processes have on staff and the organization to understand complexities and address issues as they arise.

PEPFAR II TASK ORDER

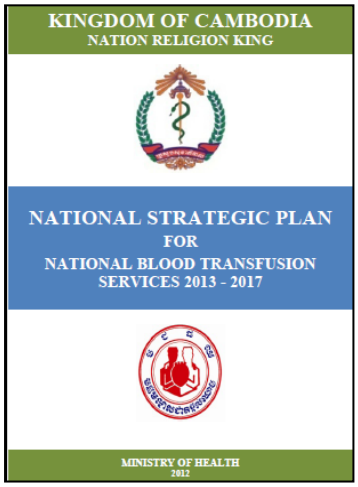
In 2011 and 2012, under the PEPFAR II task order, the Australian Red Cross Blood Service technical team undertook a comprehensive assessment of the Cambodian National Blood Transfusion System. The assessment covered national policy and legislation, hospital & clinical governance for blood transfusion, VNRBD and community & donor motivation and provision of a nationally coordinated blood service.



The technical teams assessed 22 provinces in Cambodia and conducted interviews with the National Blood Transfusion Centre (NBTC), Ministry of Health (MoH), hospitals, WHO, education institutes, patient & donor groups, Provincial Referral Hospitals & Provincial Blood Transfusion Centres, as well as Provincial Health Departments in provinces identified as potential regional centres.

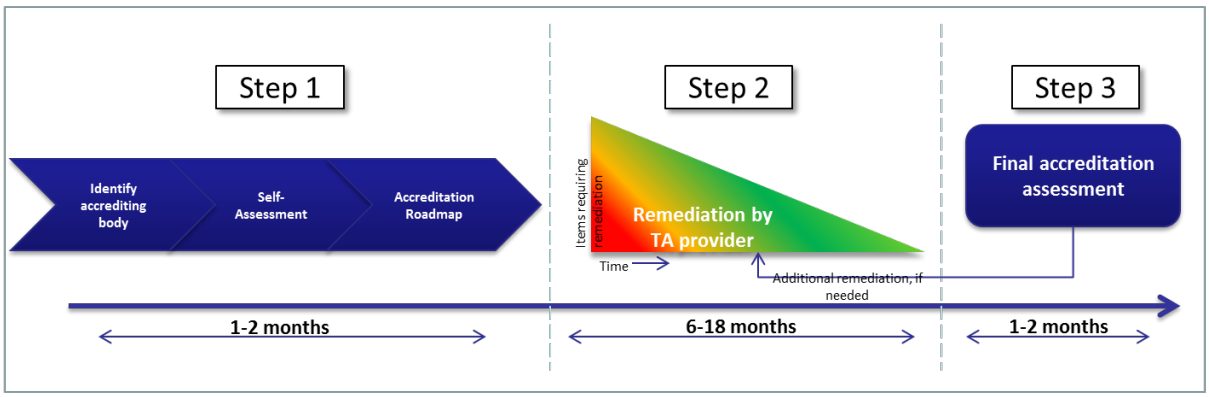
The assessment results plus the wide stakeholder consultation provided the basis for the next 5 year vein to vein strategic plan for the National Blood Service (2013-2017) which covered four (4) strategic pillars: national policy & legislation; hospital & patient blood management; community & donor motivation; and a nationally coordinated blood service. These strategic pillars were supported by training and monitoring and evaluation (M&E); and were linked to other national plans for integration within the wider health system

The Australia Red Cross Blood Service Project activities under the Cooperative Agreement with AIHA commenced in April 2013 and activities were based on the comprehensive blood system assessment that was undertaken in 2011 and 2012, and the vein to vein National Strategic Plan (NSP) for Blood Transfusion Services that was subsequently developed in 2012.



2014 CHANGE TO PROJECT PRIORITIES

In 2014, a shift in PEPFAR priorities to focus on assisting blood services to achieve accreditation and implement blood bank information management systems meant Australian Red Cross Blood Service support for clinical blood use and voluntary non-renumerated blood donation (VNRBD) ceased..



To meet the updated PEPFAR priorities, the following areas became priority for the Australian Red Cross Blood Service Technical Assistance (TA) team from 2014:

1. Accreditation and QMS, including standardised SOPs across functional areas, standardised position descriptions, and a quality manual and policy,
2. Sourcing of an appropriate BBIMS (following the NBTC building move),
3. Technical training across functional areas, with incorporated train the trainer modules, national training SOP and a national training database,
4. NBTC sustainability planning, including advocacy for cost recovery mechanism,
5. Facilities design and validation, and
6. Support for the identification, notification, counselling and referral of TTI positive blood donors.

In line with this change in PEPFAR priorities, the technical team also consolidated support to focus on the five key blood centres – the National Blood Transfusion Centre in Phnom Penh and Siem Reap, Kampong Cham, Battambang and Takeo Provincial Blood Transfusion Centres. However, where possible during relevant training, other provincial blood centres were also included, and documents and SOPs developed have been done with a view for national roll out to all provincial centres.

COMPLEMENTARY PROJECTS

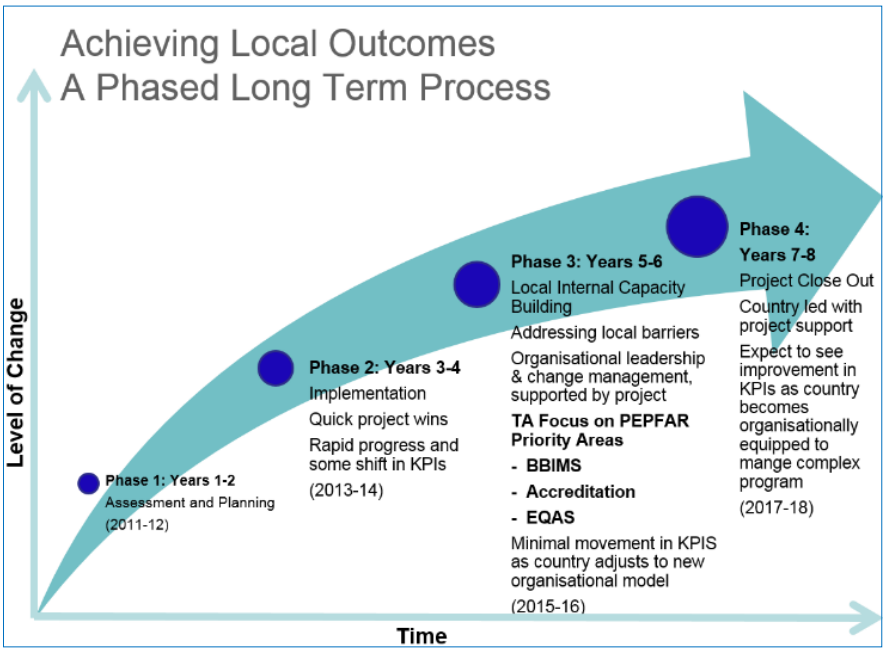
To ensure support and focus was maintained in the areas no longer supported under PEPFAR, the Australian Red Cross Blood Service received funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria for the period July 2016 – December 2017. The six key areas of support provided under this project are provided below:

1. Provide business management support to NBTC,
2. Provide support for VNRBD,
3. Review and develop new National Strategic Plan for the NBTS, aligned with new MOH NSP,
4. Progress VNRBD and hospital aspects of accreditation,
5. Provide support for M&E,
6. Promote access to blood in remote areas.

The Global Fund support also allowed the continuation of the WHO Blood Safety Officer through salary support, whose assistance with on the ground implementation and follow up with local partners has been invaluable for delivery of both PEPFAR and Global Fund project activities.

PROJECT TIMELINE

The diagram below shows the project timeline and progression, which commenced with assessment and planning in 2011/12 and concluded with project closeout and transition in 2017/18. It identifies where the project saw quick wins (earlier on) and where positive improvements in KPIs slowed (phase 3) as the country adjusted to project interventions.



MIDTERM REVIEW

The midterm review was undertaken in October 2015 and the overwhelming impression gained from the review was that there is a very high level of satisfaction with the project from the major stakeholders and recipients (USCDC, AIHA, and the staff and senior management of the NBTC, Cambodia). Feedback provided by these stakeholders consistently indicated the project was being efficiently managed, conducted collaboratively, and was achieving its intended outcomes.

Significant progress and the achievement of a number of key program activities and deliverables was evident, as observed throughout the in-country component of the review, and notably in the areas of policy and strategy, provision of technical training, development of new procedures and documentation across the breadth of blood service operations, and the construction of new purpose built blood service facilities.

Overall the project activities appeared to be in accordance with the project plan and were consistent with the timelines for the current phase of the project. In the specific instances where significant delays had occurred, modifications to the timeframes and activities were noted to have been communicated, reviewed and approved with the relevant project partners. It was also acknowledged that some project activities had been subsequently re-scoped and re prioritised to reflect the revised focus for the remainder of the project.

The review highlighted that the project was being implemented as far as was practically achievable within the current constraints of the local operating context of the Cambodian National Blood Transfusion Service, and within the cultural climate of the country. These constraints, which are further described in the report, do have the potential to negatively impact the achievement of sustainable outcomes for some key project objectives.

The single most significant barrier to the successful implementation of the project and achievement of its overall objectives was identified as the local staff culture. A notable absence of staff motivation toward their work and a general reluctance to implement any improvement initiatives was reported and confirmed during the review. This culture was most evident at the National Blood Transfusion Center (NBTC) in Phnom Penh and was particularly entrenched in the laboratory area. It was also present, but to a much lesser extent at the provincial centre of Kampong Cham, which was reported by project staff as being the most engaged regional blood centre in Cambodia. There was a widespread feeling among staff that they should receive financial compensation to attend job related training or to make any changes to their existing work practices and procedures.

Addressing the staff culture toward training and shifting it toward an culture of improvement was considered to be the most critical factor in ensuring the success of the project investment and to ensure the project deliverables are implemented at the local level. The culture will also directly influence the long term sustainability of the program outcomes and objectives, after completion of the project in 2018.

PROJECT RESULTS

INTRODUCTION

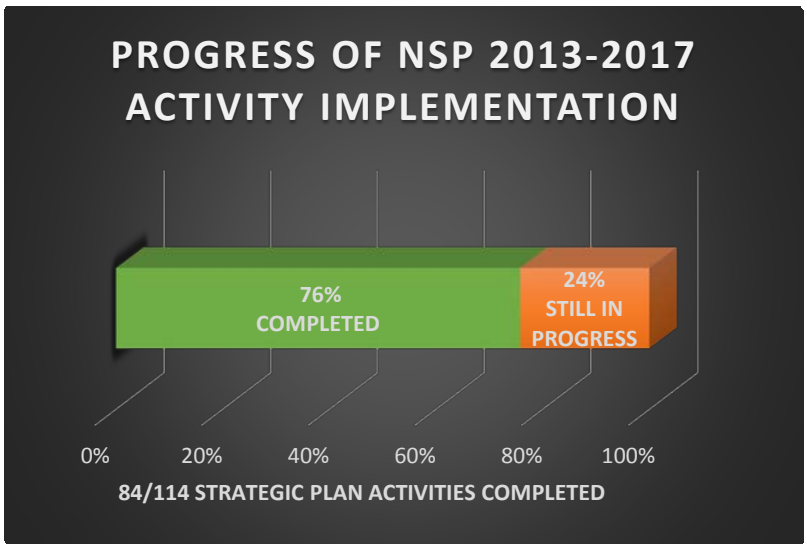
Key program achievements have included new clinical guidelines for blood use, revised donor selection guidelines, new donor counselling guidelines and improved testing algorithms, all supported through a comprehensive training program of over 35 education and training sessions, with over 500 staff trained and 95 SOPs and documents developed & implemented. A complete list of training sessions provided can be found in Appendix 1 & a complete list of documents in Appendix 2.

Particular focus was given during the project to the capacity building and scale up of activities at the National Blood Transfusion Centre, (NBTC) and the four key provincial sites (PBTC2s) – Siem Reap, Kampong Cham, Battambang and Takeo. Where possible and where relevant the other provincial blood centres were also included in the training programs.

Documents are developed with local consultation, in accordance with Good Manufacturing Practice (GMP) and are aligned to the longer term goal of accreditation for the National Blood Service. Where possible, train the trainer sessions were included as part of the training to ensure sustainability and transfer of knowledge and skills to new staff over time, with the NBTC director nominating train the trainer participants based on the topics and on a case by case basis.

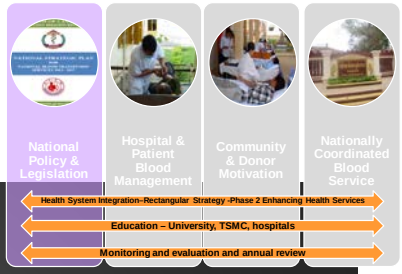
"The local staff are so committed, educated and eager to learn new things - they want to do things better and are only limited by their resources, training and funding," said Ms Nicolo. "To be able to bridge that gap for them, to guide them and present them with qualified methods to improve the availability, quality and safety of blood is an extraordinary chance for their doctors to be able to treat their patients reliably and effectively using these products. It's all about quality of life and patient treatment - that's our mission!"

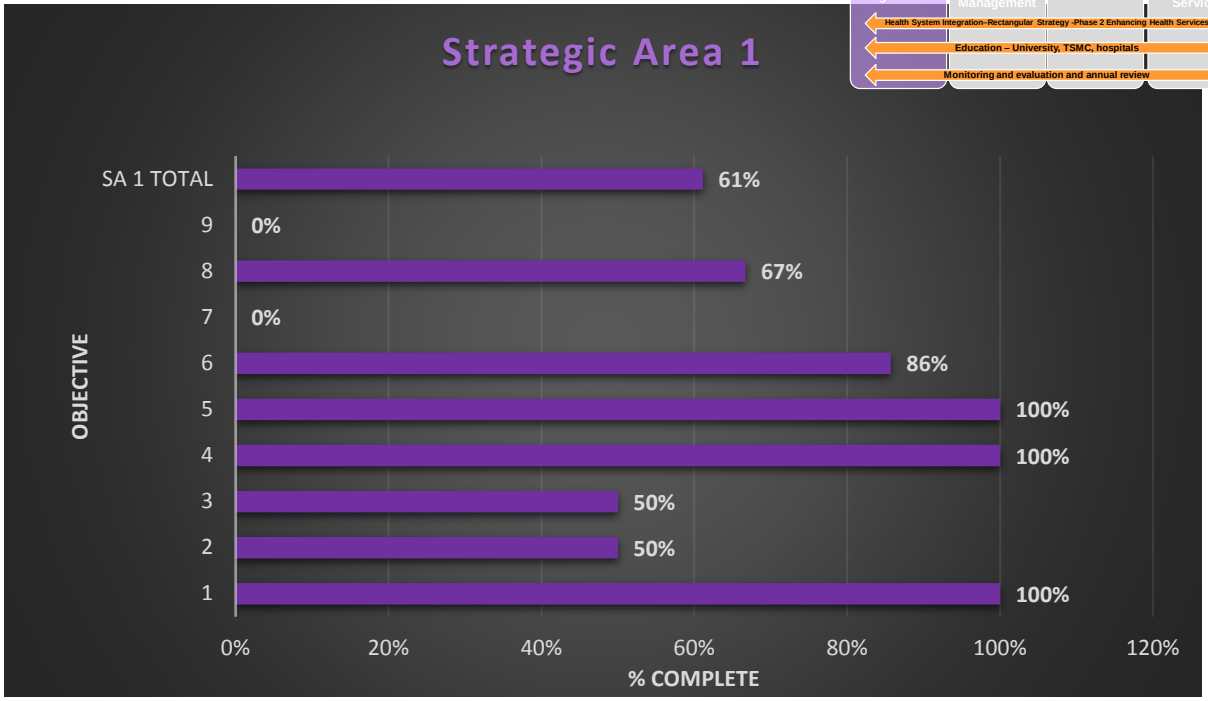
In total, 76% of the NSP activities across the four strategic pillars were implemented over the course of the project, by both the technical assistance partners and the Cambodian National Blood Transfusion Service. These are identified with a ✓. The remainder of activities are either in progress (∇), have been re-scoped due to changing country priorities / needs, have been included in the next NSP 2018-2020 (∇) or have not yet commenced (X). The following section provides the results by strategic pillar, along with recommendations for moving forward.



PILLAR 1: NATIONAL POLICY & LEGISLATION

In total, 61% (22/36 activities) have been completed under this pillar.





Dr Yos Phanita (Deputy Director General of MOH) with Ms Emily Tonks and Dr Sally Thomas after the presentation on blood safety to the Cambodian Legislative Assembly for Health.

The following achievements have been realised under the National Policy & Legislation Pillar:

Objective 1: Develop and implement appropriate policy and legislation for Blood Service Governance in Cambodia

- ✓ Development of a National Blood Policy (now flagged for implementation in 2018) (activity 1.1)
- ✓ Implementation of a PRAKAS (MOH administrative orders) by MOH for the management of the blood program (1.2)
- ∇ Wide scale communication of the blood PRAKAS is yet to fully occur, but in part has been realized through the inclusion of blood safety in the MOH NSP 2016-2020 (1.3)

Objective 2: Strengthen National and Provincial Working Groups to assist delivery of the Cambodian Blood Program 2012 - 2016

- ✓ Terms of Reference for Blood Safety Working Group (BSWG) were developed and communicated (2.1)
- X The establishment of BSWG sub-groups was not a priority and did not occur (2.2)
- ✓ MOH issued instructions for the establishment of provincial working groups in 2016, rather than integrate into existing committees. The establishment of working groups in all provinces is ongoing and included in the new NSP for VNRBD along with the need for regular provincial management meetings for all aspects of blood service delivery (2.3-2.4)

Objective 3: Define and agree respective stakeholder roles and responsibilities for Blood Service delivery

- ✓ Stakeholder roles & responsibility have been clarified & are included in the NSP 2018-2020 (3.1)
- ∇ A comprehensive stakeholder advocacy plan is yet to be developed, however during the course of the project, the TA provided advocacy whenever possible, for example (3.2)
    - o Through a presentation to the Cambodia Legislative Assemble for health on the importance and requirements for a safe and sustainable blood program
- ✓ The NBTC established working relationships with the National Donor Association, Love Club & the Union of Youth Federation of Cambodia to promote blood donation & donor recruitment (3.3)
- ∇ Development of partnerships in provincial blood centres is ongoing and is included in the new NSP (3.4-3.5)
- ✓ The TA assisted the NBTC to hold an annual review in 2013, and handed over this process to NBTC for future years (3.6)

Objective 4: Develop and Implement the structure for a Special Regional Centre model for Blood Service delivery

- ✓ Recommendations for management model, including roles and functions of each level of blood center. were presented to the BSWG in the Jul-Sept 2014 quarter (4.1)
- ✓ The cost recovery model and associated Memorandum of Understanding for provision of blood to private and NGO hospitals was develop in 2015 (4.2)

Objective 5: Develop and implement a standardised blood system financing model

- ✓ Development of a Blood Costing Model (based on the WHO model) that features: (5.1-5.2)
    - o Cost allocation rules to activities based on percentages recommended by NBTC finance manager
    - o The use of "standard" cost for consumable items (blood bags and test kits)
    - o The classification of items as "Recoverable" is a feature requested by NBTC – the blood service has the ability to 'toggle' on or off different costs.
- ✓ Development of a Chart of Accounts for NBTC, which is a requirement for the successful utilisation of the blood costing model (5.3)
- ✓ Preliminary discussions with Health Equity Fund to include blood in service packages (5.4)
- ✓ Ongoing advice and support to NBTC for the development of Global Fund grants (5.4)

Objective 6: Develop and Implement national blood service standards and regulations

- ✓ Minimum standards for blood services in Cambodia were selected (the African Society for Blood Transfusion stepwise standards), accreditation self-assessments, gap analysis and work plans for NBTC, Siem Reap, Kampong Cham, Battambang and Takeo were undertaken and support provided for implementation (6.1)
- ✓ A national training plan was developed and staff from the 5 key blood centres – NBTC, Siem Reap, Kampong Cham, Battambang and Takeo were trained in the standards (6.2 – 6.3)
- ✓ Monthly M&E results were reviewed by the technical team and feedback provided to NBTC where required. Regular reports were provided to stakeholders (6.4)
- ✓ National policy and licensing requirements for blood services was included in the draft national blood policy (6.5)
- ✓ External auditing will be carried out as part of the accreditation assessment process by the African Society for Blood Transfusion (6.6)
- X Establishment of a regulatory authority for blood is yet to occur (6.7)

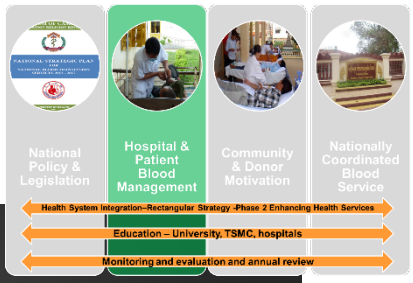
Objective 7: Establish Emergency Preparedness Plans
X Establishment of an emergency preparedness plan, and associated stakeholder roles and responsible is yet to occur (7.1-7.4)
Objective 8: Develop mechanisms for the mitigation of Blood Service risk
✓ Risk management framework for NBTS has been developed and provided to NBTC but still required dissemination (8.1-8.3)
Objective 9: Develop mechanisms for Blood Service insurance cover and recipient support
X Mechanisms for insurance cover and recipient support are not yet in place (9.1-9.3)

Recommendations for Pillar 1 – National Policy and Legislation

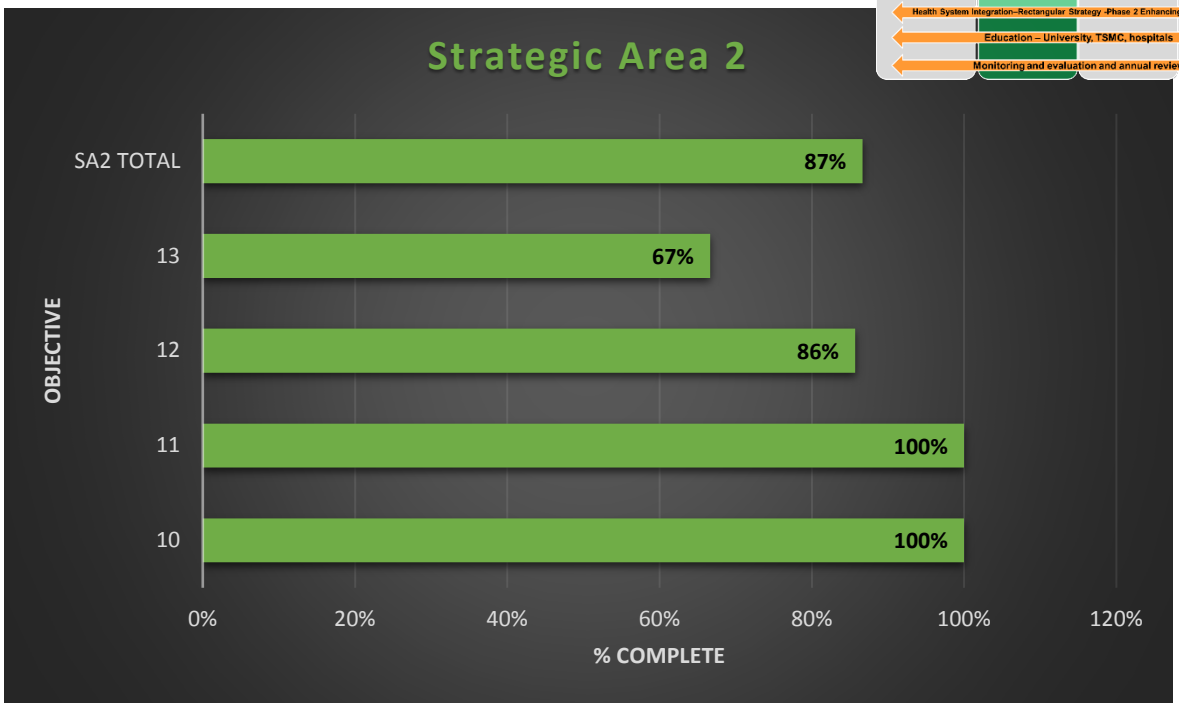
1. Review, edit with local stakeholder then submit the national blood policy to MOH for approval,
2. Review, edit and cost with local stakeholder then submit the new National Strategic Plan for Blood (NSP) 2018-2020 to MOH for approval,
3. MOH and / or NBTC to disseminate the blood policy, Prakas and new NSP 2018-2020,
4. Provincial Health Departments should be encourage to include specific focus on blood service activities and funding requirements into their Annual Operating Plans (AOP),
5. NBTC to implement the new NSP 2018-2020, including refreshed role of the Blood Safety Working Group,
6. NBTC should continue discussions with the HEF and MOH for service charge / blood financing opportunities.

Dr John Pitman, USCDC and Mr Abdullah Genc, ARCBS discuss the Cambodian blood costing model in June 2014

PILLAR 2: HOSPITAL & PATIENT BLOOD MANAGEMENT



In total, 87% (13/15 activities) have been completed under this pillar.



Dr Hok Kimcheng, NBTC Director and Dr Ben Saxon, ARCBS with the new Cambodian Clinical Guidelines in 2013

The following achievements have been realised under the Hospital & Patient Blood Management Pillar:

Objective 10: Develop & implement a clinical governance framework for blood management ✓ Development of a draft MOU for the NBTC to use to manage the supply of blood to private hospitals, which can also be provided to PBTCS (10.1-10.2)
Objective 11: Establish HTCs at all major hospitals ✓ TOR for Hospital Transfusion Committee (HTC) for all sites have been developed and provided to NBTC for distribution (11.1-11.3)
Objective 12: Establishment of National Clinical Guidelines and Training ✓ National Clinical Guidelines, including massive transfusion protocol developed (12.1) ∇ The requirements for a maximum blood order schedule (MBOS) have been included in the clinical guidelines and HTCs are being encouraged to develop them for their individual hospitals (12.2) ✓ Three training sessions were held in Cambodia to train doctors and nurses in the clinical guidelines and included train the trainer and transfer to local ownership. Over 100 doctors and nurses trained. A website for easy access to the guidelines was also set up - www.cambodiablood.com (12.3-12.6) ✓ A meeting with the medical training department of the Health Sciences University was held to encourage inclusion of the clinical guidelines into their training content (12.7)
Objective 13: Develop & implement hospital based protocols for management of blood transfusion ✓ A Blood administration checklist and other standard forms were developed and included with the clinical guidelines and implementation has been ongoing through the hospital transfusion committees and training was included in the overall training sessions held (13.1-13.2) X Implementation of patient wrist bands for identification is yet to occur is most hospitals (13.3)

Recommendations for Pillar 2 – Hospital and Patient Blood Management

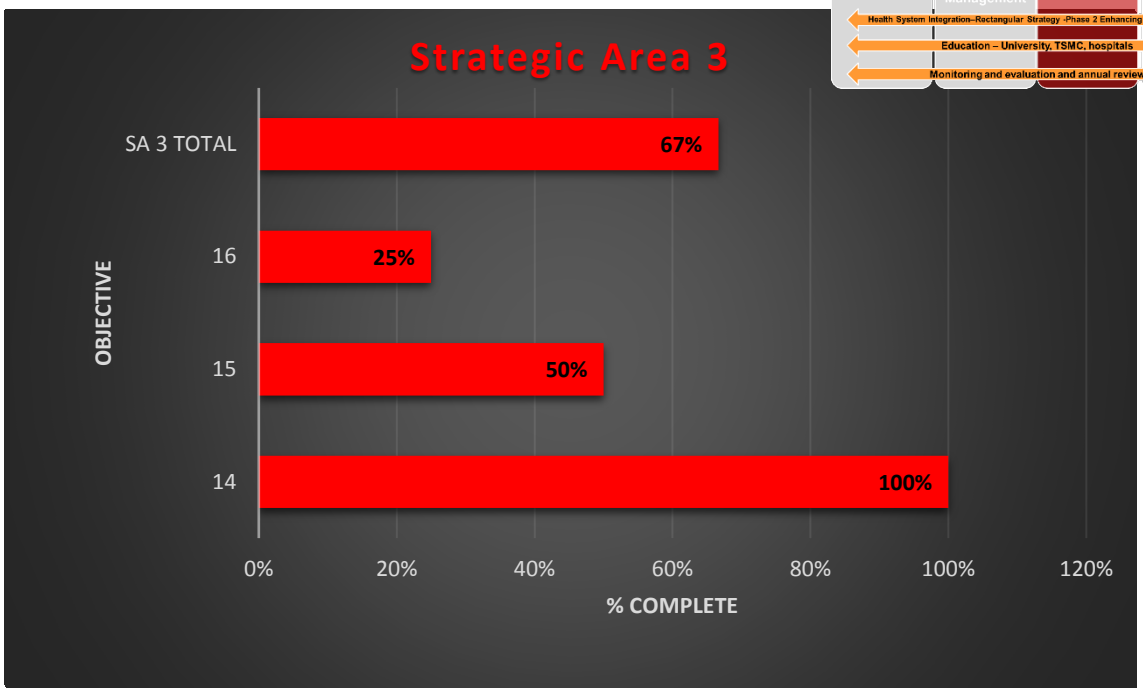
7. Continue to establish hospital transfusion committees (HTCs) in hospitals throughout Cambodia,
8. Using the HTC infrastructure:

- Continue implementation of the hospital accreditation standards for blood in each hospital,
- Promote development of maximum blood order schedules at each hospital,
- Implement reporting of patient adverse reactions back to the NBTC as part of haemovigilance,
- Encourage hospitals to implement patient wrist bands for patient identification.

Dr Bev Quested, Dr Amanda Thompson, Dr Ben Saxon (all ARCBS), Dr Sek Mardy (WHO) and Dr Hok Kimcheng (NBTC) with key NBTC staff at a 2014 workshop for blood administration, handling and management of adverse reactions

PILLAR 3: COMMUNITY & DONOR MOTIVATION

In total, 67% (10/15 activities) have been completed under this pillar.



The Blood donor room signage showing the blood collection process at the old NBTC building in 2013

The following achievements have been realised under the Community & Donor Motivation Pillar:

Objective 14: Improve the safety of the Cambodian blood supply through increasing VNRB donations.

- ✓ A national strategy for donor recruitment has been developed (14.1)
- ✓ National brand guidelines were developed and delivered (14.1)
- ✓ Donor Room signage was developed to bring donors on the donation journey (14.1)
- ✓ A VNRBD Toolkit was developed containing, guidelines, materials and messages for the recruitment and retention of voluntary blood donors (14.1, 14.4)
- ✓ A social media calendar and recruitment activity calendar were developed and delivered to recruitment staff with training (14.2)
- ✓ The Cambodian Blood Service holds a yearly mobile collection on WBDD (14.3)
- ✓ Items and designs for donor retention including wrist bands, fans and t-shirt have been provided (14.5)
- ✓ Donor counseling is in place and advice on pre donation health is provided (14.6)
- ✓ The TA talked about the need for blood donations with the NBTC Director on RFI radio in Phnom Penh (14.7)

Objective 15: Utilise community groups, institutions and resources to promote blood donation and recruit safe VNRB donors

- ✓ A framework for National Donor Association was developed and provided to NBTC (15.1)
- ∇ The donor clubs were reviewed by NBTC management, rather than the BSWG (15.2)
- ✓ NBTC created with Love Club with key community partners, such as the Union of Youth Federation of Cambodia to encourage blood donation in the community (15.3)
- ∇ The introduction of education in the school curriculum on blood donation is not yet established, however schools and universities do receive education as part of the blood mobile process (15.4)

Objective 16: Improve management of donor information in the provinces

- ✓ NBTC staff have been trained in the NBTC donor database by ARC IT volunteer (16.1)
- ∇ NBTC will upgrade its current database, with a view to including real time entry in functional areas and a system to SMS donors thank them for donating and remind them when they are due to donate again. As resources allow, the Director will implement the system at Kampong Cham, Siem Reap, Battambang and Takeo and the remaining provincial centers (16.2-16.3)
- X A system for donor appointments has not yet been implemented (16.4)

Recommendations for Pillar 3 - Community and Donor Motivation

9. Look at the option to introduce education on the need for voluntary blood donation into the school's curriculum,
10. Continue the focus on making family donors safer through self-deferral and on converting safe (TTI negative) family donors to voluntary donors,
11. Continue to encourage new businesses to sign up for mobile collection drives and schedule these regularly as well as focus on encouraging foxed site collection by voluntary donors,
12. Include the capacity for donor appointments and flagging donor deferral in the NBTC blood bank computer system when it's upgraded in 2018.

Ms Ou Banung, NBTC, Dr Sally Thomas and Dr Hok Kimcheng promote blood donation on FRI Radio in Phnom Penh

VNRBD – Quantitative Results Analysis

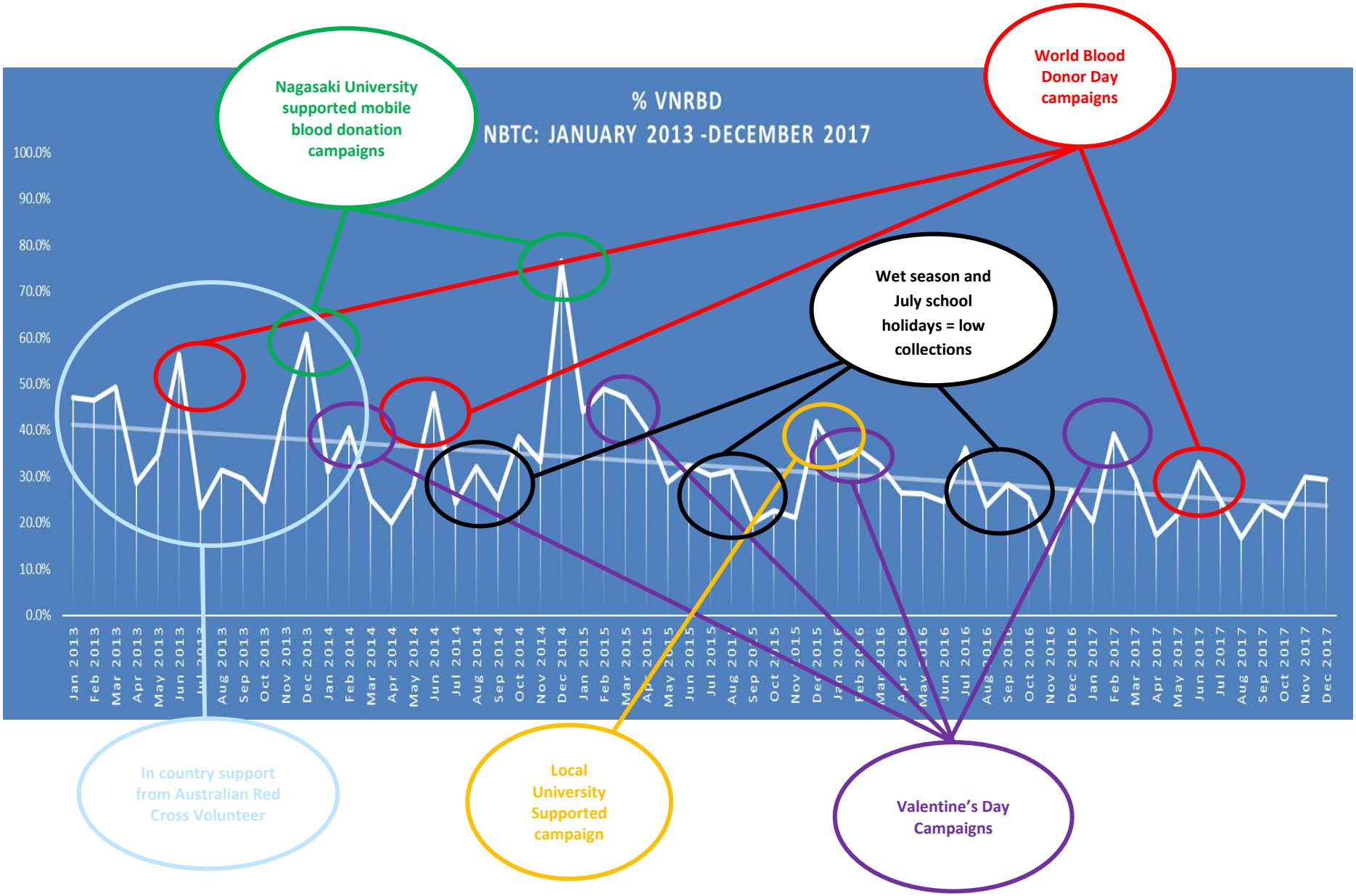
Since 2013, there has been minimal upward movement in the VNRBD rate at NBTC. The peaks in VNRBD collections coincide with large mobiles and donor events (for example World Blood Donor Day & Valentine's Day and in 2013 and 2014, the Nagasaki University supported mobiles), where significant funding and resources have been provided. Without more regular occurrence of these large funded events, the VNRBD rate remains less than 40% (34% for 2015, 28% for 2016 and 25.7% in 2017).

This suggests that generally, the NBTC is under-funded and under-resourced to continually plan, manage and undertake large mobile events, resulting in their lack of progress in this area. This is despite considerable non-financial support from technical assistance partners, including planning tools for blood demand and supply, mobiles planning and social media, training and communication and education materials.

In addition to the financial resourcing of NBTC, a number of other factors are believed to influence the VNRBD rate including:

- Low NBTC staff salaries, which affect staff performance, customer service and motivation,
- Loss of Global Fund support for donor recruitment staff and lack of sufficient dedicated MOH funded positions
- The NBTC shift work structure (part of the wider MOH health care system shift work structure) where staff are required to work 24 hour shifts, making it difficult to convince staff to attend mobiles after completing a 24 hour shift,
- The perception that blood is sold in hospitals deters people from donating voluntarily (Note a poster addressing this perception was developed under the Global Fund program),
- A general lack of available blood stocks impacting the community's attitudes and desire to donate voluntarily in case blood won't be available to them when they or their family members need it.

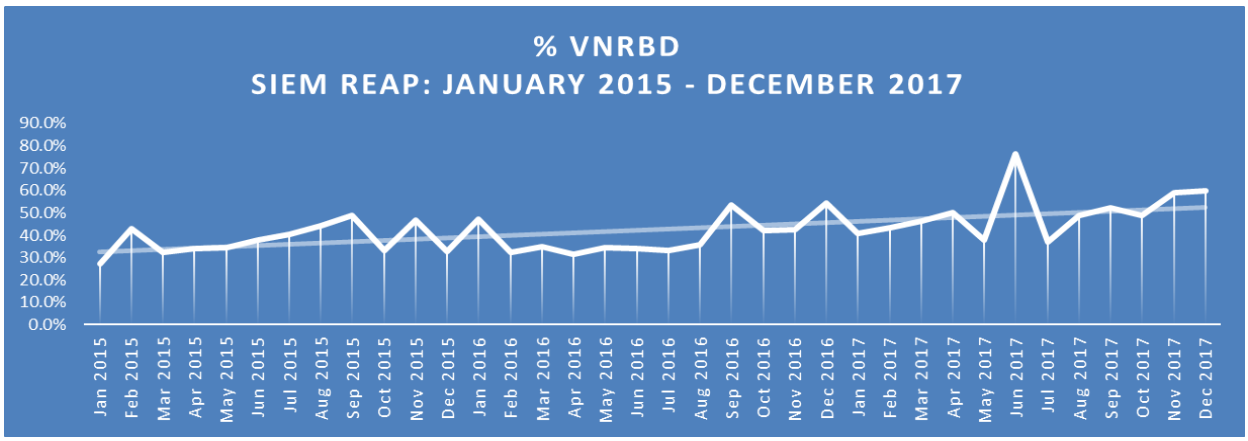
Without a change to the staff shift work and subsequent NBTC staff rostering, the ability for NBTC to undertake a sufficient number of mobile collections to significantly and consistently increase the number of voluntary donations remains a challenge. Additionally, there needs to be an increase in the number of MOH funded donor recruitment staff (there is currently only 1) in order for NBTC to have sufficient personnel resources to plan and organise regular mobile collection sessions, rather than rely on large annual campaigns.


% VNRBD
NBTC: JANUARY 2013 -DECEMBER 2017
Nagasaki University supported mobile blood donation campaigns
World Blood Donor Day campaigns
Wet season and July school holidays = low collections
In country support from Australian Red Cross Volunteer
Local University Supported campaign
Valentine's Day Campaigns

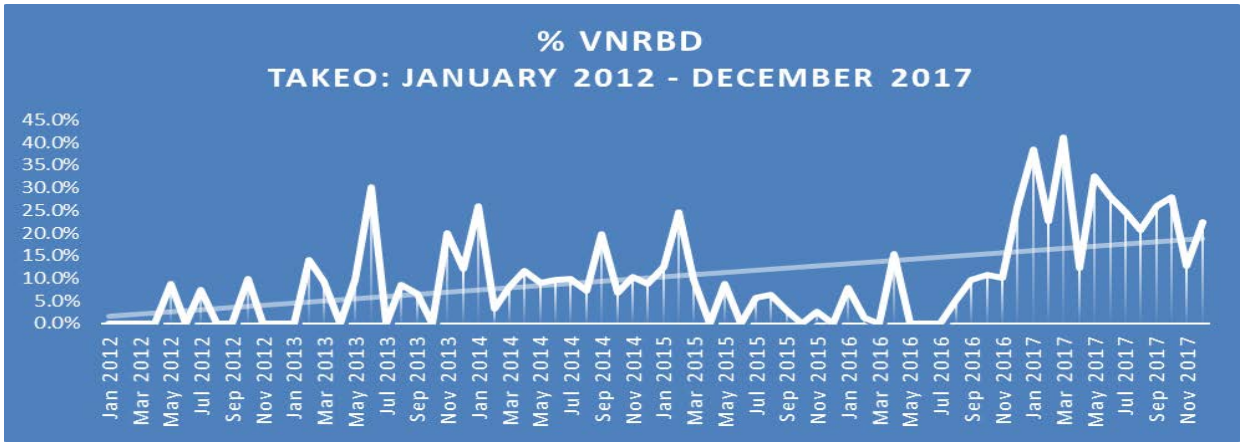
All four key provincial blood centres have shown good improvement in their VNRBD rates over the course of the project. Siem Reap[9] relies on tourist and other walk in donors for the majority of the VNRBD, as they experience competition for mobile sites with other NGO hospitals in the area.

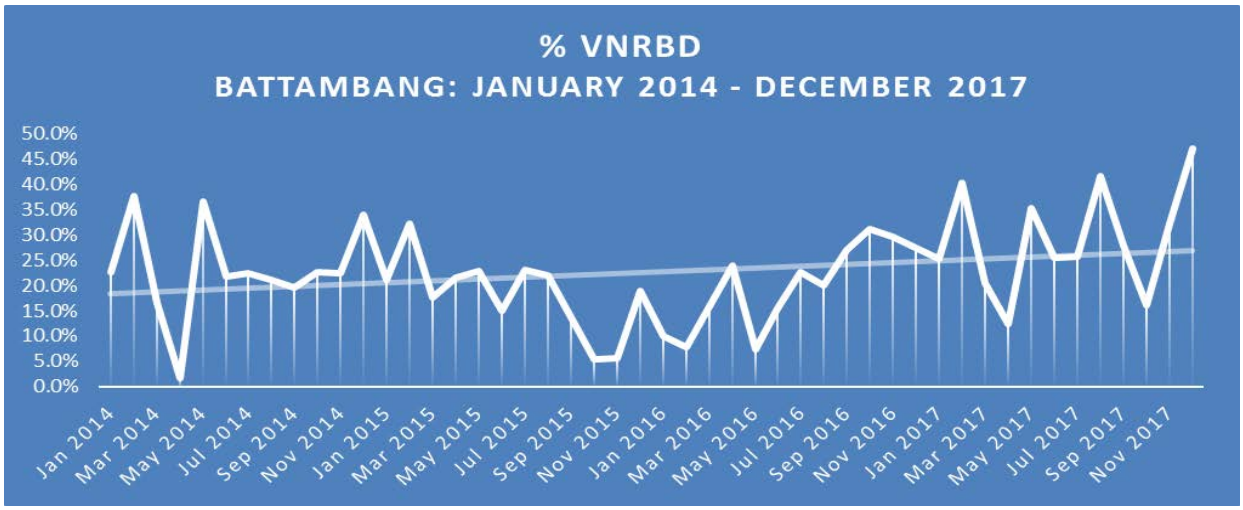
Siem Reap, Kampong Cham and Battambang have all had Global Fund supported donor recruitment officers and the decline in VNRBD at these sites can in part be attributed to the end of the GF funding for these positions.

To continue to improve their VNRBD rates, all four sites require support from their Hospitals and Provincial Health Departments to ensure there are sufficient staff and resources to conduct mobile collections. Provision for this has been included in the latest National Strategic Plan.



[9] Up until December 2015 collection data from Angkor Children's Hospital was included in Siem Reap PBTCs figures, inflating their VNRBD rate. Therefore the VNRBD data pre 2015 from Siem Reap is not presented as it is not a true representation of their voluntary donor rate.

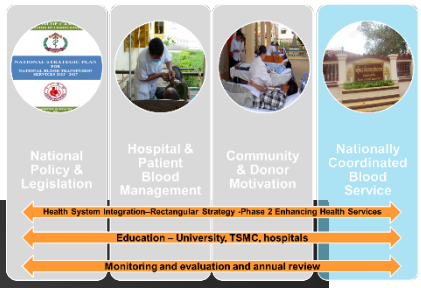


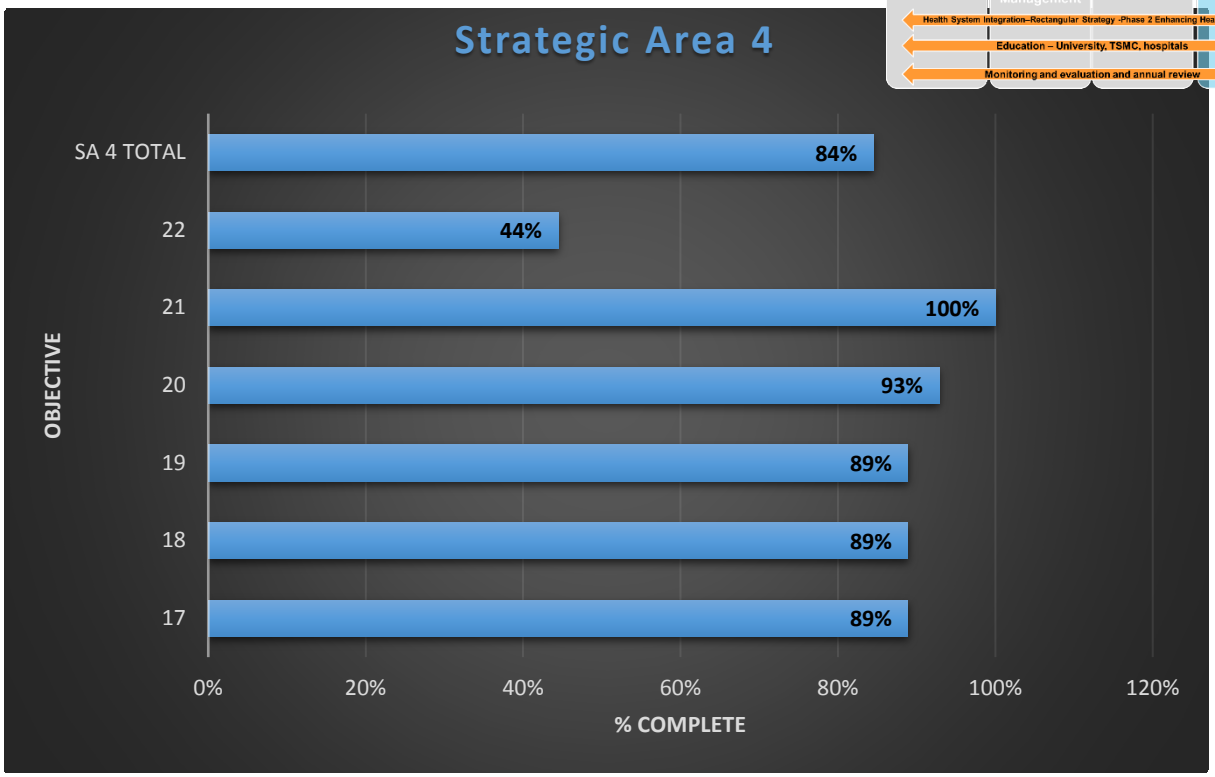


Blood donor collection at the new NBTC facility in 2017

PILLAR 4: NATIONALLY COORDINATED BLOOD SERVICE

In total, 84% (49/58 activities) have been completed under this pillar.





Mr George Putland and Ms Linda Nicolo (both ARCBS) discuss building designs with Cambodian stakeholders

The following achievements have been realised under the Nationally Coordinated Blood Service Pillar:

Objective 17: Strengthen the governance capacity of the NBTC for a Nationally Coordinated Blood Service

- ✓ The NSP was translated and used as a communications tool for reporting progress to key local and international partners by NBTC and the project team (17.1)
- ✓ Template for yearly training planner was delivered, along with all the training templates developed by TA, and handed over to the leadership team and trainers during the train the trainer training (17.2)
- ✓ Ongoing support was provided to NBTC in business and financial management throughout the course of the project, including ongoing advice for equipment, automated testing platforms and reagent procurement, including specifications and justifications (17.3)
- ✓ Cambodia was enrolled this quarter as a focus country for a research project opportunity with the Australian Department of Foreign Affairs and Trade (DFAT), for general blood safety, donation and TTI testing. News of successful project submission is expected by approx. April 2018 (17.4)
- ✓ Draft organizational chart developed for the NBTS and provided to the NBTC Director and quality manager, along with example position descriptions for key roles (17.5-.17.7)
- ▽ The PBTC-referral hospital relationships were clarified during ongoing discussions throughout the course of the project. Particular focus was given to the four key provincial sites, Siem Reap, Kampong Cham, Battambang and Takeo (17.8)
- ✓ Blood centre reporting was clarified and monthly M&E results were reviewed (17.9)

Objective 18: Establishment of Specialist Regional Centre (SRC) system

- ▽ A communications protocol between the BSWG and provincial working groups is yet to be established, however is covered in the new NSP 2018-2020 (18.1)
- ✓ SOPs, training and other materials have been made available to partner NGO blood banks, such as the Sonja Kill Memorial hospital in Kampot and Angkor Children's Hospital in Siem Reap (18.2)
- ✓ The Siem Reap blood centre has been upgraded into a key provincial centre through the new facility, standardised processes, appropriate staffing and support from the Provincial Health Department (18.3)
- ✓ All SOPs and training in operational areas have now been delivered at key functional sites, for standardized processes (18.4)
- ✓ An assessment (under the Global Fund Grant) was undertaken of the MOH identified sites requiring a blood depot and a report was delivered to the NBTC for consideration (18.5)

- ✓ Standardised equipment has been implemented as part of the facilities upgrade in Siem Reap, Battambang, Kampong Cham and Takeo (18.6)
- ✓ Requests and procurement for all equipment through Global Fund and other available sources has now been finalized. TA has handed this over and provided lists, specifications and advice for each level of laboratory equipment, including the validation protocols for relocation and validation of any new equipment (18.6)
- ✓ Critical materials and reagents have been updated according to new automation needs, and have been reprogrammed in the GF budget. Reagent lists for the new analyzers that have been developed for Global Fund are now the standard reagent lists and quantities needed for routine operations. Standard critical materials and reagent lists already exist internally for the provision of reagents by MoH (18.7)
- ✓ Cleaning SOPS and forms have all been handed over into the document control management system , and general equipment requirements and maintenance have been captured in the validation protocols developed for each item of equipment, and have been added to the NBTS document control management system (18.8)
- ✓ The requirement for blood fridge, alarms, cleaning and calibration is captured in the accreditation plan and meeting Level 1 accreditation standards (18.9)

Objective 19: Reduce the incidence of transfusion transmitted infections and reactions

- ✓ Viral screening algorithms have been finalised and distributed to all 22 provincial sites, technical training and support in Mandatory testing training (immunohematology and viral serology) has been provided (19.1-19.2)
- ✓ Procurement and assay selection is managed by the MoH. Selecting the right assay to use for testing purposes was covered at the TTI training delivered last quarter. This is included as part of the viral testing algorithm and SOP (19.3)
- ✓ Unique identifiers are now used on all blood products and samples, using printed barcode labels (NBTC, KCM only) and a unique numbering system (all sites) (19.4)
- ▽ The need for lots number is captured in the Cambodian quality standards and is with NBTC for implementation (19.5)
- ✓ All results are logged using the standard Result Worksheet across all sites. Additional log books for reactive serology test results have been developed and implemented. A database will be implemented by NBTC to electronically manage records (19.6)
- ✓ TA has provided recommendations for the delivery and transport of critical goods, including a standard inventory list according to site operations. Local staff to implement the changes recommended, as required (19.7)
- ✓ Reagents have been updated according to the new automation needs, including all the specifications for the reagents required to ensure the safest and most accurate testing possible.

Reagent lists for the new analyzers have been developed for Global Fund and are now the standard reagent lists and quantities needed for routine operations into the future. Standard reagents for provincial sites are managed by MoH contracts, including supplier agreements which cannot be altered by TA (19.8)

✓ Significant support for the care and management of donors has been provided including (19.9)

- Donor selection, counselling and care, including national donor selection guidelines and donor counselling guidelines (NBTCS and PBTC2s)
- Faster test results release for positive TTI donor counselling – improve communications between laboratory and donor counselling teams
- Letter of agreement with NCHADS for referral of HIV and syphilis reactive donors.
- Confirmation of a referral process with Kossamak Hospital and MSF for referral of HCV and HBV reactive donors
- Identified potential clinic for referral of high risk donors

Objective 20: Strengthen quality management and safety

✓ The Quality Manual, including a forward, was completed as a resource for guidance on the management and implementation of an effective Quality Management System. This will also help in meeting Level 1 accreditation standards. A mentorship program has also been developed to assist the PBTC2's reach Level 1 accreditation (20.1)

✓ Auditing has been covered in the QMS mentor workshops and training delivered by TA throughout the project, and all required tools given to the QA manager to develop checklists and scheduling for audits (20.1)

▽ PBTCs are yet to all appoint dedicated quality managers (20.2)

✓ A Staff Safety Policy and Infection Control Standard have been developed, translated and implemented into the document control management system. They have also been delivered through training (20.3, 20.10)

✓ The established document control system was handed over to NBTC last quarter, onto a dedicated PC in the office area, accessible only to document controllers. All documents will be managed centrally and distributed as required. Current phase is the review and updating of existing documentation onto the system (20.4)

✓ Training and support has been provided across technical areas, accreditation and quality systems implementation, including: (20.4)

- Document control management system, including development all required SOPs (all sites)
- 95 + SOPS / forms / guidelines and protocols developed

- Cold chain (transport and storage) (NBTC and all provinces)
- General quality management principles (all sites)
- Development and handover of quality management documentation
- Infection control policy and standards

✓ Records management is included in the quality manual and training has been provided (20.5)

✓ A packing consignment form has been developed and delivered along with associated SOPs for packing, according to the validation results (20.6-20.7)

✓ Recommendations for provision of EQAS in 2018-19 and EQAS training provided for all sites (20.8)

✓ NBTC waste is now managed onsite with the newly installed hospital incinerator (20.9)

✓ Cleaning procedures and forms have been implemented at NBTC and PBTC2's. These will be rolled out to the PBTC1's by the local training teams (20.11)

✓ Public access to laboratories has been captured in the Cambodian Quality Standards and Quality Manual (under review), and built in as part of new facility design. It will be audited and monitored as part of the accreditation work plan activities and audit corrective actions, as part of the accreditation work plan activities and audit corrective actions, as required (20.12)

✓ The Jembi BSIS system was planned for pilot implementation at Kampong Cham, however funding was cancelled. Instead the NBTC Director will work with a local IT company to expand the functionality of the current NBTC database and eventually this will be implemented in the provincial centres (20.13)

✓ Quality workshops, training, a Quality Policy and Manual, Audit checklists and scheduling tools, and the Cambodian Quality Standards and accreditation standards have all been developed and delivered by TA throughout the project. These tools have been handed over to assist the local quality team to implement QMS at the central and satellite sites (20.14)

Objective 21: Provide enough safe blood on time

✓ A demand & supply planning too, including mobile collection planning, was developed along with donor and collection targets (21.1)

✓ The mobile venue assessment tool was provided to NBTC (21.2)

✓ Donor Selection Guidelines have been developed, translated, and delivered to all sites (21.3)

✓ Label printers are awaiting installation. Action has been captured in the Accreditation work plans and will be monitored by audits against these standards. Auditing has been handed over to the QA manager (21.4)

✓ Technical training and support including SOP developed for (21.5)

- Component production training (NBTC and PBTC2)

- Process control and testing (NBTC and PBTC2)

✓ All component SOPs and forms for manufacture and management have been delivered by TA throughout the project. KPI's show the increase in component availability since the start of the project (21.6)

✓ Blood grouping has been reviewed in all sites, SOPs updated and recommends made for updated equipment at NBTC. Blood grouping EQAS recommendations have been made for 2018-2019 (21.7) All SOPs, forms and training developed by TA have now been delivered, and practice embedded at all key and regional sites. These will be rolled out to the PBTC1's by the local training teams (21.8)

Objective 22: Strengthen the facilities and environment for blood service activities at NBTC and PBTC

✓ Support for 5 new state of the art facilities - funded by US PACOM, with construction managed by US Army Corp of Engineers (USACE) (22.1)

- Design and GMP advice for all sites
- Validation (equipment, buildings and transport containers), and capacity building of local validation NBTC team (tools, frameworks, protocols and training)

X Incinerators temperatures are not yet assessed (22.2)

✓ NBTC has sufficient operational budget to run their generator (22.3)

✓ Public access to laboratories has been captured in the Cambodian Quality Standards and Quality Manual (under review), and built in as part of new facility design. It will be audited and monitored as part of the accreditation work plan activities and audit corrective actions, as part of the accreditation work plan activities and audit corrective actions, as required (22.4)

✓ NBTC has included its generator in its capital replacement program (22.5)

X There are no maintenance contracts in place for blood refrigerators or processing equipment (22.6-22.9)

Ms Emily Tonks, Mr Peter Walton, Dr Sally Thomas and His Excellency Mam Bunheng, Cambodian Minister for Health and the opening of the new NBTC in Phnom Penh on June 14 2016

Recommendations for Pillar 4 – Nationally Coordinated Blood Service

13. NBTC should consider the recommendations in the blood depot assessment report when working with the MOH and other partners to upgrade blood depot sites for improved blood access in remote areas,
14. NBTC should work with MOH to ensure that efficient reagents and other consumables, such as tips, are ordered annually for the running of the automated analysers (NEO, Architect and ELISA machines),
15. Better systems should be developed to manage reagent and consumable supply to the provincial sites,
16. NBTC should investigate options for ongoing equipment maintenance of their specialised equipment. The option to send 1-2 staff members to complete a Biomedical Equipment Technology course should be considered,
17. Continue to implement the quality standards and technical accreditation standards with the aim to reach level 1 certification from the African Society for Blood Transfusion at NBTC and the four regional sites,
18. NBTC should assist and encourage the other 17 Provincial Blood Transfusion Centre sites to undertake a gap analysis against the technical standards and progress with addressing the gaps, with a view to reach level 1 accreditation nationally,
19. NBTC should develop and implement an annual plan for internal auditing, which includes:

- Auditing of departments across NBTC (collections, testing, components distribution)
- Auditing of PBTC's

20. NBTC should continue with implementation of its document control management system, including distribution of controlled documents to all provincial sites,
21. Quality managers or delegates should be appointed in each blood centre across Cambodia,
22. NBTC should explore with MOH the opportunity to change the 24 hour shift requirement, as this would support more effective rostering of staff to cover both fixed site and mobile collections,
23. Battambang and Takeo are strongly encouraged to follow the facilities move plan and building and equipment validation protocols provided by the technical assistant team to manage their upcoming facilities moves,
24. Each blood centre should ensure they have regular (ideally weekly) access to an incinerator and discuss this with their hospital director / PHD if this is not the case. Checks of incinerator temperature should be performed to ensure the temperature is in line with requirements for blood incineration.

Ms Linda Nicolo trains the Kampong Cham Provincial Blood Centre Staff to produce their first platelets in 2014

Accreditation

Since 2014, and in line with the change to the PEPFAR priorities, the project team has been focussing on the implementation of accreditation standards at the National Blood Transfusion Centre and the four key regional sites – Kampong Cham, Siem Reap, Battambang and Takeo.

The local quality teams in all five sites have completed the self-assessment against the chosen step wise standards (AfSBT[10]). The TA team then assisted the staff to perform a gap analysis of the standards against the self-assessment results, which was used by the sites and the project team to develop a work plan to address the gaps. Some key gaps that were identified include:

1. Working with MoH to qualify suppliers and developing a preferred list of suppliers,
2. Documentation for and validation of transport and logistics procedures, including cold chain,
3. Improving the control and documentation of testing discrepancies and investigations,
4. Availability of antibody investigation at blood transfusion centres,
5. Installing a method to create historical records of ABO, RhD and antibody results to compare to current results, and
6. Working with hospitals to improve patient identification and requests for blood and components.

Siem Reap Accreditation Work Plan

STANDARD Section 2: Blood Donor Management	Level One		Current Status Cambodia	Related documents - complete list (Cambodia reference)	P	Gap analysis for Level 1 accreditation	Remediation	Actions Person(s) Responsible	Timeframe
2.2 DONOR SELECTION CRITERIA /									
2.2.2 The facility shall have procedures to en-sure that medical consultation is available when necessary. Records of such consult-ation and outcome shall be kept.	2.2.2 Guidelines are in use for the deferral of potential donors who do not meet the selection criteria for medical and surgical conditions, medications and exposure to potential transfusion transmissible infections.	P	NBTS Donor Selection Guidelines A comprehensive medication list is not available to determine eligibility of donor's currently on medication, only by their current or past health condition.	NBTS Donor Selection Guidelines	P	Partially met, a reference guide for medications needs to be developed.	Develop the medication list for interviewing staff to reference during the donor interview. Staff training to follow once developed for implementation.		
2.2.2	2.2.2	P			P				
2.2.3 Assistance shall be given by donor registration personnel to donors with special needs, including illiterate donors according to facility defined criteria.	2.2.3 Arrangements are in place for assisting donors with special needs.	X	DONORS WITH SPECIAL NEEDS ARE NOT CURRENTLY ELIGIBLE FOR DONATION.	Policy for identifying and assisting donor with special needs	X	Donors with special needs should be assessed on an individual basis and a policy for acceptance and assistance developed.	Develop a policy for assisting donors with special needs and train staff in its application.		
2.2.3	2.2.3	X			X				
2.3 DONOR SCREENING /									
2.3.2 Donors shall be interviewed to determine their suitability for donation. This interview shall be conducted in a manner that preserves the privacy of the donor.	2.3.2 A private interview is conducted with each donor.	P	Private interview rooms are available in the new facility, but are not always used for interviewing donors privately		P	Partially met. Rooms are not always used for private interviews	Instruct staff of the GMP and accreditation requirements and through quality training to consistently use the room for every donor interview. Monitor with audits		
2.3.2	2.3.2	P			P				
2.5 DONOR COUNSELLING /									
2.5.2 Donors found to be reactive during screening for one or more TTI shall be provided with counselling services. When counselling services are not available, the facility shall identify and refer donors to appropriate external medical services.	2.5.2 When counselling services are not available, facility refers donors to appropriate external medical services	P	Staff are being trained to provide counselling, and working with referral centres for referral of donors with reactive TTI results. In implementation phase.	Donor Counselling Guidelines MOU with NCHADS MOU with specialist healthcare providers	P	Requirement mostly met	Identify and engage eligible specialist healthcare providers; develop MOU's with them.		
2.5.2	2.5.2	P			P				

Example of the gap analysis and suggestions remediation performed for each accreditation standard

In December 2017 and January 2018, as part of the project close out, the technical team conducted assessments at NBTC, Kampong Cham and Siem Reap to assess each centre's readiness to achieve accreditation certification. Due to time constraints, a selection of 60 standards were reviewed in Siem Reap and Kampong Cham in December and were followed up in January. One additional critical non-conformance was identified in Kampong Cham in January, taking their total standards assessed to 61.

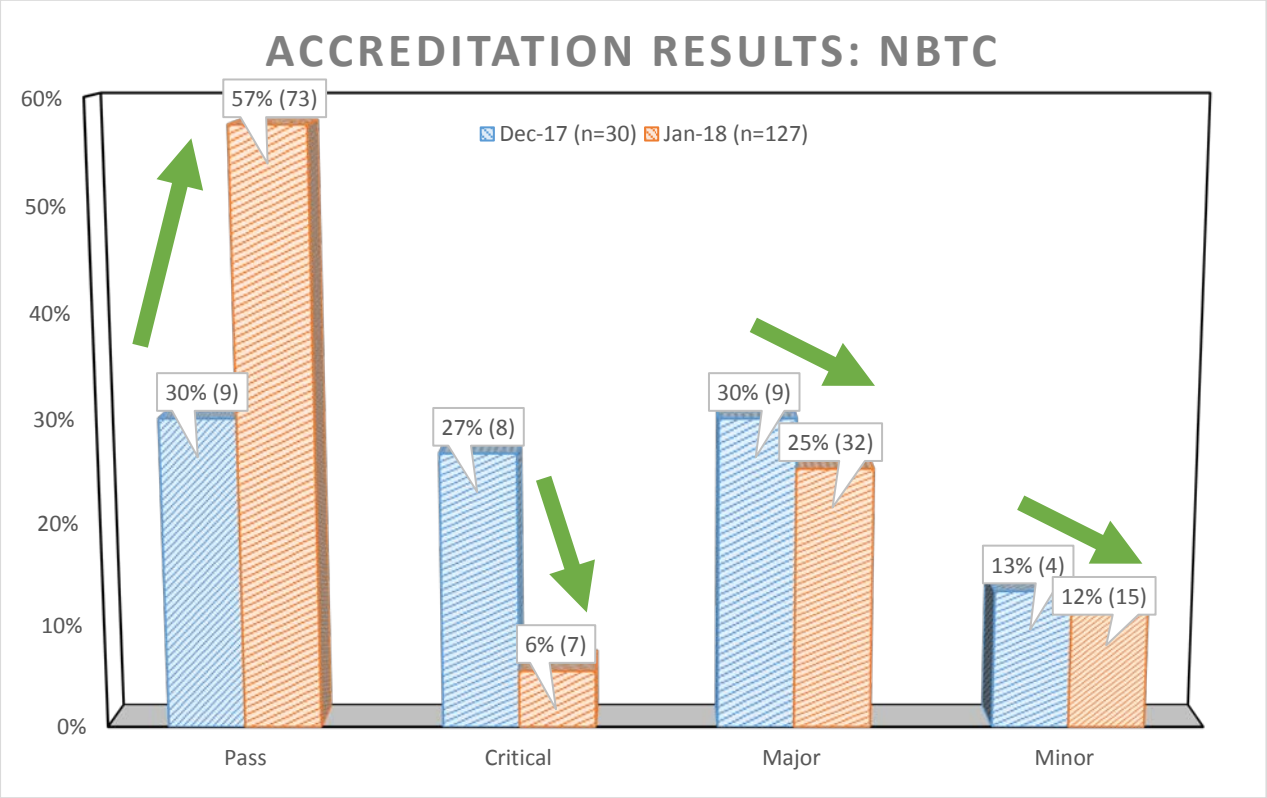
[10] NOTE: these standards currently exclude a quality section, as permission was not received from AABB to use the quality section in the AfSBT standards. Instead, the quality standards will be developed from the Kyrgyzstan quality standards, provided by AIHA.

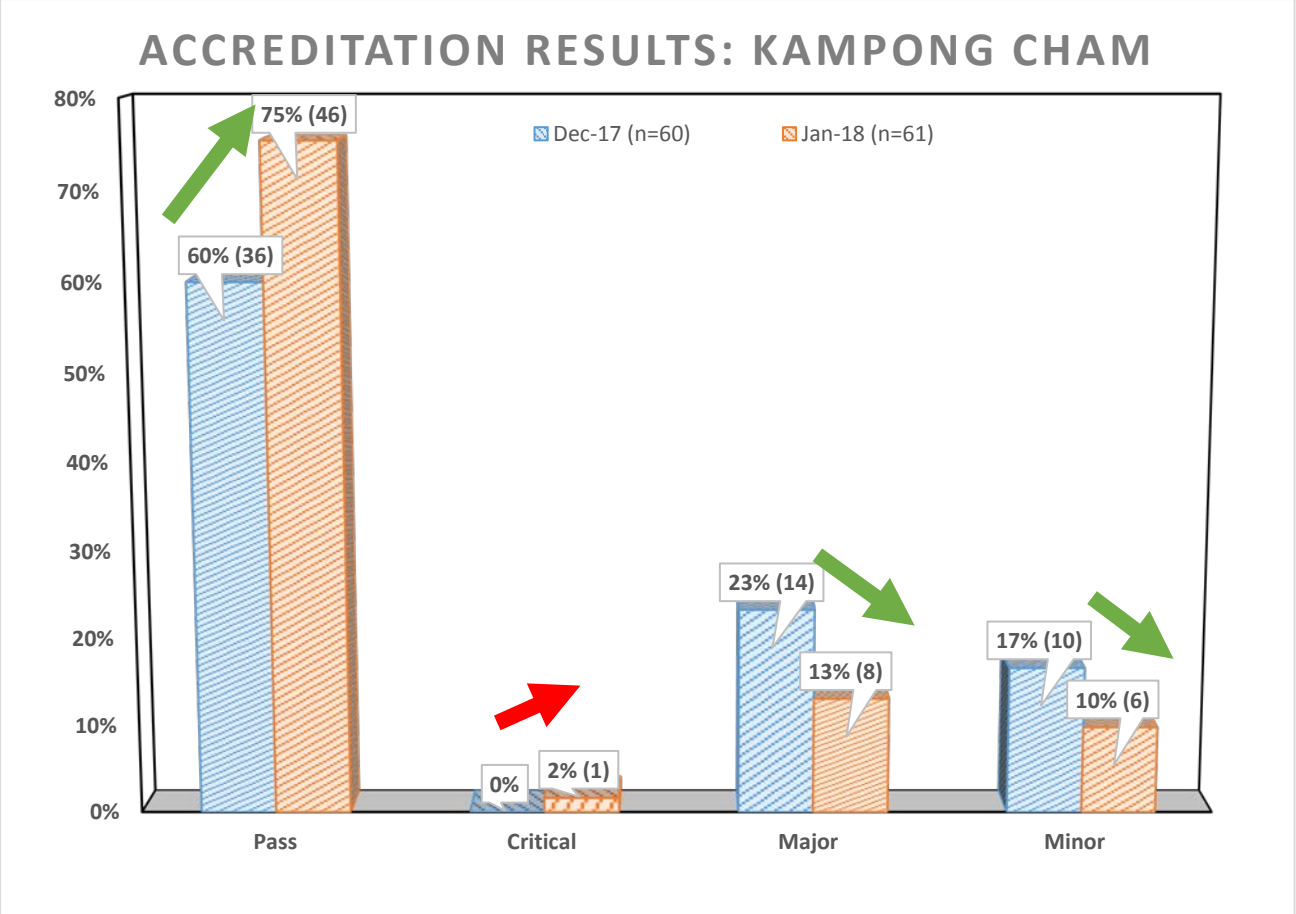
At NBTC, only 30 standards were assessed in December 2017 due to time constraints, however 127 standards were reviewed in January 2018. The full accreditation review reports may be found in Appendix 3.

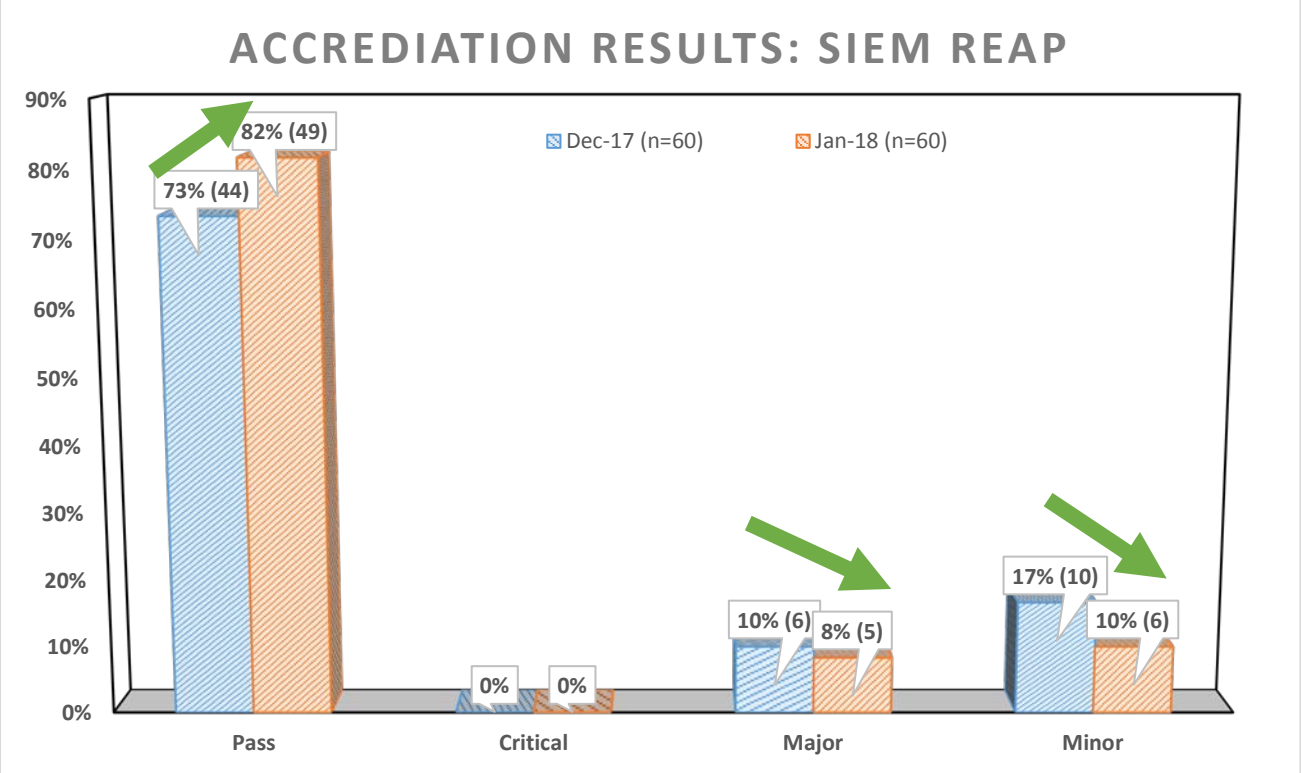
Due to the nature of the standard requirements, some common findings were observed which should have corrective actions applied nationally in order to reach compliance at all sites, as follow:

1. Lack of SOPs, standard processes and compliance for blood handling and packing configurations (Ref standard 4.1)
2. Insufficient segregation of materials and products (Quarantining) (Ref standard 4.4.4.1)
3. Blood group investigations not performed or investigated, and not recorded, including Weak D testing (Ref standards 5.2.1.3)
4. ABO titre testing not performed (Ref standard 5.2.2)
5. Review of blood request forms (Ref standard 7.2.4)
6. Cross-matched and issued units are not labelled with patient details (Ref standard 8.2.4)

The three graphs below show the progress of the NBTC, Kampong Cham and Siem Reap against the technical blood standards. All three sites have made good progress, although more effort is required to reach full compliance. This has been covered in the transition planning, with US PACOM and other PEPFAR funded consultants to continue to assist the NBTS after the conclusion of the ARCBS project in February 2018.



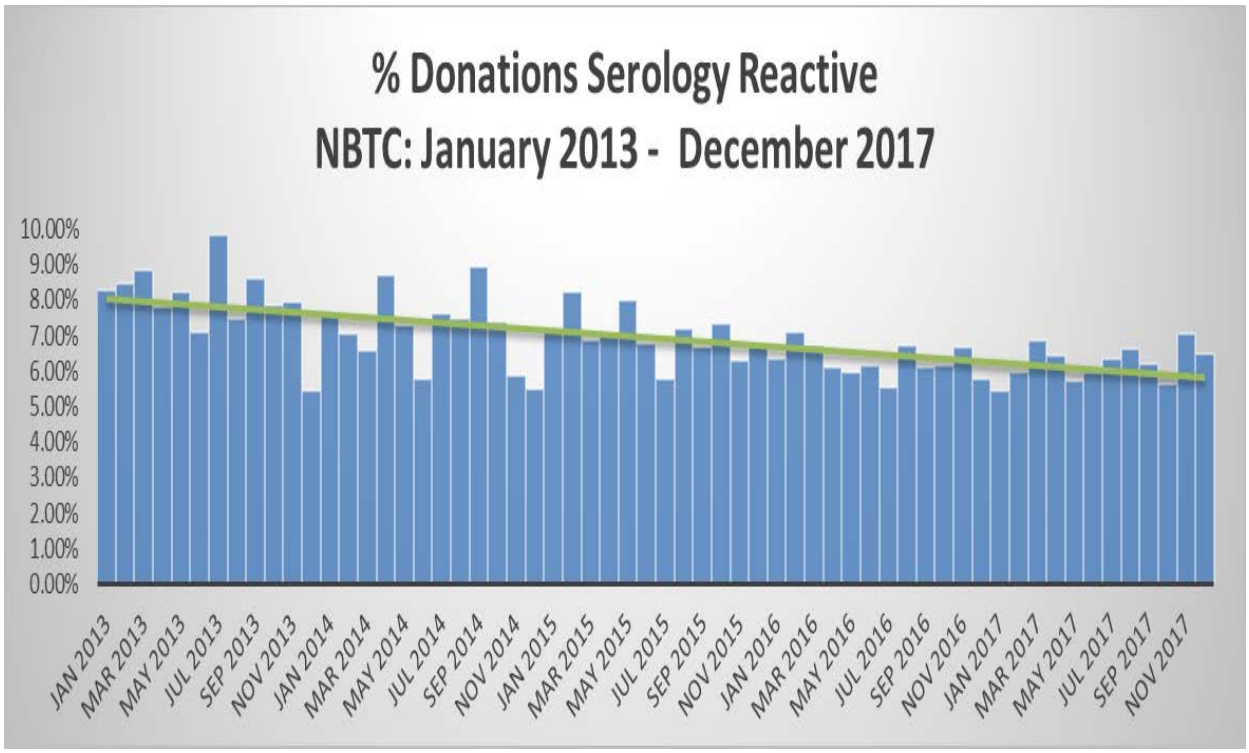

ACCREDITATION RESULTS: KAMPONG CHAM
80%
70%
60%
50%
40%
30%
20%
10%
0%
Dec-17 (n=60)
Jan-18 (n=61)
75% (46)
60% (36)
0%
2% (1)
23% (14)
13% (8)
17% (10)
10% (6)
Pass
Critical
Major
Minor


ACCREDIATION RESULTS: SIEM REAP
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Dec-17 (n=60)
Jan-18 (n=60)
82% (49)
73% (44)
0%
0%
10% (6)
8% (5)
17% (10)
10% (6)
Pass
Critical
Major
Minor

Transfusion Transmissible Infection (TTI) Results

The percentage of total serology positive results at NBTC has been in steady decline since 2013. Interventions such as the implementation of the Donor Selection Guidelines in March 2014 have also contributed to the continued downward trend. Certain periods do show a peak in results. This may be due to various factors such as:

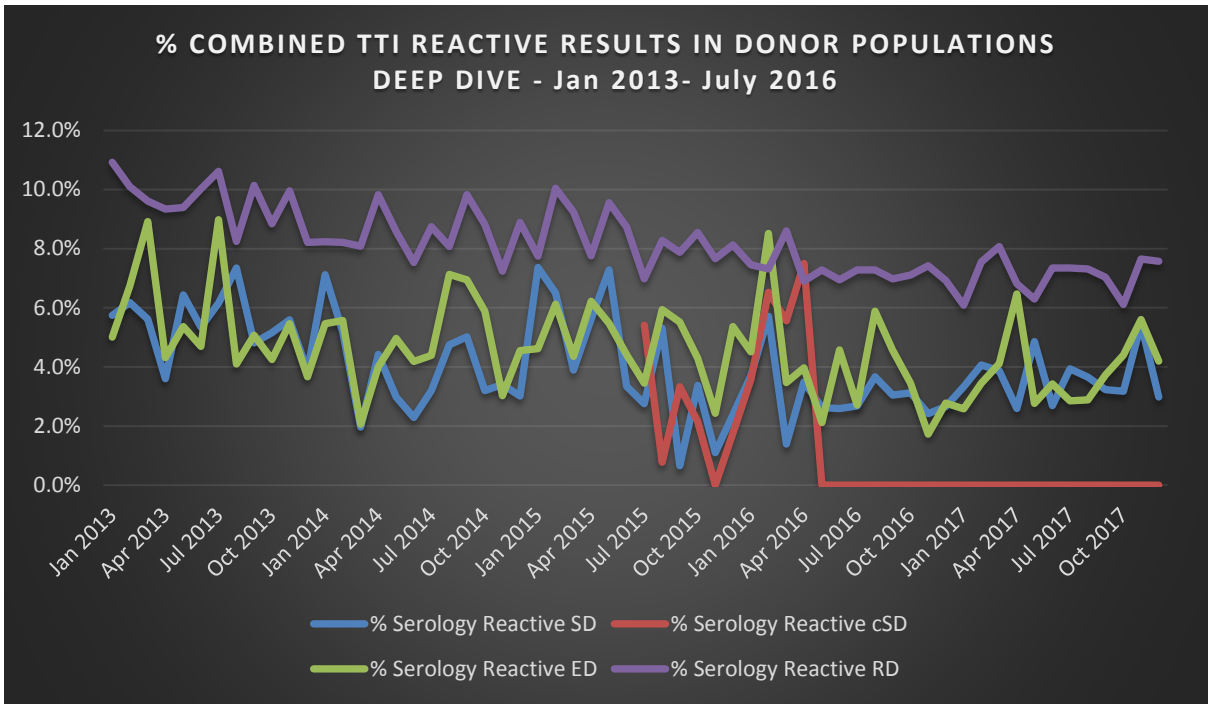
- Introduction of new testing methods (ELISA testing for HIV and hepatitis),
- Changes in the donor groups (some months may have more replacement donors or voluntary donors than others),
- Capability of staff to collect data, and
- Changeovers in staff.



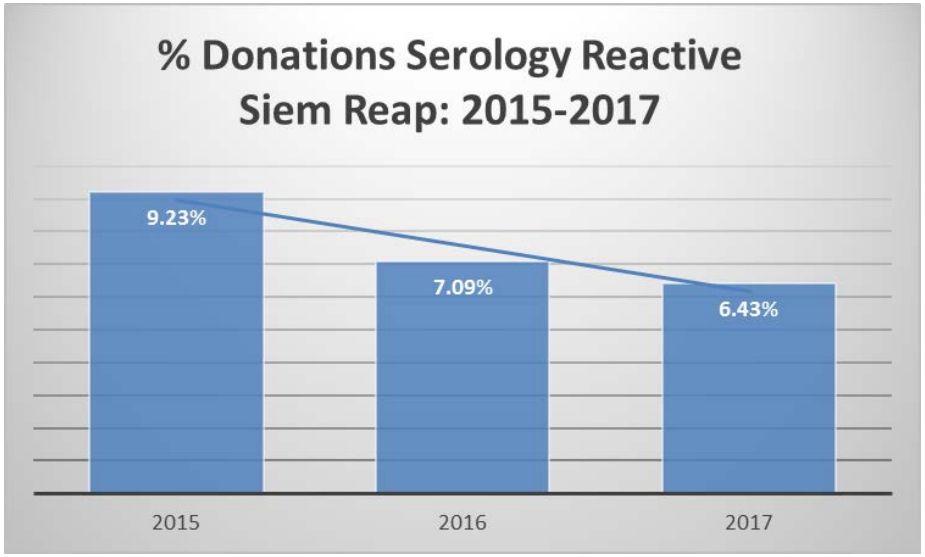
Note: Data on deferral rates is still not collected at blood centres. Collecting this data among potential donors would assist in determining if serology rates are decreasing due to better screening or if there is an issue with testing. For example, if there was an increase in deferrals and a decrease in reactive serology results, it would indicate better screening, however if there was a constant rate of deferrals and a decrease in reactive serology results, it could indicate an issue with testing.

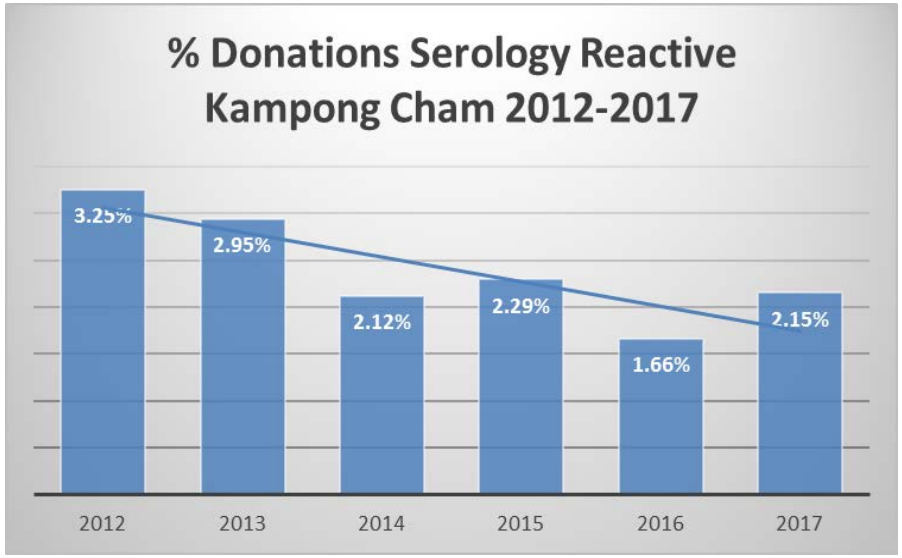
Mr Keo Bunrattana, NBTC with the Donor Selection Guidelines

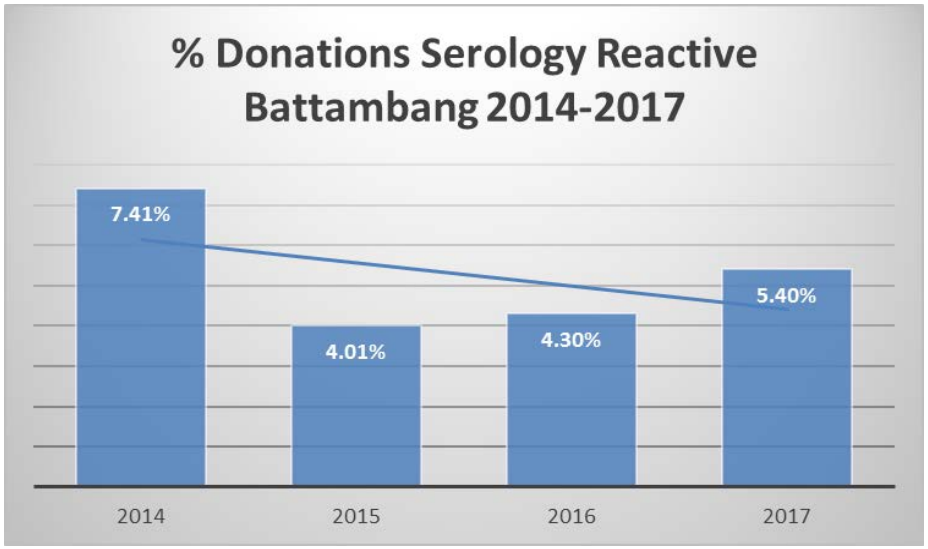
Since the beginning of 2013, all TTI rates have been generally declining among all donor types. Peaks can often be attributed to certain events or mobiles where less private interview locations may have resulted in less honest responses to donor questionnaire by voluntary donors donating with their peers. For example, February 2016 saw an increase in TTI rates among voluntary donors as the number of donors increased due to Valentine's Day collection. There was also a corresponding decrease in replacement donors in February 2016 as blood stock levels were met.

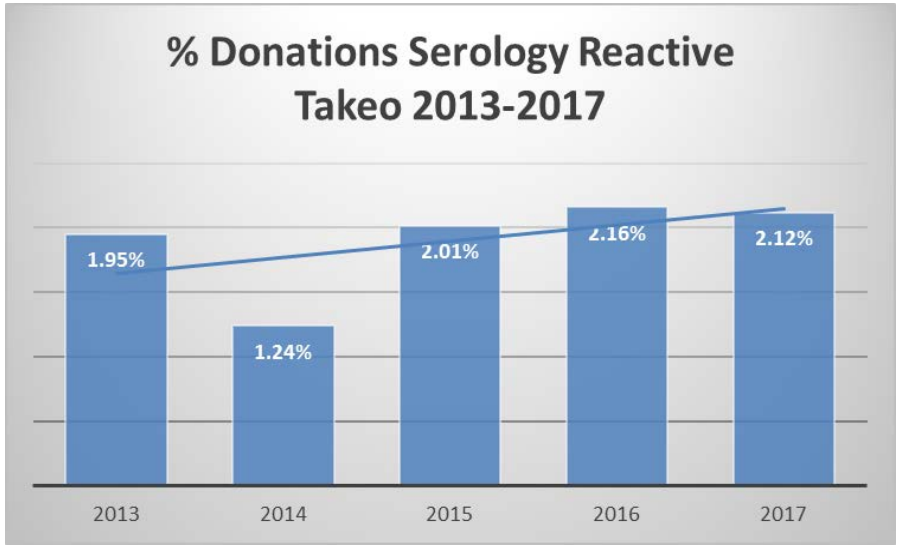


TTI rates in three of the four key provincial sites (Kampong Cham, Siem Reap and Battambang) have decreased over the course of the project, a result of more robust donor selection processes. The exception is Takeo where there has been a slight increase in the TTI rate, however Takeo's TTI rate is comparatively quite low.


% Donations Serology Reactive
Siem Reap: 2015-2017
9.23%
7.09%
6.43%
2015
2016
2017

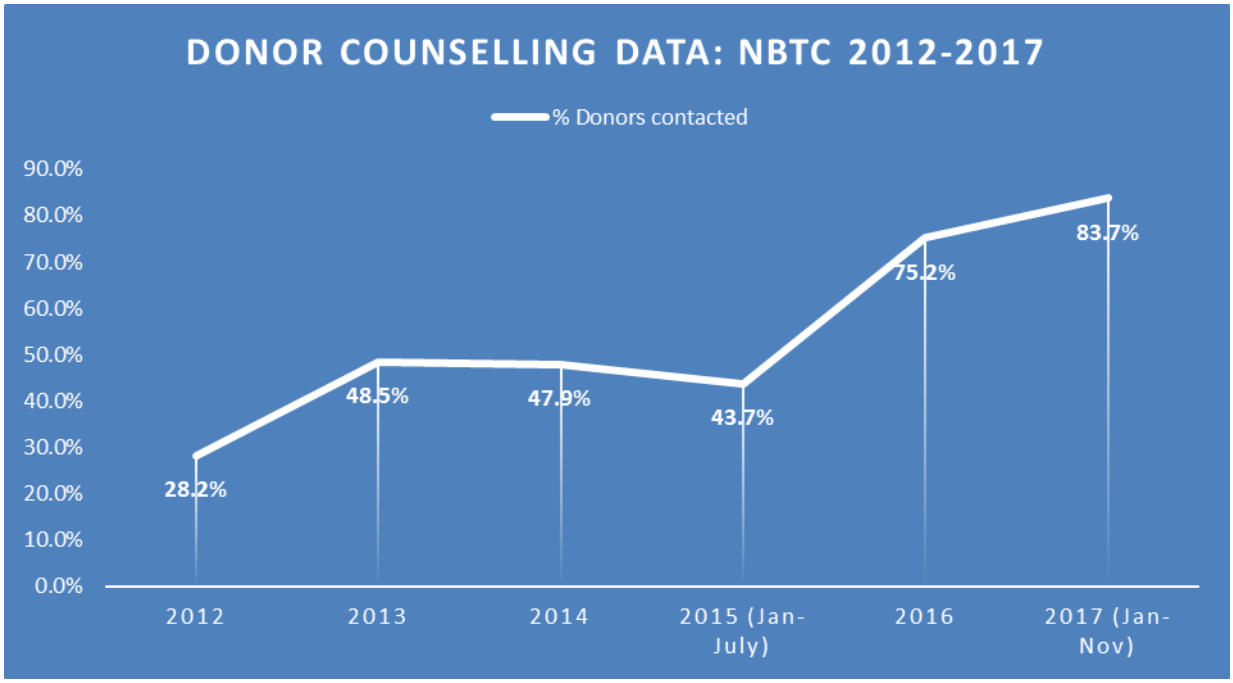

% Donations Serology Reactive
Kampong Cham 2012-2017
2.95%
2.12%
2.29%
1.66%
2.15%
2012
2013
2014
2015
2016
2017


% Donations Serology Reactive
Battambang 2014-2017
7.41%
4.01%
4.30%
5.40%
2014
2015
2016
2017


% Donations Serology Reactive
Takeo 2013-2017
1.95%
1.24%
2.01%
2.16%
2.12%
2013
2014
2015
2016
2017

Donor Counselling

Donor counselling has seen a positive improvement over the course of the project. The Blood Service worked closely with the NBTC to implement donor counselling guidelines, forms for data capture and reporting, an MOU for the referral of HIV and Syphilis positive donors to confidential counselling and treatment programs and more recently have identified a mechanism for the referral of Hepatitis B and C positive donors to Kossamak Hospital in Phnom Penh.

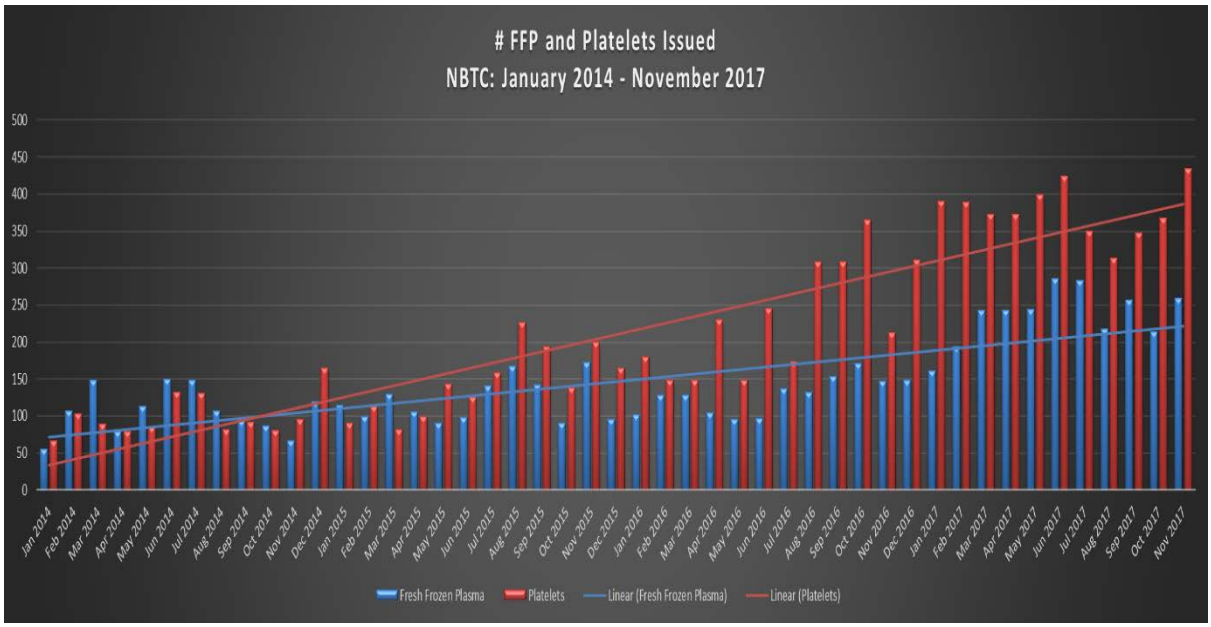


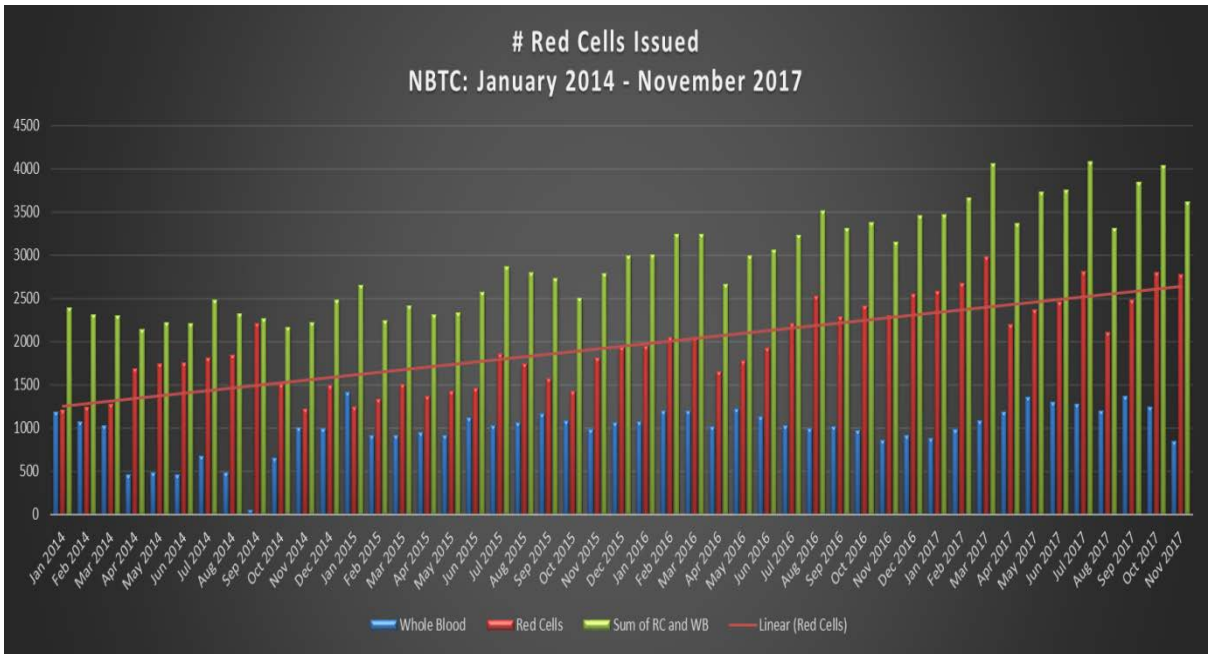
Dr June Lee and Ms Lois Somers (both ARCBS) work through donor counselling and care issued at the NBTC in 2015

Blood Components

The number of red cells, FFP and platelets issued at NBTC has continued to increase over the course of the project.

In January 2016 hospital transfusion committees were established and active in the promotion of the use of blood components. The number of platelets and fresh frozen plasma continues to increase overall and is affected by seasonal disease, such as Dengue, and availability from donors as platelets are produced from voluntary donations only. Following the training workshops held in December 2016 for components, platelet use has increased and remained steady; decreasing only slightly when NBTC moved to the new facility and all production was temporarily decreased.





Facilities and Equipment

After almost three years of planning, the NBTC along with key international partners including US CDC, AIHA, US PACOM and the Australian Red Cross/Blood Service has designed, validated and moved into three new blood centre facilities in Cambodia.

The state-of-the-art buildings in Kampong Cham, Siem Reap and Phnom Penh, which opened in February, March and June 2016 respectively, and are both donor centres and processing sites. They represent significant progress in helping Cambodia provide the safest and most sustainable blood supply possible.

Support will continue to be provided by US PACOM for two further buildings in Takeo and Battambang, and these are set to officially open in mid-2018. The Australian Red Cross Blood Service has been involved in the design of these buildings well, and has drawn upon the learning from the first three buildings for an improved design. Key learnings / improvements included:

- Scaled down safety shower to reduce the footprint,
- Removal of pillars in laboratory area for a more open space,
- A sink in the components area,
- Removal of the glass wall between the reception and donor refreshment area,
- Design of the windows so that the sills are outside to reduce dust catchment,
- Relocation of the door to the female night room to increase wall space for equipment in the laboratory
- Relocation of power points to underneath benches, and
- Larger meeting room.

Mr Scott Olsen, USACE, review building designs in preparation for the Battambang and Takeo builds with the technical assistance team, blood centres and the construction company, Clover in 2016

Mr Scott Olsen and Dr Sally Thomas at the site of the new NBTC building in 2014

The technical team trained and assisted NBTC, Kampong Cham and Siem Reap staff to plan their building move and associated validation activities (building and relocated / new equipment). A suite of validation documents were developed and translate and handed over to the both NBTC quality team and the Battambang and Takeo staff for the upcoming building moves in 2018.

National Blood Transfusion Centre

Relocation Plan for the Specialist Regional Centres

Document approval

	Position Title	Name and Signature	Date
Approved by NBTS Director	NBTS Director	Dr Hok Kimcheng	24/05/17
Approved by Quality Assurance	Quality Manager	Dr Sokhim Chea	24/05/17
Approved by Regional Blood Centre Director	Regional Centre Director	Battambang	

Purpose

This document outlines the logistical requirements and phased approach for relocating premises, and moving blood bank operations into a new purpose built facility. The reason for a phased approach for relocation is to maintain operations and blood supply during the move and while the new site is being validated. Blood banking is maintained at the old site until the new site has had all the required checks which ensure it is safe to use for all blood bank activities.

This document should be used to guide activity during the move. For ease of use, activities are listed chronologically and should be undertaken in the given order. Any exceptions to this plan must be discussed and approved by the move coordinator at NBTC before they are actioned.

IMPORTANT! ALL STEPS 1-15 MUST BE COMPLETED BEFORE USING THE NEW FACILITY, INCLUDING THE OPENING CEREMONY. THE NEW SITE CANNOT BE USED FOR ANY OPERATIONS OR HOLD ANY BLOOD PRODUCTS UNTIL THESE STEPS HAVE BEEN FULLY COMPLETED IN THE ORDER DESCRIBED.

Scope

The following are not described in this document. They will be developed independently and are outside the scope of this document:

- Validation documents, guidelines or protocols
- A detailed timeline of specific activities

Example validation document

Over the course of the project the Australian Red Cross Blood Service has donated a number of equipment items to the Cambodian National Blood Transfusion Service as follows:

- 10 plasma presses
- 4 maggy lamps
- 1 Semi-automated ELISA rocker and incubator
- 1 Water bath
- 1 Sample centrifuge
- 12 calibrated pipettes
- Various sample racks, glassware, pasture pipettes and weights
- 2 microscopes.

Australian Red Cross Blood Service plasma presses in use at the NBTC

The team has also provided guidance and input for the purchase of new automated laboratory equipment for NBTC, including infectious disease screening and immunohematology. To support their recommendations, a cost benefit analysis was undertaken, an example of the analysis taken is provided on the following page.

Testing Strategies for the NBTS - Cambodia: A Cost Benefit Analysis

		IMMUNOHAEMATOLOGY					
		Preferred Options			Recommended Option for New Facility (requires Temp control storage)		Not Recommended
	Testing Platform/ Supplier	Option 1		Option 2	Option 3		Option 4
		Abacus Immucor		Abacus Immucor	Diamed (BioRad)/ OrthoClinical Diagnostics		Manual Method
		Neo 4th generation Automation (large):	Echo 3rd generation Automation (small):	Neo 4th generation Automation:	Automated Gel card analyser:	Semi-automated gel cards:	Manual tubes/tiles:
Testing Parameters	**Required Donor Testing** ABO Group, Single pooled panel cell Ab screen, DAT	1 analyser in Testing laboratory		1 anayser in Testing laboratory for all donor and patient testing	1 automated analyser in Testing laboratory	**Back up:** Semi automated Gel 2 x 6-card centrifuge (or 1 x 12 card) 1 x gel card incubator	Current method
	Required Patient Testing ABO Group, 3 cell panel Ab screen, IgG XM, DAT		1 analyser in crossmatch/issue lab			Semi automated Gel 2 x 6-card centrifuge (or 1 x 12 card) 1 x gel card incubator	
	Throughput / Capacity	70 samples/hour; 224 sample capacity when fully loaded	20 samples/hour (ABO Rh & screen); ~6 patients XM/hour	70 samples/hour; 224 sample capacity	~50 samples/hour; 180 sample capacity	10-20 samples/hour; 24 card capacity	
	Reagent requirements and source	Closed system; manufacturer reagents only	Closed system; manufacturer reagents only	Closed system; manufacturer reagents only	Gel cards specific to system	Gel cards specific to system. Reagents can be non specific (MoH provided antisera and LISS can be used)	Fully open system, according to reagent availability and provision
Option Analysis	**Strengths**	~ **Higher sensitivity** than manual tube methods; ~ **Increased accuracy** due to IgG specific technology; ~ **Sensitive Ab screening** removes need for AHG crossmatch on every sample; ~ **Complete process control** in a temperature controlled system; ~ **Contingency** if one analyser fails; ~ Removes human subjectivity in performance and interpretation of results; ~ Reactions are clearer to read; ~ Can test paediatric samples with minimum volumes between 750 uL - 1 mL; ~ Possibility of provision of manual equipment to perform tests manually as extra contingency/back up - Easy to use; ~ The patient system can be used to partially identify antibodies in donors that come up positive in the pooled panel screen; ~ Possible direct support for maintenance;		~ **Higher sensitivity** than manual tube methods; ~ **Increased accuracy** due to IgG specific technology; ~ **Sensitive Ab screening** removes need for AHG crossmatch on every sample; ~ **Complete process control** in a temperature controlled system; ~ Removes human subjectivity in performance and interpretation of results; Reactions are clearer to read; Can perform testing on paediatric samples with minimum volumes between 750 uL - 1 mL; One system can be used for all testing; Only one analyser requiring validation and maintenance; Possible direct support for maintenance	~ **Higher sensitivity** than manual tube methods; ~ **Increased accuracy** ~ **Sensitive Ab screening** removes need for AHG crossmatch on every sample; ~ **Complete process control** in a temperature controlled system; ~ Removes human subjectivity in performance and interpretation of results; ~Reactions are clearer to read; ~ Versatile and common reagents and consumables mean it is easy to revert to semi-automated methods in the event of downtime;	~ **Higher sensitivity** than manual tube methods; ~ **Increased accuracy** as reactions are easy to read and interpret; ~ **Sensitive Ab screening** removes need for AHG crossmatch on every sample; ~ Very easy to use, conducive with **individual testing** (do not need to batch test samples for efficiency); ~ Can perform testing on paediatric samples with minimum volumes of 1 mL; ~ Cards can be kept safely for retrospective reference. Reactions are maintained in the gel for a long period of time; ~ Small volumes of reagents and sample are required;	Not reliant on analyser maintenance or continous performance; Available for all sites;
	Weaknesses	~ **Requires strong facility** surroundings (new buildings pending); ~ **Requires strict staff compliance** to procedures for maintainenance, calibration and use;		~ **Requires strong facility** surroundings (new buildings pending); ~ **Requires strict staff compliance** to procedures for maintainenance, calibration and use; ~ **No automated contingency** in case of failure - revert to manual methods; ~ **Require 2 samples for each patient test** - Analyser will be on Level 2 of the new fit out. Patient samples will have to be sent up along with donor samples and tested simultaneously. Two sample tubes would be required for each patient to be able to test group and screen on level 2 and to perform immediate spin crossmatch in the issue area once testing is complete. This would involve a change in hospital processes Requires comprehensive staff training for a novel process,	Requires controlled room temperature facilities for storage of gel cards (critical store - addressed in new facility planning)		~ **Human subjectivity** in performance and interpretation of results; ~ **Increased false negatives** due to "tube shaking" technique and disruption of the cell button; ~ **Low sensitivity method**, weak antibodies can potentially be missed; ~ **Large sample volumes** required. Difficult to perform testing on small samples. Limitation for testing paediatric samples; ~ **Poor efficiency**, low throughput, increased backlog; ~ **Low sensitivity requires crossmatch** for every patient sample. Time consuming when issuing urgent blood; ~ **Poor to no process control**; ~ Very little room for testing improvements or increased testing platforms to accommodate growth; ~ If used as a back up for automation, need provision of different reagents at a 3% concentration
	Opportunities	~ **Additional testing platforms** to accommodate growth - Platelet Antibody testing; CMV; Full Ab Identification; Donor phenotyping; Ag screening; Syphilis testing; ~ **Comprehensive staff training** for a novel process facilitates upskilling of staff ~ **Syphilis testing availability** on this analyser can reduce the need for rapid tests for TP; ~ **Interface opportunity** with the availability of a BBIS, to reduce transcription errors	~ **Additional testing platforms** to accommodate growth - Patient phenotyping; Full Ab Identification; Weak D; ~ **Interface opportunity** with the availability of a BBIS, to reduce transcription errors ~ **Comprehensive staff training** for a novel process facilitates upskilling of staff	~ **Additional testing platforms** to accommodate growth - Platelet Antibody testing; CMV; Full Ab Identification; Donor phenotyping; Ag screening; Syphilis testing; ~ **Syphilis testing availability** on this analyser can reduce the need for rapid tests for TP; ~ **Interface opportunity** with the availability of a BBIS, to reduce transcription errors ~ **Comprehensive staff training** for a novel process facilitates upskilling of staff	~ **SRC's can implement semi-automated testing** with no need for procurement of additional or different reagents; * ~ **Additional testing platforms** to accommodate growth - Full Ab identification * Included below is the cost for rolling out the semi automated equipment to two SRC's (Battembang and Kampong Cham) and the Model A sites (Siem Reap and Kampot)		~ Can be used as a **back up/contingency** system for all other options, with the supply of required specific reagents for manual methods (3%)
	Threats	Uninterrupted provision of reagents;		Uninterrupted provision of reagents;	Uninterrupted provision of reagents and consumables; **No local direct support in Cambodia**; only Service Engineers trained by manufacturer able to service the system.		~ **Patients with urgent needs at risk** due to slow methods; ~ **Patients at risk of transfusion reactions** due to low sensitivity of method, missing weak antibodies; ~ **Held up blood supply** due to backlog and poor efficiency in testing could affect inventory if donor group and screening cannot be completed in time

1

Support to Key Provincial Blood Transfusion Centres

A large scale training program was undertaken as part of project implementation, which focus on both the national and key provincial sites. Table 1 below shows the training provided to each of the key provincial centres as part of the technical assistance program. The training topics and plan were developed using the 2011 assessment results and linked closely to the issues and challenges found at the time. Table 2 outlines the key provincial issues identified during the 2011 assessment phase of the project in 2011/12, as well as the current status as at February 2018, and a number of positive improvements have been made as a result of the training, plus the activities described in the pillar 4 achievements section and the support and activities of the Cambodian National Blood Transfusion Service, MOH and Provincial Hospitals and Health Departments.

TABLE 1: PROVINCIAL CENTRE COMPLETED TRAINING AS AT FEBRUARY 2018				
TRAINING	**Siem Reap**	**Kampong Cham**	**Battam-bang**	**Takeo**
Appropriate Clinical Use of Blood & Hospital Transfusion Committee	✓	✓	✓	
National Training for Nurses on Blood Administration, Handling and Management of Adverse Events	✓	✓	✓	
Donor recruitment	✓	✓	✓	✓
Donor Collection, Care and Counselling	✓		✓	
Blood and Blood Product Manufacturing – Practice and Principles	✓	✓		✓
Component manufacture—FFP and Red Cells		✓	✓	
Preparation of platelet concentrates		✓		
Donor TTI testing and Infection Control	✓	✓	✓	✓
Immunohematology training	✓	✓	✓	
Immunohematology refresher	✓	✓	✓	✓
QMS and accreditation	✓	✓		✓
QMS and GMP	✓		✓	
Validation and qualification	✓	✓		

Validation	✓		✓	✓
Train the Trainer—quality mentor training	✓	✓	✓	✓
QMS Workshop with PACOM	✓	✓	✓	✓
EQAS	✓	✓	✓	✓

TABLE 2: KEY PROVINCIAL BLOOD CENTRE CHALLENGES AND IMPROVEMENTS					
ISSUE		**Siem Reap**	**Kampong Cham**	**Battam-bang**	**Takeo**
CLINICAL EDUCATION	**2011:** Lack of clinical education for hospital staff on correct use of blood and products	X	X	X	X
	2018: Improved clinical education for hospital staff on correct use of blood and products	✓	✓	✓	X
VNRBD	**2011:** Low VNRBD rate	X	X	X	X
	2018: Increasing VNRBD rate	✓	✓	✓	✓
DONOR CARE	**2011:** Poor management of donors, including post donation counselling of transfusion transmissible infection (HIV, HBV, HCV, syphilis) reactive donors	X		X	X
	2018: Better management of donors, including post donation counselling of TTI (HIV, HBV, HCV, syphilis) reactive donors	✓	✓	✓	**Requires more training**
	2011: Lack of consistent or standardised BDSG – different selection criteria observed between centres	X	X	X	X
	2018: Standardised BDSG	✓	✓	✓	✓
FACILITIES	**2011:** Facilities not fit for purpose	X	X	X	X
	2018: Facilities fit for purpose	✓	✓	**Mid 2018**	**Mid 2018**

EQUIPMENT CONSUMABLES & RESOURCES	**2011:** Inadequate blood banking equipment and equipment maintenance	X	X	X	X
	2018: Sufficient blood banking equipment and equipment maintenance	✓	✓	Mid 2018	Mid 2018
	2011: Supply of critical materials and consumables	X	X	X	X
	2018: Supply of critical materials and consumables	X	X	X	X
	2011: Relationship with hospital / PHD for resourcing	X	X	X	X
	2018: Improved relationship with hospital / PHD for resourcing	✓	✓	✓	✓
STAFF AND TRAINING	**2011:** Insufficient staff	X			X
	2018: Sufficient staff	✓	✓	✓	X
	2011: Lack of staff training across functional areas and poor staff compliance	X	X	X	X
	2018: Staff training across functional areas and staff compliance	✓	✓	✓	Require more training
QUALITY SYSTEMS	**2011:** Lack of centrally managed, controlled SOPs for technical processes, including donor collection and interview, testing, storage and component manufacture	X	X	X	X
	2018: Centrally managed, controlled SOPs for technical processes, including donor collection and interview, testing, storage and component manufacture	✓	✓	✓	✓
	2011: Little or no quality management	X		X	X
	2018: Quality management	In progress	In progress	In progress	In progress

QUALITY SYSTEMS	**2011:** No accreditation standards followed	X	X	X	X
	2018: Accreditation standards under implementation	✓	✓	✓	✓
	2011: Poor records management, including lack of secure storage for donor records	X		X	X
	2018: Improved records management, including secure storage for donor records	✓	✓	Mid 2018	Mid 2018
	2011: Poor infection control measures (PPE, no cleaning, no quarantining and poor waste management)	X		X	X
	2018: Infection control measures in place	✓	✓	Mid 2018	Mid 2018

Training and support was provided to the provincial sites over the duration of the project across multiple technical areas

PROJECT INSIGHTS

KEY LOCAL LEARNINGS

The project implementation approach has seen large scale success in the provincial areas (improved KPIS, good audit results), but has been challenged at the central, NBTC level. The factors identified that may contribute to this are around the central vs provincial management structures, policy and funding structures, politics and resulting blood center dynamics.

Provincial Blood Transfusion Centers (PBTCs) report to their provincial referral hospitals under Cambodia's devolved health care structure (the exception is Battambang PBTC which reports to the provincial health department). This structure has a number of benefits:

- Support is received directly from the hospital directors (HD) and / or provincial health directors (PHD),
- This support from HD/PHD means PBTC chiefs can progress with managing and running the blood bank, without their attentions being unduly diverted,
- The majority of the blood from the PBTCs is utilized at the hospital they report to, meaning there is more impetus on the Hospital to provide good support, and
- The PBTC's receive their staff from the hospital and because hospitals can charge patient fees which have an inbuilt incentive component for hospital staff and the PBTC staff have access to this incentive as well.

At the National Blood Transfusion Centre (NBTC), the management structure is different, in that NBTC reports directly to MOH, which has many competing priorities affecting their capacity to focus on the blood service and drive change. Additionally:

- The NBTC is not attached to any one hospital, therefore staff are not able to receive hospital incentives. Additionally this means that resource support from hospitals for mobiles is not available,
- For NBTC to be able to pay staff incentives, they need to become 'semi-autonomous' so they can cost recover, and the current political landscape has so far prevented this from occurring,
- Low government salaries mean that staff often have a 2nd job or business which can interfere with NBTC work, general staff motivation and attendance at work or training programs,
- Staff must adhere to MOH 24 hour shift work structure, which has a flow on impact to
    - Staff attendance for VNRBD collections at mobiles,
    - Implementation of project activities, for example staff attendance at training and implementation of accreditation work plans, and
    - NBTC's ability to provide technical and quality / audit support to the provincial centers.

- The staff are paid by MOH based on this 24 hour shift structure, which makes changes to rostering (eg implementation of shorter shifts) extremely difficult and unlikely,
- The NBTC director is not able to hire or dismiss his own staff as they are assigned by the MOH. The process of requesting additional staff appears complicated and is not guaranteed success. This impacts the directors ability to:
    - Delegate tasks,
    - Have appropriate oversight in each department,
    - Have staff who are qualified for their roles, and
    - Discipline staff when required.

The overall impact of this is a challenged chain of command at NBTC and a lack of staff accountability and work program ownership throughout the organization. From a project implementation perspective, the ineffective NBTC management structure has led to last minute requests to assist with preparation of presentations/reports/funding applications, where a longer lead time would meant they are more comprehensive and better prepared with more input, leadership and ownership from the NBTC.

Accreditation Learnings

A learning from later in the project whilst conducting accreditation checks, was around staff comprehension. Whilst junior staff should be expected to understand and explain the processes they are undertaking, they should not necessarily be expected to be able to explain the theory or logic behind them. This higher level of comprehension should be expected of the blood centre leadership team only. Additionally, during audits it should be the staff who perform the tasks that explain them, not a different staff member who might have better English. For this reason, when the centres are being audited, the following format should be used:

1. The auditor should ensure that the staff undertaking the process they are observing are the people that regularly perform the tasks. The staff member should also be fully trained (not on probation / new). They should only be expected to *explain* what they are doing, not *why*,
2. A member of the senior leadership should be present at all times during the audit, and
3. There must always also be a translator present.

Voluntary Non-Remunerated Blood Donation (VNRBD) Learnings

An earlier understanding on the cultural impact of ceasing family donors (when culturally people want to only donate for family), would have changed the project approach for VNRBD, because on reflection, there was an underestimation of the cultural impact on donor behaviour at the beginning of the project.

Typically, blood from altruistic voluntary donors is the best way to ensure a safe and sufficient blood supply as these donors usually have a lower rate of TTIs than other types of donors, such as family and replacement donor or paid donors. Because of this, VNRBD has become a surrogate marker for a safe blood supply.

In Cambodia (and many other developing countries), the blood supply is largely provided by family and replacement donors (FRD). There are a number of reasons for this, which makes the transition from FRD to 100% VNRBD a complex and long-term process. These reasons include:

- A lack of effective blood supply and demand planning – blood centres don't receive blood need estimates from hospitals, making the proactive collection of blood difficult as they don't know how much to collect or what blood components may be required,
- Inefficient blood ordering processes - hospitals will advise patients or their families that they need blood and it becomes the responsibility of the family to source the required blood units. This system promotes family and replacement donation, rather than voluntary non-remunerated donation, and a culture of donating / saving blood for the family,
- A desire / belief that 'I should save my blood for my own family', meaning even when mobiles are organised or new donors are encouraged to donate at a fixed site location, there can be limited success with VNRBD. These cultural attitudes and behaviours associated with family and replacement donors will require a long term approach if we are to shift their donation pattern to that of a regular voluntary donor.

With the goal to assist the Cambodian Blood Service to deliver a sustainable supply of blood from safe donors, the following two strategies[11] were developed during the project:

1. A strategy to address the safety risks associated with blood from family and replacement donors by promoting the self-deferral of unsafe donor populations and the implementation of private and confidential donor interviews to promote full disclosure by donors of their relevant medical history and risk behaviours,
2. A strategy to leverage altruistic, safe family and replacement donors and convert them to regular voluntary donors and shift the cultural norm from 'donating for my family' (family donor) to 'donating for my community' (voluntary donor).

[11] Due to the change in PEPFAR priorities in 2014, these strategies were implemented under the Australian Red Cross Blood Service's contract with the Global Fund.

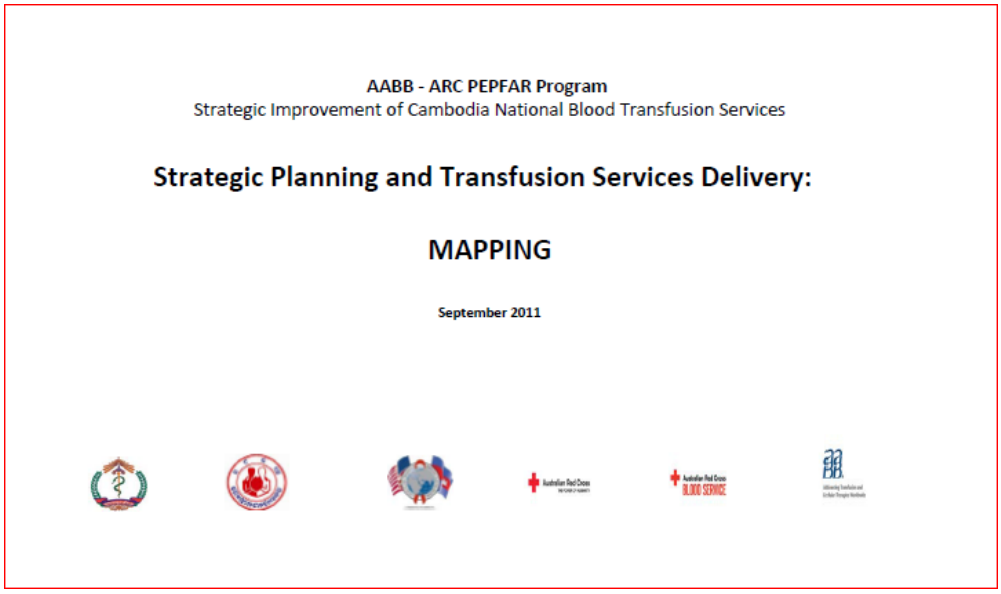
STRATEGY TO ADDRESS THE SAFETY RISKS ASSOCIATED WITH FAMILY AND REPLACEMENT DONORS	
COMMUNICATION APPROACH	**FAMILY AND REPLACEMENT DONORS**
Objective	Improved safety of donations
Key Messaging	Self-deferral
Channel	Staff, hospital collateral, clinics, donor centres
Target Audience	30-60 general public (patient link)
Key Influences	Community elders, authority figures, medical staff
Barriers	Family pressure to donate
Target	Decrease transfusion transmissible infections in family and replacement donation population by 2% per year

STRATEGY TO LEVERAGE SAFE, ALTRUISTIC FAMILY DONORS AND CONVERT THEM TO REGULAR VNRBD	
COMMUNICATION APPROACH	**FAMILY AND REPLACEMENT DONORS**
Objective	1. Education of ongoing (general) need for blood 2. Generate a conversion mechanism from FRD to repeat VNRBD
Key Messaging	1. Why a safe and sustainable supply of blood is important 2. Save your friend/family then save others. If you donate again, hospitals can save more lives
Channel	Staff, hospital collateral, clinics, donor centres
Target Audience	30-60 more traditional general public (patient link)
Key Influences	Community elders, authority figures, medical staff
Barriers	Motivation based on family need only Lack of knowledge/fear/myths
Target	10% conversion from FRD to VNRBD over the project period

PROJECT SUCCESS FACTORS

A number of factors have been identified as having contributed to the success of the Cambodian Blood Safety project, commencing with the original PEFPAR II project task order design. This design utilised a collaborative approach between CDC (Cambodia & Atlanta), NBTC and MoH; was comprehensive and covered all aspects of the blood system: vein to vein + policy and included both a national and provincial focus. The task order facilitated development of a sound project design by the Australian Red Cross Blood Service and a preliminary in country visit allowed the technical team to confirm and modify the project implementation design with key project stakeholders.

The project design included a mapping exercise where prior consultant and development partner work as well as existing documentation was identified to reduce duplication and to build upon previous training and work undertaken. This mapping also facilitated identification of the country context (see page 9), barriers to change and was the driver for the National Strategic plan 2013-2017 four pillars plus the three crosscutting areas of education, M&E and health system integration.


AABB - ARC PEPFAR Program
Strategic Improvement of Cambodia National Blood Transfusion Services

Strategic Planning and Transfusion Services Delivery:

MAPPING

September 2011

The project delivery model was also a critical success factor as it enabled real time, adaptable project support, could be tailored to local requirements and had a balanced mix of in country and Australia based support which allowed delivery of activities and sufficient time for the local teams to implement and sustain changes without the TA present. This meant that if during subsequent visits, specific activities or processes had not been sustained, they could be identified, the underlying reason workshopped and changes made accordingly. Where possible, with the NBTC Director, the project team met with and reported to the Cambodian Blood Safety Working Group (attendees from MOH, Hospitals, partners and NBTC), a group which provided advice and guidance on local blood service delivery as well project implementation which not only built local ownership, but helped ensure project deliverables remained relevant.

The project team consisted of a core team who provided technical advice, project oversight and management throughout the course of the project, as well as a wide array of Australian Red Cross Blood Service technical experts, who provided short term support to the project as required for

specific deliverables (e.g. donor counselling, finance and clinical education). All of the team worked closely with local stakeholders to provide mentorship and training, and to develop documents, including policies, SOPs and forms. The core team was a critical factor in building trust and good relationships over time.

When developing policies and documents, these were initially developed and discussed with local staff in English and were translated once the content had been agreed, as early on, it was discovered that editing Khmer documents was difficult to the point that it was easier to have the document completely retranslated. This approach built local ownership and left behind the plans and skills necessary for local staff to continue implementation of activities.

The project team implemented a practice of triangulation of information early on, to ensure accurate comprehension of the information being received. This triangulation of information occurred through both checking facts across multiple stakeholders and rechecking facts with the same stakeholder over time. This process was necessary as it took time to build trust and rapport with local stakeholders and to receive truly accurate and detailed answers.

Another success factor was allowing enough trip flexibility to respond to changing local priorities whilst ensuring the 'must do' tasks and activities were delivered. The beginning of each trip commenced with a meeting with the NBTC Director to discuss and confirm the trip schedule as required and incorporate any new requests for support.

In 2015 a 'trip book' was introduced which included all current work (for example, newly developed SOPs). This book was distributed to key in country stakeholders and was used as a project communication tool to update on progress and seek feedback on key items.

Finally, and as touched on earlier, the role and support of the local CDC office in Cambodia has been paramount in ensuring project success. They have facilitated access to donors and documents, provided insight to local challenges and situations, including 'no-go' areas (like cost recovery), have ensured integration with other CDC health programs (labs, HIV, maternal health), provided an ongoing presence at blood meetings and events and have provided considered feedback and recommendations for activities and reports.

OPPORTUNITIES FOR FUTURE PROJECTS

Following a retrospective review of the project implementation and learnings, the following factors are worth consideration for future projects:

- Increased focus in the first year to fully understand blood centre staffing structures, including payment and shift work. This would have identified earlier on the 24 hour shift work roster and resulting impact on activities,
- Early focus on understanding the blood service supply chain management processes, including involvement of third parties such as Ministry of Health,
- Early focus on improving blood safety through promotion of self-deferrals, and conversion of safe family donors and associated communication,
- Increased buy-in by MOH through more engagement by external partners,
- Identification of local partners for equipment and facilities maintenance and disposal,
- Reset project gateway goals constantly throughout the project with a particular focus on sustainability, local priorities and capacity,
- Adoption of a harder line to address management issues at NBTC – and withdrawal / suspension of project support/funding if issues are not addressed,
- Early identification and workshopping with local stakeholders to identify barriers to shifting M&E, such as VNRBD,
- Increased focus on ensuring the drive for change at the regional sites came from the central level as opposed to TA conducted training,
- Ensuring the correct staff are chosen for training, 'trainer the trainer' and development opportunities by acknowledging that it's not just about knowledge, but about their people skills, their resilience, their understanding and adaptability.

From a project management perspective, longer timeframes for budgeting and reporting would have been beneficial as at times the short turnaround times placed a considerable burden on the team infrastructure with potential for deflecting focus from project activities.

SUSTAINABILITY AND TRANSITION PLANNING

SUMMARY OF RECOMMENDATIONS

1. Review, edit with local stakeholder then submit the national blood policy to MOH for approval
2. Review, edit and cost with local stakeholder then submit the new National Strategic Plan for Blood (NSP) 2018-2020 to MOH for approval
3. MOH and / or NBTC to disseminate the blood policy, PRAKAS and new NSP 2018-2020
4. Provincial Health Departments should be encouraged to include specific focus on blood service activities and funding requirements into their Annual Operating Plans.
5. NBTC to implement the new NSP 2018-2020, including refreshed role of the Blood Safety Working Group.
6. NBTC should continue discussions with the HEF and MOH for service charge / blood financing opportunities
7. Continue to establish hospital transfusion committees (HTCs) in hospitals throughout Cambodia
8. Using the HTC infrastructure:
    - Continue implementation of the hospital accreditation standards for blood in each hospital
    - Promote development of maximum blood order schedules at each hospital
    - Implement reporting of patient adverse reactions back to the NBTC as part of haemovigilance
    - Encourage hospitals to implement patient wrist bands for patient identification
9. Look at the option to introduce education on the need for voluntary blood donation into the school's curriculum
10. Continue the focus on making family donors safer through self-deferral and on converting safe (TTI negative) family donors to voluntary donors
11. Continue to encourage new businesses to sign up for mobile collection drives and schedule these regularly
12. Include the capacity for donor appointments and flagging donor deferrals in the NBTC blood bank computer system when it's upgraded in 2018
13. NBTC should consider the recommendations in the blood depot assessment report when working with the MOH and other partners to upgrade blood depot sites for improved blood access in remote areas
14. NBTC should work with MOH to ensure that efficient reagents and other consumables, such as tips, are ordered annually for the running of the automated analysers (NEO, Architect and ELISA machines)
15. Better systems should be developed to manage reagent and consumable supply to the provincial sites
16. NBTC should investigate options for ongoing equipment maintenance of their specialised equipment. The option to send 1-2 staff members to complete a Biomedical Equipment Technology course should be considered
17. Continue to implement the quality standards and technical accreditation standards with the aim to reach level 1 certification from the African Society for Blood Transfusion at NBTC and the four regional sites
18. NBTC should assist and encourage the other 17 Provincial Blood Transfusion Centre sites to undertake a gap analysis against the technical standards and progress with addressing the gaps, with a view to reach level 1 accreditation nationally
19. NBTC should develop and implement an annual plan for internal auditing, which includes:
    - Auditing of departments across NBTC (collections, testing, components distribution)
    - Auditing of PBTC's

20. NBTC should continue with implementation of its document control management system, including distribution of controlled documents to all provincial sites
21. Quality managers or delegates should be appointed in each blood centre across Cambodia
22. NBTC should explore with MOH the opportunity to change the 24 hour shift requirement, as this would support more effective rostering of staff to cover both fixed site and mobile collections
23. Battambang and Takeo are strongly encouraged to follow the facilities move plan and building and equipment validation protocols provided by the technical assistant team to manage their upcoming facilities moves
24. Each blood centre should ensure they have regular (ideally weekly) access to an incinerator and discuss this with their hospital director / PHD if this is not the case. Checks of incinerator temperature should be performed to ensure the temperature is in line with requirements for blood incineration.

PROJECT ACTIVITY TRANSITION PLAN

In order to ensure sustainability and the smooth transition of project activities, the following transition plan has been developed and was delivered to local and international partners as part of the project close out visit in January 2018. The plan contains the latest status of key activities, recommendations for next steps and responsible persons as well as any relevant reference documents. The blue tables are PEPFAR funded activities, and the green tables are Global Fund supported activities, included in this report to ensure all activities and areas are captured for a cohesive approach moving forward.

PEFPAR KEY PERFORMANCE AREAS	STATUS	RECOMMENDATIONS FOR CLOSE OUT AND\OR NEXT STEPS	RESPONSIBLE PERSON	REFERENCE DOCUMENTS
1. SUSTAINABILITY				
a. Financial Sustainability:				
MoA with Private Hospitals	Developed and provided to NBTC Director	Implement MOAs as required with private hospitals to facilitate blood supply arrangements	NBTC Director	MOA
Cost recovery model	Developed and provided to NBTC Director	Available to NBTC to use as required to establish a justifiable service fee for provision of blood and blood products to hospitals	NBTC Director	Cost recovery model and associated presentation
Chart of Accounts	Developed and provided to NBTC Director	NBTC to update information in COA as required – this will drive the cost recover model	NBTC Director	Chart of Accounts and associated training materials

Health Equity Fund (HEF)	Initial discussions held with Tapley Jordanwood (Chief of Party, USAID Social Health Protection Project / University Research Co.), who provided HEF documents. Discussions paused in 2017 on advice of CDC.	NBTC to take forward with HEF	NBTC Director	HEF documents
Research	Extended opportunity to NBTC to participate in a research project funded by Australian Department of Foreign Affairs and Trade (DFAT). Outcome of research bid will be known in mid-2018.	The Blood Service will advise NBTC if/when the research project is approved	AuRC	Research proposal overview
b. Human Resources				
Global Fund positions	Global Fund positions have ceased end of 2017, ie. M&E Officer, VNRBD support.	NBTC and PBTCs should work with the MOH/PHD respectively to ensure adequate skilled human resources are available to meet the work load.	NBTC Director	
Incentives	GF incentives for staff ended in 2016. Staff incentives / per diems for mobiles are an important resource for mobilising staff to work additional hours to conduct mobiles. Hospital staff (inc PBTC staff) receive incentives through the hospital cost recovery / patient fees models, however NBTC is not eligible for this.	Per diems could be factored into the cost recovery modelling or be provided through sponsorship by other funding or corporate partners	NBTC Director	

WHO support	Current support ceased end of December 2017.	Option for PACOM support to assist transition and end of ARCBS and WHO support	PACOM	
2. FACILITIES				
Relocation & Validation Activities	Validation tools have been developed by TA, eg. Qualification Protocols, Relocation Plan SOP etc and training delivered. TA will provide final validation preparation support to Battambang and Takeo in January 2018	• NBTC must ensure equipment distribution for Battambang and Takeo sites, and time this so their equipment is delivered directly to the new buildings. • NBTC Validation team (3 persons) to support Battambang and Takeo validations. • Ideally US-PACOM need to oversee this process • A relocation folder prepared by TA can be used as a guide to open the new sites.	NBTC Quality Manager and Validation team with US PACOM Assistance	Validation documentation
3. BBIMS				
Jembi BSIS	Advice received from CDC in Dec 17 that no funding to progress BSIS.	• Dr Cheng is engaging a local IT company to expand the current NBTC donor database	NBTC Director	Database modification email

	PACOM has procured equipment for KC pilot site – some laptops would assist KC, however the remainder could be reallocated to NBTC	to allow real time data entry by staff in each department. • TA has sent advice regarding modification of the current system		
4. ACCREDITATION & QMS				
Training – Additional identified requirements				
Auditing	TA covered auditing in Takeo mentoring workshop in October 2017. TA has provided all the tools, including a schedule and checklist templates to NBTC Quality Manager.	NBTC now need to develop an internal audit program for both NBTC and PBTC audits. NBTC needs to explore external auditing options (eg with NIPH or MOH QA department) to ensure there is an external auditing program per quality accreditation standard requirements. (section 12)	Added to PACOMs workplan moving forward	
Paediatric Units	Refer to management and logistics comments – equipment has been provided by PACOM but not yet installed.	NBTC needs to install and validate the equipment in order to commence production of paediatric units. NBTC should also add paediatric packs to their standard supply lists, and seek training for their manufacture.	NBTC Director and Lab Manager	

Work Health & Safety – Hazard and Incident Reporting	Safety policy, cleaning and infection control standards have been developed and introduced through infection control training conducted by TA at all 5 key regional sites.	NBTC needs to conduct training for all NBTC and PBTC staff in these protocols. A system for hazard and incident reporting and associated corrective action still requires development and NBTC will need to take this forward.	NBTC Director, Quality Manager and team and all staff	
a. Documents				
Staff Training Records	All scanned copies of training records conducted by the TA have been provided to the NBTC Quality Manager. . Templates for future training sessions have been uploaded onto the document control management system, and were distributed to the ToT team during training at NBTC in Feb 2017.	Maintenance of training schedule post-March 2018 (? Quality Team)	NBTC Quality Manger and document control management system lead	
Organisational Chart and Staff PDs	Org chart and example PDs have been provided to the NBTC Quality Manager and Director. These are essential for accreditation.	NBTC needs to finalise their organisational chart and ensure there are position descriptions for all roles / staff. NB position descriptions are reliant on the org chart being complete	NBTC Director and, Quality Manager	Organisational chart and PDs

Standard Documents for Accreditation	The majority of standard documents (ie. SOPs & forms) related to Accreditation Activities will have been developed and implemented by February 2018 as part of the accreditation work plans and TA close out. This will be reviewed in January 2018 to identify gaps in required SOPs.		NBTC Director, Quality Manager and team and all staff	Master Document List
Staff Training Records	All scanned copies of training records conducted by the TA have been provided to the NBTC Quality Manager. . Templates for future training sessions have been uploaded onto the document control management system, and were distributed to the ToT team during training at NBTC in Feb 2017.	Maintenance of training schedule post-March 2018 (? Quality Team)	NBTC Quality Manger and document control management system lead	
Organisational Chart and Staff PDs	Org chart and example PDs have been provided to the NBTC Quality Manager and Director. These are essential for accreditation.	NBTC needs to finalise their organisational chart and ensure there are position descriptions for all roles / staff. Note: position descriptions are reliant on the org chart being complete	NBTC Director and, Quality Manager	Organisational chart and PDs
Standard Documents for Accreditation	The majority of standard documents (ie. SOPs & forms) related to Accreditation Activities will have been developed and implemented by February 2018 as part of the accreditation work plans and TA close out. This will be		NBTC Director, Quality Manager and team and all staff	Master Document List

	reviewed in January 2018 to identify gaps in required SOPs.			
Antibody Register	This is reliant on introduction of antibody screening. This has not yet occurred due to delay in receipt of the reagents for the Neo.	The antibody register template and a work instruction require development. The TA will develop as part of project close out	NBTC Director and Lab Manager	
Risk management framework	The TA risk management framework will be adapted and handed to NBTC as part of project close out.		TA with NBTC Director	
a. Certification				
Accreditation Road Map	NBTC and the 4 PBTC2s all have a work plan to address their accreditation standard gaps. TA conducted audits at NBTC, Siem Reap and Kampong Cham C in December 2017 and conducted follow up site audits in January 2018.	TA will ensure work plans are up to date with clear instructions for moving forward for the sites to address the gaps.	Added to PACOMs work plan moving forward	

Accreditation Certification	An Accrediting Body needs to be selected and enrolment into an accreditation program to follow. TA is investigating the African Society of Blood Transfusion as a possible option.	The accreditation process needs guidance and oversight post March 2018 (ie. selection, payment, enrolment, oversight of activities etc	Added to PACOMs work plan moving forward	
5. DONOR COUNSELLING				
Donor Counselling Guidelines	Completed and translated and provided to NBTC. Currently under review by Dr Lim Bophasi before distribution	NBTC to organise printing and distribution of guidelines once finalised internally. TA can pay for printed copies if organised by end of January 2018. Training to be conducted with distribution to all sites.	NBTC Director and Donor Counselling Team	
NCHADS	MOA with NCHADS for the referral of HIV and syphilis reactive donors is in place	NBTC needs to ensure that they are reporting regularly to NCHADS on the referred donors. A report form has been provided by the TA for this purpose.	NBTC Director and Donor Counselling Team	
MSF MoA / Hepatitis C	No MOA required. MSF operates its HCV clinic through Kossamak hospital. TA has met with Kossamak & MSF, & a process has been agreed. NBTC can refer the HBV and HCV reactive donors to Kossamak. If they meet criteria for MSF HCV treatment program they will be admitted. If they bring a referral form	NBTC needs to implement the referral form to send HBV and HCV reactive donors to Kossamak hospital	NBTC Director and Donor Counselling Team	Referral form

	from NBTC, they will be given priority status, meaning they can avoid wait times if a place opens up.			
Hepatitis B	HBV donors are managed at Kossamak, including testing of status		NBTC Director and Donor Counselling Team	
Process of referral for at TTIs and high risk donor management	TA has identified a organisation called Khana – who may be able to assist high risk donors	NBTC needs to confirm their management policy for high risk donors and follow up with Khana if required. NBTC to ask Khana for information pamphlets to give identified high risk donors, which outline the details of Khana clinic.	NBTC Director and Donor Counselling Team	

GLOBAL FUND KEY PERFORMANCE AREAS	STATUS	RECOMMENDATIONS FOR CLOSE OUT AND\OR NEXT STEPS	RESPONSIBLE PERSON	REFERENCE DOCUMENTS
Hospital Interaction	Had been managed by Dr Mardy (WHO). Hospital communication plan required with interaction between NBTC and Hospitals.	Draft NSP clarifies blood bank-hospital interactions and associated responsibilities	NBTC Director	

Budget	MOH support in 2018 is still unclear. Requires ongoing follow up.	Operational funding requirements such as reagents, consumables, staff, per diems and mobiles costs should be calculated based on estimated demand and included in Annual Operations Plans	NBTC Director	
National Coordination	This pillar will drive progression of the NSP 2018-2020. It is vital this support mechanism is established. This includes re-establishing the Blood Safety Working Group (or similar committee) to provide direction and oversight for the national blood program, including coordination with the provincial sites.	NBTC will need to lead this activity once the NSP is signed off.	NBTC Director	
NATIONAL STRATEGIC PLANNING	The NSP has been drafted and translated. Several sections require input from the NBTC Director.	A workshop to undertake a file edit the plan, and agree the content with key MOH and PHD stakeholders is recommended. The plan also requires costing.	NBTC Director with TA	Draft NSP version 10
Blood depots	The blood depot assessments have been completed and the final report with recommendations completed and provided to NBTC.	NBTC to take forward implementation of the recommendations as required with the EmONC (Emergency, Obstetric Neonatal Care) upgrade program and other relevant stakeholders.	NBTC Director	Blood Depot Assessment Report

PROJECT TEAM

Lead Technical Consultant
Dr Sally Thomas – Director International Services

- Clinical and Management Experience in hospitals, health departments and the Blood Service
- Experienced clinical practitioner in both public and private practice
- Experienced medical administrator for the West Australian Health Department
- 25 years experience in blood banking sector as Director, Assistance Director, Manager of Business Strategy and Medical Staff
- Head of Secretariat – ABO
- Head of Secretariat – APBN
- Head of Secretariat – GAP

Program Manager
Ms Emily Tonks – Technical Program Manager, International Humanitarian Program Manager

- Background in medical science (Biomedical & Molecular Biology)
- Master of Business Administration
- 14 years' experience in blood banking sector
- Project management
- Quality auditing (NATA Accredited)
- Provided benchmarking, horizon scanning and analysis to ABO and APBN Networks
- Part of GAP Secretariat, providing priority country support and technical advice
- 9 years' experience in humanitarian sector, providing technical support and management in Aceh, Jakarta, PNG, India, East Timor, Bangladesh, Nepal & Cambodia

Humanitarian Project Scientist
Linda Nicolo

Linda was previously employed by the International Services department of the Australian Red Cross Blood Service as the Humanitarian Project Scientist, working primarily on the PEPFAR Cambodian Blood Safety Project. Part of her work in this role involved developing and delivering standard testing models, including a defined viral testing algorithm for infectious disease screening (TTI testing), standard procedures for manual and automated blood group serology testing, as well as standardised processing techniques for producing blood products, validated by set specifications and product sampling.

Linda is currently employed in the role of Technical Project Leader for the Global Advisory Panel (GAP) on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies – aimed at improving the supply of safe blood globally through the provision of specialist technical advice and expertise to enable the delivery and coordination of GAP Projects, including in country support. A large proportion of this work is conducted in the Asia Pacific region.

Project Officer
Laicey Colum

With previous experience as a Medical Scientist specialising in Transfusion Medicine and Haematology and working with developing communities in Ethiopia, Laicey was formerly employed as Humanitarian Project Officer, principally for the PEPFAR Cambodian Blood Safety Project, by the Australian Red Cross Blood Service International Services department. She was involved in the development of the Cambodian Blood Donor Selection Guidelines, Blood Donor Counselling Guidelines; standard procedures for the collection of blood; assessment for accreditation; implementation of quality management systems; and the monitoring and evaluation of project deliverables.

At this time, Laicey is employed as Project Officer for the Global Advisory Panel and is involved in developing a Global Mapping report which provides visibility of the global engagement of National Societies (NS) in the provision of blood programmes and the role of the NS and Blood Service in each country and GAP Self-assessment allowing National Societies to assess whether they have appropriate measures in place to maintain a blood service.

Project Officer
Alexandra Brown

Alexandra worked as an International Project Officer for the Australian Red Cross Blood Service on the Cambodian Blood Safety Project, where she was involved in National Strategic Planning, monitoring and evaluation, reporting, and the development and implementation of VNRBD tools, resources and training.

Alexandra is currently employed in the role Voluntary Non-Renumerated Blood Donation (VNRBD) Project Officer for the Global Advisory Panel (GAP) – aimed at improving the rate of VNRBD and the supply of safe blood globally. A large proportion of this work will be conducted in the Asia Pacific region.

Technical Team

Sandra Boyd	Technical Laboratory Support
Nicole Humphry	Project Support
Michelle Wsolak	Quality & Audit Support
Joseph Patkes	Laboratory Training Support
Noelle Chow	Quality & Technical Support
Maureen Tay	Quality & BBIMS support
Dr Anthony Keller	Clinical Support
Dr Ben Saxon	Clinical Support
Dr Amanda Thompson	Clinical Support
Bev Quested	Clinical Nursing Support
Sheila Ward	Strategy & Management Support
James Bargh	Facilities Support
George Putland	Facilities Support
Dr June Lee	Donor Care & Counselling Support
Dr Barbara Bell	Donor Care & Counselling Support
Lois Somers	Donor Collection Support
Alyson Pearce	VNRBD Support
Ben Scales	VNRBD Support
Clara Hilsen	VNRBD Support
Abdullah Genc	Finance Support
Adele Welch	Finance Support

Staff in Siem Reap attend Donor Collections, Care and Counselling training from Dr June Lee

GLOSSARY

ABO	Alliance of Blood Operators
AfSBT	African Society for Blood Transfusion
AIHA	American International Health Alliance
AOP	Annual Operational Plan
APBN	Asia Pacific Blood Network
ARC / BS	Australian Red Cross / Blood Service
BBIMS	Blood Bank Information Management System
BDSG	Blood Donor Selection Guidelines
BSIS	Blood Safety Information System
BSWG	Blood Safety Working Group
DFAT	Australian Department of Foreign Affairs and Trade
ELISA	Enzyme Linked Immunosorbent Assay
EmONC	Emergency Obstetric and Neonatal Care
EQAS	External Quality Assurance Scheme
FFP	Fresh Frozen Plasma
FRD	Family / Replacement Donation/Donor
GAP	Global Advisory Panel on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies
Global Fund / GF	The Global Fund to Fight AIDS Tuberculosis and Malaria
GMP	Good Manufacturing Practice
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HD	Hospital Director
HEF	Health Equity Fund
HIV	Human Immunodeficiency Virus
HTC	Hospital Transfusion Committee
IT	Information Technology
KPI	Key Performance Indicator
MBOS	Maximum Blood Order Schedule
MDG	Millennium Development Goals
M&E	Monitoring and Evaluation
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MOH	Ministry of Health
MSF	Médecins Sans Frontières
NBTC	National Blood Transfusion Centre
NBTS	National Blood Transfusion Service
NCHADS	Cambodian National Centre for HIV, AIDS, Dermatology and STI's
NGO	Non-Government Organisation
NIPH	Cambodian National Institute for Public Health
NSP	National Strategic Plan
PBTC	Provincial Blood Transfusion Centre
PD	Position Description
PEPFAR	US President's Emergency Program for AIDS Relief
PHD	Provincial Health Department / Director
PPE	Personal Protective Equipment
Prakas	MOH administrative order (legislation)

QA	Quality Assurance
QMS	Quality Management System
RBC	Red Blood Cells
SDG	Sustainable Development Goals
SOP	Standard Operating Procedure
TA	Technical Assistance
ToT	Train the Trainer
TTI	Transfusion Transmissible Infection
UNDP	United National Development Program
USACE	United States Army Corp of Engineers
US CDC	United States Centers for Disease Control and Prevention
US PACOM	United States Pacific Command
UYFC	Union of Youth Federation of Cambodia
VNRBD	Voluntary Non-Remunerated Blood Donation/Donor
WB	Whole Blood
WBDD	World Blood Donor Day
WHO	World Health Organization

APPENDIX 1 – TECHNICAL TRAINING SUMMARY

Date	Name of Training	Location	Duration	Number/Type of Individuals Trained
April – June 2013	Calmette Hospital Clinical Lecture with Q & A Session	Phnom Penh	3.5 hours	30 health professionals from surgery, anesthesiology, obstetrics, nurses and laboratory departments Calmette Hospital
July – Sept 2013	NBTC Donor Selection and Counselling training	Phnom Penh	6 hours	10 NBTC clinical staff
	Laboratory training (cleaning)	Phnom Penh	4 hours	10 NBTC laboratory staff
	Laboratory training	Phnom Penh	4 hours	15 new NBTC laboratory staff and refresher for trained staff
	Laboratory training (Rapid plasma freezing and manufacture of FFP)	Phnom Penh	3 hours	2 key NBTC laboratory staff
	Laboratory training (Document Control)	Phnom Penh	3 hours	3 key NBTC laboratory staff
	Clinical use of blood in hospital setting (BQ)	Phnom Penh	3.5 hours	Calmette Hospital National Paediatric Hospital Khmer Soviet Friendship Hospital
Oct – Dec 2013	National workshop on Appropriate use of Blood and Hospital Transfusion Committee	Phnom Penh	2 days	61 x clinicians
	National training for nurses on Blood Administration, Handling and Management of Adverse Effects	Phnom Penh	2 days	63 x nursing staff
	Immunohaematology wet practical session	Phnom Penh	2 days	13 x laboratory staff
	Training of Europcontinent engineers	Phnom Penh	2 days	2 x engineers
Jan – March 2014	PR donor recruiter training	Phnom Penh	2 days	29 PR officers, donor recruiters and clinicians.
	Preparation of Platelet Concentrates (PP)	Phnom Penh	2 days	3 Laboratory staff NBTC
	Preparation of Platelet Concentrates (KC)	Kampong Cham	2 days	7 Laboratory staff Kampong Cham

	Donor counselling and collection	Phnom Penh	5 days	24 Donor clinicians, collection nurses & staff
April – June 2014	Donor Recruitment Planning Session	Phnom Penh	2 days	7 PR officers, donor recruiters
	Preparation of Platelet Concentrates (PP)	Phnom Penh	2 days	4 Laboratory staff
	National Workshop on Appropriate Clinical Use of Blood & Hospital Transfusion Committee	Siem Reap	2 days	44 clinicians
	National Training for Nurses on Blood Administration, Handling and Management of Adverse Events	Siem Reap	1.5 days	45 nurses
	Training on Blood Costing Models	Phnom Penh	1 day	4 NBTC finance staff
July - Sept 2014	Immunohematology training	Phnom Penh	4 days	30 laboratory, clinical & nursing staff
	Immunohematology training	Battambang	2 days	11 Laboratory staff
	Immunohematology training	Siem Reap	3 days	5 Laboratory staff
	Clinical Use of Blood	Phnom Penh	2 days	40 Clinicians
	Blood Administration	Phnom Penh	2 day	39 nurses
Oct – Dec 2014	Immunohematology training	Kampong Cham	2 days	5 Laboratory staff
	Manufacture of Component training (FFP and Red Cells)	Battambang	2.5 days	10 Laboratory staff
	Serology training	Phnom Penh	3.5 days	9 Laboratory staff
	Post donation donor counselling	Phnom Penh	2 days	16 donor care staff
Jan-Mar 2015	Donor Care, Collection and Selection training	Siem Reap	5 days	13 Nurses and Blood Centre staff
	Component manufacture FFP, RBC	Kampong Cham	2.5 days	5 Laboratory staff
	Serology training	Phnom Penh	3.5 days	16 Laboratory staff
	Donor Counselling & Database training	Phnom Penh	0.5 days	6 Medical Officers and Senior Nurses
	QMS & GMP	Phnom Penh	2 days	2 NBTC Senior staff
	QMS & GMP	Siem Reap	2.5 days	5 SRP Laboratory staff

Jul-Sep 2015				1 NBTC staff
	QMS & GMP	Battambang	2 days	8 BTB Laboratory Staff 1 NBTC staff
Jan-Mar 2016	Validation and Qualification	Kampong Cham	5 days	6 KCM Laboratory staff 5 NBTC staff 1 SRP Laboratory staff
Jul-Sep 2016	Infection Control	NBTC	1 day	8 NBTC Staff
	Serology TTI Refresher	NBTC	1 day	7 NBTC Staff
Oct – Dec 2016	Blood and Blood Product Manufacturing – Practice and Principles	NBTC	7 days	16 Laboratory staff from NBTC, KCM, SRP, Takeo, AHC and SKMH
Jan – Mar 2017	QMS & Accreditation	NBTC	2 days	14 staff from NBTC, KCM, SRP, BTB and Takeo
	Trainer the Trainer	NBTC	2 days	14 NBTC staff
	Validation	NBTC	1 day	8 staff from Quality Teams in NBTC, KCM, SRP, BTB and Takeo
	Document Control	NBTC	2 days	NBTC Quality Team (5 staff)
	Cold Chain	NBTC	2 days	NBTC Quality Team (5 staff)
Apr-Jun 2017	Donor TTI Testing and Infection Control	KCM	3 days	17 Laboratory Staff from BTB, KCM, SRP and Takeo
	Donor TTI Testing and Infection Control	BTB	3 days	
Jul-Sep 2017	Immunohaemtology Testing - Refresher Training	SR	2 days	8 Laboratory staff, 6 from SR and 2 from BTB

		NBTC	2 days	4 Laboratory staff, 2 from Tk and 2 from KCM
	QMS Workshop with PACOM	SR	3 days	30 staff from NBTS from all sites
Oct 2017	Train the Trainer – Quality Mentor training workshop and Accreditation Work Planning for Blood Transfusion Services	Takeo	3 days	16 staff from Quality Teams in NBTC, KCM, SRP, BTB and Takeo
Dec 2017	EQAS Training Workshop	PP	1 day	31 staff from every site and NBTC

APPENDIX 2: DEVELOPED DOCUMENT SUMMARY

NBTC Master Document List - Controlled and Uncontrolled Documents

		Department	CONTROLLED DOCUMENT Name	Version	Translated
FUNCTIONAL AREA	ADMINISTRATION (ADM)	**DONOR RECRUITMENT (DNR)**			
			Refer to separate VNRBD document register		
		FINANCE (FIN)			
			Refer to uncontrolled documents section		
		HUMAN RESOURCES (HR)			
			Refer to uncontrolled documents section		
		INFORMATION TECHNOLOGY (IT)			
			Not yet developed		
		WAREHOUSE (WH)			
			Not yet developed		
	QUALITY MANAGEMENT SYSTEMS (QMS)	**DOCUMENTATION (DOC)**			
		QUA-MAN-001	NBTC Quality Manual	v001	y
		QMS-DOC-S001	Document Control Management System	v001	y
		QMS-DOC-S002	Maintaining the Signature Register	v001	y
		QMS-DOC-W001	Document Control - Managing Documents	v001	y
		QMS-DOC-W002	Document Control - Document User	v001	y
		QMS-DOC-F001	Document Log	v001	y
		QMS-DOC-F002	Signature Register	v001	y
		EQUIPMENT (EQU)			
		QMS-EQU-F001	Centrifuge Spin Details	v002	y
		QMS-EQU-F002	Platelet Reciprocator – 3 Monthly Oscillation and Annual Check	v001	y
		QMS-EQU-F003	Centrifuge Performance Verification Form	v001	y
		MATERIAL MANAGEMENT (MAT)			
		QMS-MAT-F001	Critical Material Relocating Form	v001	y
		TRAINING (TRA)			
		QMS-TRA-S001	The Training Process	v001	y
		QMS-TRA-F001	Training Session Plan	v001	y
		QMS-TRA-F002	Training Participation Record Form	v001	y
		QMS-TRA-F003	Pre Training Evaluation Questions	v001	y

	QMS-TRA-F004	Post Training Evaluation Questions	v001	y
	QMS-TRA-F005	Observational Assessment Form	v001	y
	QMS-TRA-F006	Training Certificate	v001	y
	QMS-TRA-F007	Observational Assessment Form – General Cleaning	v001	y
	QMS-TRA-F008	Observational Assessment Form – Preparation of Platelet Concentrates	v001	y
	QMS-TRA-F009	Observational Assessment Form – Product Sampling	v001	y
	QMS-TRA-F010	Observational Assessment Form – Manufacture of Red Cells and FFP	v001	y
	QMS-TRA-F011	Observational Assessment Form - Cryoprecipitate	v001	y
	VALIDATION (VAL)			
	QMS-VAL-F001	IOQ Electronic Blood Collection Monitor	v001	y
	QMS-VAL-F002	IOQ Tube Sealer – Benchtop or Portable Sealers	v001	y
	QMS-VAL-F003	IOQ Electronic Balance	v001	y
	QMS-VAL-F004	IOPQ Blood Refrigerator (Stand Alone)	v001	y
	QMS-VAL-F005	IOQ Laboratory Waterbath	v001	y
	QMS-VAL-F006	IOQ Hemoglobinometer	v001	y
	QMS-VAL-F007	IOQ Laboratory Serofuge	v001	y
	QMS-VAL-F008	IOQ Cell Washer	v001	y
	QMS-VAL-F009	IOPQ Plasma Freezer (Stand Alone)	v001	y
	QMS-VAL-F010	IOPQ Platelet Incubator with Shaker	v001	y
	QMS-VAL-F011	IOQ Blood Bag Centrifuge	v001	y
TECHNICAL (TEC)	**BLOOD COMPONENTS (BC)**			
	TEC-BC-W001	Manufacture of Platelet Concentrates from Whole Blood Donations	v001	y
	TEC-BC-W002	Manufacture of Red cells and Fresh Frozen Plasma (FFP)	v001	y
	TEC-BC-W003	Manufacture of Cryoprecipitate from Whole Blood FFP	v001	y
	TEC-BC-F001	Components Record Form	v001	y
	TEC-BC-R001	Plasma Colour Comparison Chart	v001	y
	TEC-BC-R002	Component Time Guide	v001	y
	TEC-BC-R003	Packing Double and Triple packs for Centrifugation	v001	y
	TEC-BC-R004	Trouble shooting guide	v001	y
	TEC-BC-R005	Component Calculations	v001	y
	TEC-BC-R006	Weight to Volume Conversion Matrix Wall Chart	v001	y
	CLINICAL INTERFACE (CLI)			
	COLLECTION (COL)			

TEC-COL-S001	Donor Interview	v002	y
TEC-COL-S002	Donor Health Screen	v002	y
TEC-COL-S003	Donor Haemoglobin Check	v002	y
TEC-COL-S004	Whole Blood Collection	v002	y
TEC-COL-S005	Donor Reception	v002	y
TEC-COL-S006	Post Donation Information	v002	y
TEC-COL-S007	Identifying and Managing Donor Adverse Events	v001	y
TEC-COL-S009	Blood Donor Infectious Disease Counselling	v002	TBC
TEC-COL-S012	Preparation and Use of Copper Sulphate solution	v001	y
TEC-COL-F001	Blood Donation Form and Health Questionnaire	v003	y
TEC-COL-F002	Donor Notification Letter - Pos or discordant	v001	y
TEC-COL-F003	Donor Notification Letter - BFR	v001	y
TEC-COL-F004	Medical Officers Counselling Form	v001	y
TEC-COL-R001	NBTS Donor Selection Guidelines	v001	y
TEC-COL-R002	Blood Donor Classification Chart	v001	n
DONOR COUNSELLING AND CARE (DCC)			
TEC-DCC-S001	Cambodia Donor Counselling Guidelines FINAL	v001	y
TEC-DCC-R001	Script to explain referral process to Kossamak Hospital for Hepatitis B and C reactive donors	v001	n
TEC-DCC-R002	Flow Chart of Stages in Blood Donor Counselling	v001	n
IMMUNOHAEMATOLOGY (IH)			
TEC-IH-S001	Basic Principles for Manual Methods	v002	y
TEC-IH-S002	Manual ABO and Rh (D) Blood Grouping	v002	y
TEC-IH-S003	Investigation for Blood Group Variants	v002	y
TEC-IH-S004	Direct Antiglobulin Test (DAT)	v002	y
TEC-IH-S005	Antibody Screening using the Indirect Antiglobulin Test (IAT)	v002	y
TEC-IH-S006	Manual Crossmatch Immediate Spin & Indirect Antiglobulin Test (IAT)	v002	y
TEC-IH-S007	Investigation of Adverse Transfusion Reactions	v002	y
TEC-IH-S008	In House Preparation of Red Cell Reagent	v002	y
TEC-IH-S009	Investgating Blood Group Anomalies	v001	n
TEC-IH-F001	Immunohematology – Quality Control (QC) Record Form	v001	y
TEC-IH-F002	Transfusion Reaction Investigation Form	v001	y
PROCESS CONTROL (PC)			
TEC-PC-W001	Sampling Blood for Quality Control Testing	v001	y

	PRODUCT ISSUE AND DISTRIBUTION (PID)			
	TEC-PID-S001	Release labelling	v001	n
	TEC-PID-S002	Cold chain transport	v001	n
	TEC-PID-F001	Consignment form	v001	y
	TEC-PID-F002	Critical Material Relocating Form	v001	y
	SEROLOGY (SER)			
	TEC-SER-S001	Viral Serology Testing Algorithm		n
	TEC-SER-F001	Reactive Donor Notification Form		y
	TEC-SER-R001	Viral Testing Algorithm		y
	TEC-SER-R002	Single Assay Viral Testing Algorithm		y
	TEC-SER-R003	Inconclusive Results Viral Testing Algorithm – Investigation Process		y
GENERAL (GEN)	**BIOSAFETY (BIO)**			
	OPERATIONS (OPS)			
	GEN-OPS-S001	General Cleaning	v001	y
	GEN-OPS-F001	Daily Cleaning Record	v001	y
	GEN-OPS-F002	Weekly Cleaning Record	v001	y
	GEN-OPS-F003	Monthly Cleaning Record	v001	y
	GEN-OPS-F004	Discards Log	v001	y
	GEN-OPS-F005	Equipment Temperature Log	v001	y
	GEN-OPS-F006	Room Temperature Log	v001	y
	GEN-OPS-R001	Reference Guide for Heat Sealing	v001	y
	GEN-OPS-R002	Safe Use of Centrifuges	v001	y
	WORK HEALTH AND SAFETY (WHS)			
	GEN-WHS-P001	Work Health and Safety Policy	v001	y
	GEN-WHS-S001	Infection Control Standard	v001	y
	GEN-WHS-F001	Blood Spill Kit Checklist	v001	y
UNCONTROLLED DOCUMENTS		**UNCONTROLLED DOCUMENT Name**		
		National Blood Policy		y
		National Strategic Plan 2018-2020		y
		Chart of Accounts		N/A
		Blood Costing Model		N/A

			MOA with Private Hospitals		n
			National Clinical Guidelines		y
			TOR for Hospital Transfusion Committees		TBC
			NBTC risk management matrix		N/A
			MOA with NCHADS for referral of HIV and syphilis donors		n
			Draft Organsiational chart for NBTC		n
			Example staff PDs (VNRBD, donor counselling, lab 2IC)		N/A
			Blood demand and supply planning tool		N/A
			Blood depot report		y

APPENDIX 3: JANUARY 2018 ACCREDITATION ASSESSMENT REPORTS

Follow Up of Audit Conducted in December 2017 – Review of Findings and Corrective Actions at NBTC

22nd January, 2018

PART 1: CRITICAL NON CONFORMANCES

The following form part of the critical non-conformances found at the NBTC at time of audit. Corrective actions should be closed out **within a week** of reporting.

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
Collection				
Donor identity not confirmed with donor - SOP not being followed. Donor Health Questionnaire (DHQ) does not follow the donor throughout the collection procedure, with critical labelling not checked against donor record at time of collection.	10.8.4 Blood samples taken from the donor during collection must be identified and linked to the donated unit and handled appropriately for testing SOP *TEC-COL-W004 – Whole Blood Collection* 5.1.1 Blood banking activities should be performed in a logical sequence to minimize the risk of errors and ensure effective cleaning and	DHQ must follow donor to the collection chair, where the donor identity is checked against the documentation before collection and labelling starts. All staff to re-read SOP ***TEC-COL-W004 – Whole Blood Collection***, and sign acknowledgement.	Paperwork still not consistently following the donor to the bedside. Staff need refresher training *Attach copy of re-signed SOP*	**Remains open**
More than one donor is bled at one time by the same staff member.		Configuration of donor floor should be one set of collection equipment per trolley, and each bed has its own trolley.	Configuration of donor floor set up remains the same, with multiple donors being bled at	**Remains open**

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
Donors are bled side by side at one time by the same staff member – this increases the risk of labelling errors and mixed up donor bags/samples.	maintenance and to minimise the risk of contamination.	Each trolley should be separated by a bed, so they are not side by side. Rearrange donor floor to the configuration stated above (bed/trolley, bed/trolley) to minimise error.	once by one staff member. *Attach photo of floor set up as recommended*	
Donor and Patient Grouping				
Reverse grouping not performed for donor ABO groups. SOP not being followed in the donor grouping area, where only forward groups were being performed to determine the donation blood group.	5.2.1.2 The serum or plasma is tested with A and B cells for the detection of expected antibodies SOP *TEC-IH-S002 – Manual ABO and Rh (D) Blood Grouping*	Commence reverse grouping on all blood donor samples immediately. Make reverse cells according to SOP *TEC-IH-S008 – In House Preparation of Red Cell Reagent.* All staff to re-read SOP ***TEC-IH-S002 – Manual ABO and Rh (D) Blood Grouping*** and sign acknowledgement.	**In place at time of audit**  IMG_0513.JPG  IMG_0513.JPG	**COMPLETE**
SOP not followed for reading and transcribing tube results. Staff were observed to read all tube reactions in the rack at once, and then record the results on the worksheet for all 15 samples at once, rather than individually, as described in their SOP.	SOP *TEC-IH-S001 – Basic Principles for Manual Methods*	Staff should follow the SOP instructions regarding reading of reactions, outlined in SOP ***TEC-IH-S001 – Basic Principles for Manual Methods,*** and as trained.	**In place at time of audit**	**COMPLETE**

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
ABO grouping tubes were unlabelled during testing. Tubes used for donor ABO grouping were not labelled with an appropriate donor/ donation identifier, as described in their SOP.	SOP *TEC-IH-S001 - Basic Principles for Manual Methods*	Staff should follow the SOP instructions regarding required labelling for testing, outlined in SOP ***TEC-IH-S001 - Basic Principles for Manual Methods*** and ***TEC-IH-S002 - Manual ABO and Rh (D) Blood Grouping***, and as trained.	Unlabelled tubes are still being used to perform donor groups. *Attach copy of re-signed SOP and training records*	**Remains open**
Group discrepancies are not being resolved. Blood group on the request form is being used as a confirmatory blood group, even though this group is unconfirmed. Blood group discrepancies are not actioned (ie: new sample not requested).	5.1.2 Discrepancies are resolved before the unit is released from quarantine and made available for transfusion 8.3.2 In the case of anomaly or error detection during the time of issue, the unit shall be withheld for further investigation and appropriate corrective and preventive action taken	Patient sample should be recollected and testing repeated to try to resolve the discrepancy. Senior staff to be informed/consulted for any discrepant results that need resolving before any blood is issued - Group O packed red cells should be used in emergency situations. Investigations to resolve patient blood group discrepancies should be recorded – develop an error log book to record errors and associated corrective actions.	Requires a national SOP to address investigating discrepant results, and forms to record investigation processes. *Attach copy of SOP outlining the procedure to investigate blood group discrepancies, and the error log developed to record corrective actions taken.*	**Remains open** TA has developed SOPs for investigating blood grouping anomalies and the viral algorithm to address TTI testing. A result sheet still needs development
Infection Control				

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
Stock segregation was not maintained (quarantined vs released units). Untested (quarantined) blood was moved to a fridge holding released units for crossmatch, but not segregated or labelled as untested. The primary fridge had malfunctioned, and therefore untested blood was moved to functional fridges containing released units. Unmarked fridges with mixed blood bags for usage in them are considered a critical citation, as the risk of issuing unusable units is extremely high. Segregation of usable units vs unusable units must always be observed.	4.4.4 The facility shall use designated storage areas to limit deterioration and prevent damage to materials, in-process and final components. The facility shall control access to such areas. 5.1.1 The facility shall have procedures for the appropriate segregation and quarantine of untested units or those waiting further testing	Immediate actions – segregate unreleased units from released units and label fridges accordingly until routine fridge for untested blood can be fixed and used. Develop SOP for the management of stock as part of contingency planning (in the event of equipment or power failures).	**In place at time of audit**	**COMPLETE**
Equipment and work areas were not cleaned/ disinfected to GMP standards.	5.1.1 Blood banking activities should be performed in a logical sequence to minimize the risk of errors and ensure	Clean areas daily using approved cleaning agents, which are rated hospital grade disinfectants, as per SOP and as trained.	Areas appeared cleaner, however no	**Remains open** Still no cleaning

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
Floors, walls, beds, shelves and general work spaces were observed to be dirty, with blood visible on some equipment and floor spaces. Cleaning records had not been completed.	effective cleaning and maintenance and to minimise the risk of contamination SOPs *GEN-OPS-W001 - General Cleaning GEN-WHS-S001 - Infection Control Standard*	Implement daily, weekly, monthly cleaning forms, ensuring tasks are completed and recorded as per required schedule in the SOP, and as trained. All staff to re-read SOP ***GEN-OPS-W001 - General Cleaning*** and ***GEN-WHS-S001 - Infection Control Standard***, and sign acknowledgement.	cleaning records were available upon request. *Attach copy of re-signed SOP, cleaning forms and training records*	records available.
Clinical waste not disposed or stored correctly and safely. • Biohazard waste was observed discarded/left unguarded and in a public space outside the building • The dedicated locked up room in the basement designed to store biohazard waste was instead used to store empty boxes • Leaking plasma bags were found under the benches in the crossmatch area, with	5.6.1 There must be a dedicated area for the safe disposal of infectious waste SOP *GEN-WHS-S001 - Infection Control Standard*	Chute room should be emptied of all non-infectious materials and waste (boxes etc), and room made for infectious and clinical waste to be stored until it is collected/incinerated. All infectious and clinical waste must be placed in the lower floor chute room, and secured by the roller door, as per design requirements. Staff were instructed to use clear containers with bleach in it to differentiate and decontaminate waste consumables produced in the TTI lab, such as tips and container waste from clean and usable items (such as gloves). All staff to re-read SOP regarding waste management, in ***GEN-WHS-S001 - Infection Control Standard.***	**In place at time of audit**	**COMPLETE**

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
plasma leaking on the floor • A glove box in the TTI section was being used to store and dispose of infectious tips and waste after infectious disease screening – No segregation or labelling between useable consumables and infectious waste - ***Extremely high risk of staff or visitor reaching into the box to get gloves, and exposing them to infectious biological material.*				
Food/drink found in GMP laboratory areas. Drinks were observed in GMP areas where blood is collected/handled.	4.4.5 Refrigerators or freezers used for blood storage shall contain only donor blood, blood specimens, reagents or blood components and no other items, such as food stuffs. *GEN-WHS-S001 - Infection Control Standard*	Food/drink is NOT to be consumed in any GMP/laboratory areas – to be discussed with all staff at a staff meeting. All staff to re-read SOP ***GEN-WHS-S001 - Infection Control Standard***, and sign acknowledgement.	Food and drink found in the reagents fridge in the components laboratory. Food found on the crossmatch bench. *Attach copy of re-signed SOP and a copy of the meeting minutes.*	**Remains open** Design a "No Food Area" sign for the doors of GMP areas.

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit 22nd Jan, 2018	Status
Collected blood is currently being stored in an unsecured area. Walk in fridge for WIP in components area remains out of order. The blood is currently being stored in the walk in fridge in outdoor basement level, in an unsecured and public space, easily accessible by anyone.	4.4.4 The facility shall use designated storage areas to limit deterioration and prevent damage to materials, in-process and final components. The facility shall control access to such areas.	Recommend the fridge is locked to ensure blood is secured, and to reduce the risk of blood being taken or being accessible to the general public. Sight orders/plans to have the storage walk in refrigerator in the components laboratory fixed.	The walk in fridge in the basement area had been locked, however access to laboratory storage areas remains unsecured.	**Remains open**

PART 2: OTHER FINDINGS

The following form part of other findings cited against each standard at the NBTC at time of audit, which can range in classification from *Major* to *Pass.*

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
Section 2: Blood Donor Management				
2.1 Pre-donation education is performed that includes information about the donation process and the risk of	Unassessed – contact person unavailable			

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
transmission of infectious diseases through blood transfusion.				
2.1.1 Populations that are at low risk for transfusion transmitted infections have been identified.	Unassessed – contact person unavailable			
2.1.1 There is a defined facility plan to progress towards 100% non-remunerated voluntary blood donation.	Unassessed – contact person unavailable			
2.1.2.1 There is a plan in development to encourage repeat (regular) donors.	Unassessed – contact person unavailable			
2.1.4 Donors are recognized for their donations using incentives that do not discourage honest responses to screening questions prior to donation.	Donor refreshments and acknowledgment tokens (t-shirts, pins, certificates) are used to recognise VNRBD and repeat donors	Pass	N/A	N/A
2.2.1 Donor selection criteria are available and in use. Donors meet requirements with regard to age, weight, blood pressure, pulse and haemo-globin / haematocrit.	Donor Selection Guidelines were found in the interview rooms and in use	Pass	N/A	**Changed from Fail to Pass**
2.2.2 Guidelines are in use for the deferral of potential donors who do not meet the selection criteria for medical and surgical conditions, medications and	Donor Selection Guidelines were found in the interview rooms and in use	Pass	N/A	**Changed from Fail to Pass**

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
exposure to potential transfusion transmissible infections.				
2.2.3 Arrangements are in place for assisting donors with special needs.	No policy or procedure available for management of donors with special needs.	Fail	Develop a policy to manage donors with special needs.	**Minor** – may impact donor experience
2.3 A donor health history questionnaire is used.		Pass	N/A	N/A
2.3.1 A medical history questionnaire (in a language which is understood) is completed by each donor prior to donation. Donors are informed of any medically significant abnormality detected.		Pass	N/A	N/A
2.3.2 A private interview is conducted with each donor.		Pass	N/A	N/A
2.4.1 Information is provided at pre donation counselling.	The Donor Counselling Guidelines which cover this task have not yet been distributed, and will require staff training.	Fail	Finalise and distribute the Donor Counselling Guidelines as soon as possible, with associated training to all sites.	**Major** – may impact accuracy of donor responses to the questionnaire which can affect the screening process and safety of the donation.
2.4.2 Written consent is obtained from the donor prior to donation.		Pass	N/A	N/A
2.4.3 There is a mechanism in place for the confidential exclusion of donation (CUE).	The Donor Counselling Guidelines which cover this task have not yet been distributed, and will require staff training.	Fail		**Major** – may have an impact on blood safety if high risk donors don't know to inform the BTC after donation of any

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
				previously undisclosed risk factors.
2.5.1 Donors counselled confidentially about any significant abnormality detected during testing.		Pass	N/A	N/A
2.5.2 When counselling services are not available, facility refers donors to appropriate external medical services		Pass	N/A	N/A
Accreditation Standard Assessed	**Report Findings 22nd Jan, 2018**	**Pass /Fail**	**Recommendation / Evidence**	**Citation Classification / Status**
Section 3: Collection of Blood from Donors				
3.1.1 Blood is collected using a closed system.		Pass	N/A	N/A
3.1.2 Blood collection equipment guaranteed pyrogen-free by manufacturer.		Pass	N/A	N/A
3.1.3 Suppliers of blood collection equipment qualified.	Outside NBTC scope of control.	Fail	NBTC have limited selection of suppliers. They are supplied by the MoH, who use their own internal procurement policies to procure reagents/consumables.	N/A

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
			Current supplies are from reputable brands.	
3.1.4 Collection equipment is single use only.		Pass	N/A	N/A
3.2 The blood container is inspected prior to collection.		Pass	N/A	N/A
3.2.1 The venepuncture site is disinfected.		Pass	N/A	N/A
3.2.2 Blood is collected by a single venepuncture with a continuous flow of blood.		Pass	N/A	N/A
3.3 Blood specimens are collected at the same time as the blood collection. Specimens are labelled before the donation begins and are re-identified with the blood container immediately after filling.	Samples are labelled prior to collection, however re-identification of the donor does not occur after filling the tube, as the paperwork still does not follow the donor.	Fail	Re-identification of donor must take place by asking donor details and checking with the paperwork once the samples are filled with blood.	**Remains open** **Major –** high risk of mislabelling or mix up of tubes, leading to incorrectly tested donations.
3.3.1 Each specimen is labelled using a system that enables traceability back to the donor and to the recipient/ patient.		Pass	N/A	N/A
3.3.2 Integral pilot tubing is used for subsequent compatibility testing.		Pass	N/A	N/A
3.4 The volume of blood collected is proportionate to the volume of anticoagulant.	Collection monitor is used to weigh the collection volume to within the specifications of the blood bags. No logs for	Intermediate	Require equipment maintenance logs of the collection monitors with calibration and validation details	**Changed from Pass to Intermediate (Minor)** – may affect the initial volume of the whole blood being collected.

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
	equipment maintenance/calibration			
3.4.1 The blood is gently agitated during collection and is sufficient to ensure that anticoagulant and blood are properly mixed.		Pass	N/A	N/A
3.5 After collection, the blood is stored under conditions appropriate for the components to be made from it.		Pass	N/A	N/A
3.6 Resources are available and personnel trained in the management of donor reactions at mobile and fixed sites.		Pass	N/A	N/A
Accreditation Standard Assessed	**Report Findings 22nd Jan, 2018**	**Pass /Fail**	**Recommendation / Evidence**	**Citation Classification / Status**
Section 4: Handling, Transportation and Storage				
4.1 Blood and blood components are handled, stored and transported in a manner that prevents damage, limits deterioration and meets specified requirements.	Transport conditions are not monitored.	Fail	Blood is mostly handled according to specification, and these are included in various component manufacturing SOPs Cold chain remains an area for further development. Container packing and consignment checking SOPs to be developed based on validation data.	**Remains open** **Major** – transport conditions are unknown and could pose a risk to blood product quality.
4.2 Following collection blood is placed in containers that allow for cooling towards +2°C to +10°C unless platelets are to be prepared, in which case blood	Units from mobiles are packed with ice bricks for transport.	Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
donations are cooled towards +22°C until arrival at the processing laboratory.				
4.4.1 Storage devices shall have the capacity and design to ensure that the correct temperature is maintained.	Storage equipment used is specialised for blood storage, and equipped with temperature displays, recording and alarms.	Pass		
4.4.2 Refrigerators, freezers, and platelet incubators have their temperature either continuously monitored or monitored at least 3 times at regular time intervals over 24 hours.	Temperatures are not recorded consistently.	Fail	Standardised Equipment and Room Temperature logs have now been developed, to be distributed by the NBTC document management team. To be put into use and used consistently.	**Remains open** **Minor** – temperature excursions which could impact product quality may be missed without continuous monitoring.
4.4.4 The facility shall use designated storage areas to limit deterioration and prevent damage to materials, in-process and final components. The facility shall control access to such areas.	Entry into storage areas, or areas that hold storage equipment remains unsecured.	Fail	Secure areas which contain blood and blood products.	**Remains open** **Major** – allows public access to restricted areas, a risk to blood products.
4.4.5 Refrigerators or freezers are not used for storage of food stuffs or any other non-clinical materials.	Refer to Part 1: Critical Non Conformances – food found in GMP areas.	Fail	Refer to Part 1: Critical Non Conformances – food found in GMP areas.	Refer to Part 1: Critical Non Conformances – food found in GMP areas.
4.4.6 The facility shall have procedures to maintain blood and blood components at the required	In the event of a power failure, a generator will provide back up power. No contingency procedures exist.	Intermediate	Develop a procedure to outline the use of the back up generator, and contingency in the event of equipment failure.	**Minor** – the back up generator will keep up power supply to the NBTC. Need a process to

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
temperature, in the event of failure of power or equipment.				move critical items in the event of equipment failure.
4.5 Storage devices for blood and blood components are equipped with alarms.		Pass		
4.5.1 The alarm is set to activate under conditions that will allow timely action to be taken before blood or blood components reach an unacceptable temperature.	Alarm set points were observed set as required. Alarms are not regularly checked, and some had been turned off.	Fail	Requires equipment maintenance plan for checking alarms, and repairing those not working.	**Changed from Intermediate to Major –** risk to product when alarm systems are switched off.
4.5.3 There is a process for immediate action when the alarm is activated. Action taken is documented.	There is no procedure, record forms or evidence of actioned alarms.	Fail	Develop SOP/log for alarm actioning.	
4.6 Containers used for the transportation of blood and blood components maintain the required temperatures.	Transport conditions are not logged. Validation results are still pending.	Intermediate	Finalise the validations performed as part of the relocation. Use temperature monitoring in the interim to log transport temperature.	**Minor** – temperature monitors can be used to monitor transport conditions. Interim validation results suggest temperature is maintained under current packing configuration.
4.6.1 The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges.	Evidence of transport conditions being checked or logged do not exist.	Fail	Put consignment form developed into use.	**Major** – transport conditions are not verified by staff, risking the quality of products being used after transport.

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
Section 5: Testing of Donated Blood				
5.1 Blood group serology and testing for infectious diseases is carried out on every unit of whole blood or apheresis unit collected.		Pass		
5.1.1 The facility has procedures for the appropriate segregation and quarantine of untested units or those waiting further testing.		Pass		
5.1.2 Discrepancies are resolved before the unit is released from quarantine and made available for transfusion.	Algorithm being followed to reach a final conclusion for TTI status/resulting.	Pass		**Changed from Fail to Pass**
5.2 Records of testing for blood groups are maintained.		Pass		
5.2.1 ABO and RhD group shall be tested at each donation. In new donors, the ABO and RhD group shall be confirmed by performing two independent determinations prior to transfusion. In repeat donors, the ABO and RhD group obtained shall be compared with previous records from the same donor and shall concur.		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
5.2.1.2 The ABO group is determined for each collection by testing the red cells with anti-A and anti-B reagents.		Pass		
5.2.1.3 The RhD type is determined with anti-D reagent. If blood is initially typed as RhD negative it is further tested to detect weak D. When the test for weak D is positive, the unit is labelled as Rh positive. When the tests for RhD and weak D are negative, the unit is labelled as Rh negative.	No record or evidence of Weak D testing	Fail	Commence testing for Weak D on units initially grouped as RhD negative, to determine the final conclusive Rhesus status. Record the results on the donor grouping worksheet.	**Major** – a unit could be labelled as Rh Neg and transfused to a Rh Neg patient when it is actually weakly Rh Pos.
5.2.2. Group O donations shall be tested for ABO antibodies of a high titre i and whole blood units found to contain high titre allo-agglutinins shall be labelled as such and issued only to group O patients.	Titre testing not performed	Fail	Implement a testing method to detect and label high titre Group O units for whole blood and plasma. To minimise risk, issuing group identical plasma products to Group O patients addresses this issue.	**Minor –** Group specific units are currently used for patients, so the risk of reaction is low, regardless of titre results.
5.2.2.1 Donations from which the plasma shall not be transfused, need not be tested for high titre allo-agglutinins.	Titre testing not performed	Fail		
5.2.2.2 Whole blood donations converted into red cell concentrates by removal of most	Titre testing not performed	Fail		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
of the plasma need not be labelled high titre.				
5.2.2.3 Group O plasma containing high titre allo-agglutinins shall be labelled as such and transfused only to group O patients	Titre testing not performed	Fail		
5.2.3. Serum or plasma from donors is tested for unexpected antibodies using a method known to detect clinically significant antibodies. When these are detected, plasma from these units is not used for transfusion.	Plasma is fully AHG crossmatched prior to issue.	Pass		
5.3.1 As a minimum, the following tests are performed on a blood specimen taken at the time of collection:				
5.3.1.1 HIV: anti-HIV-1, anti-HIV-2.		Pass		
5.3.1.2 HBV: HBsAg		Pass		
5.3.1.4 Syphilis: VDRL or anti-T. pallidum.		Pass		
Accreditation Standard Assessed	**Report Findings 22nd Jan, 2018**	**Pass /Fail**	**Recommendation / Evidence**	**Citation Classification / Status**
Section 6: Blood Component Production				
6.1 Methods that ensure the quality and safety of components,		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
including aliquots and pooled components, are employed.				
6.1.1 Blood components are separated from whole blood no more than 24 hours after collection.	Components Record Form not consistently used, so no record of processing time.	Fail	Commence using the component form to record dates and times components are processed and put into storage.	**Major** – no record of products meeting or not meeting specifications.
6.1.2 The expiry date of any component is calculated by considering the day of donation as day zero.		Pass		
6.1.3 The sterility of all components is maintained. If the closed system is compromised, there is evidence of a process to ensure that components are expired 4 hours from the time of opening.	Blood mostly remains in a closed system, however it was noted that in emergency situations a whole blood bag will sometimes be cut open to remove plasma and convert it to a packed red cell. No procedure exists to manage this process, and no system is used to identify a compromised pack.	Fail	Record reduced expiry date on unit and on Components record form once a unit is open.	**Major** – high risk of bacterial contamination.
6.2.1 The component is physically inspected for container integrity and normality of appearance prior to release. Action is taken if anomalies or errors are detected.	No record or discard log evidence to demonstrate this occurs.	Fail	Discard Log has now been developed – to be distributed by the NBTC document management team and put into use by the laboratory head.	**Major** – a clotted or haemolysed unit could be issued and transfused if not inspected prior to issue.
6.3.1 All blood and blood components are accurately		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
labelled using clear and legible labels that adhere firmly to pack surfaces at the range of temperatures experienced.				
6.3.2 Label(s) do not interfere with inspection of the contents or normal function of the container. Additional labels affixed do not obscure/cover existing labels.		Pass		
6.3.3 The facility shall use a numeric or alpha-numeric system that will make it possible to:		Pass		
6.3.3.1 Uniquely identify every component and its status at any stage during process.		Pass		
6.3.3.2 Trace any unit of blood or component from source to final disposition and recheck records applying to the specific unit.	Components Record Form not consistently used to log components made.	Intermediate	Commence using the component form to record dates and times components are processed and put into storage.	**Minor** – unit can be alternatively traced between collection and issue
6.3.4 The numeric or alphanumeric identification on the label is applied by the collecting facility to each unit of blood and/or its components.		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
6.3.5 After processing the blood, a final label shall contain the following information, as a minimum:				
6.3.5.1 Name of the component.	The name of the component is not logged on the unit, nor consistently on the components record form.	Fail	Commence writing the name of the component on the unit as part of routine labelling. Develop a release labelling SOP.	**Major** – unable to identify between a red cell or whole blood, which could lead to a transfusion reaction if crossing groups
6.3.5.2 The unique numeric or alphanumeric identification.		Pass		
6.3.5.3 The date of collection of the blood or component from the donor.		Pass		
6.3.5.6 Storage and transport temperature.		Pass		
6.3.5.7 Expiry date, and time where appropriate.		Pass		
6.3.5.8 The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required).		Pass		
6.3.5.9 Name of the facility.	Barcode is unique to NBTC and indicates location of unit.	Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
Accreditation Standard Assessed	**Report Findings 22nd Jan, 2018**	**Pass /Fail**	**Recommendation / Evidence**	**Citation Classification / Status**
Section 7: Receipt, Ordering, Selection and Issuing of Blood and Blood Components				
7.1.1.1 All incoming blood and blood components are checked for component integrity, expiry date, group and temperature on receipt.	Evidence of transport conditions being checked or logged do not exist.	Fail	Put consignment form developed into use.	**Remains open** **Major** – transport conditions are not verified by staff, risking the quality of products being used after transport.
7.1.1.2 There are written procedures for the receipt and inspection. Any discrepancies are reported to the collecting facility and are resolved before the units are used.		Fail		
7.2.1 All requests for blood are authorized by a medical practitioner or other authorized healthcare professional.		Pass		
7.2.2 The request form for blood or blood components accompanies the recipient's blood specimens, is legible and includes the following information:		Pass		
7.2.2.1 Recipient's given name and surname.		Pass		
7.2.2.2 Hospital number (or second identifier, if not available).		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
7.2.2.3 Date of birth, sex, hospital, ward.		Pass		
7.2.2.4 Name of individual ordering blood.		Pass		
7.2.2.7 Date and time the blood is required.		Pass		
7.2.2.9 Name and signature of the individual completing request form.		Pass		
7.2.2.10 Date and time the request form was completed.		Pass		
7.2.3 The individual taking the recipient's specimen shall label the specimen with at least the following information:				
7.2.3.1 Recipient's given name and surname.		Pass		
7.2.3.3 Name of hospital and ward.	Insufficiently labelled samples	Fail	Further training of nurses and communication with the HTC's is recommended to meet minimum labelling requirements. Rejection of samples should also be enforced, with sample acceptance criteria included in the crossmatching SOP. Implement the system Siem Reap employs.	**Major** – no assurance that the sample belongs to the correct patient, who will be transfused with units of blood.
7.2.3.4 Date taken.		Fail		
7.2.3.5 Name or signature of individual taking the blood specimen.		Fail		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
7.2.4 The request form and blood specimens which are received in the laboratory are reviewed. In case of discrepancy, incomplete forms, unsuitable specimens, or doubt, the specimen is not used; a new specimen and request form is requested and used.	No records showing rejection or request for new samples	Fail	Rejection of samples should also be enforced, with sample acceptance criteria included in the crossmatching SOP. Implement the system Siem Reap employs.	**Major** – no assurance that the sample belongs to the correct patient, who will be transfused with units of blood.
7.3.1.1 Recipients receive whole blood and red blood cell-containing components which are ABO compatible.		Pass		
7.3.1.2 RhD negative recipients receive RhD negative whole blood or red blood cell-containing components.	Group O is used. No procedure available outlining the process in the event Rh Neg units not available.	Intermediate	Develop a procedure to describe what units to use in the event the correct ones are not available.	**Minor** – Group O is routinely used
Accreditation Standard Assessed	**Report Findings 22nd Jan, 2018**	**Pass /Fail**	**Recommendation / Evidence**	**Citation Classification / Status**
STANDARD Section 8: Compatibility Testing				
8.1 Each blood specimen submitted is tested for ABO group and RhD type.		Pass		
8.2.1 For compatibility testing a specimen of the recipient's serum or plasma is compatibility tested against a specimen of the donor's red cells from an originally		Pass		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
attached whole blood segment before administration				
8.2.1.1 A historical record of ABO group and Rh type is reviewed and compared to current records. Discrepancies are investigated and action taken before a unit is issued for transfusion.	Electronic system not in place, making historical lookback difficult using a paper based system. Differences in blood groups from the request form are not investigated.	Fail	Include database system upgrade to include crossmatch records. Request a repeat sample when blood group variations occur between sample tested and group on the request form. Test sample twice using different methods or reagents.	**Minor –** the sample can be tested twice to confirm blood group.
8.2.1.2 During the compatibility testing the detection of ABO incompatibility is performed.		Pass		
8.2.3 A blood transfusion record is completed for each recipient and includes all units of blood or components issued, indicating the:	The blood issue book was reviewed. Two days' worth of crossmatch information was incomplete. It was also observed that in some cases it was not signed by the person performing the cross match or issuing the blood. It was not co-signed by the person collecting the blood.	Fail		**Remains open** **Major –** insufficient crossmatch records impede traceability.
8.2.3.1 Recipient's name.		Pass		
8.2.3.2 Hospital identification number.	Not consistent – only when available and provided by hospital is it logged.	Intermediate		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
8.2.3.3 Recipient ABO group and RhD type, if applicable.		Pass		
8.2.3.5 Donor ABO group and RhD type.		Pass		
8.2.3.7 Name/signature of the individual who performed the compatibility testing.		Pass		
8.2.3.8 Date of issue for transfusion.		Pass		
8.2.4 A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:	No unit labelling is used for crossmatched and issued units.		NBTC should introduce printed labels for issued blood packs using the recently received zebra printers. The label should include: recipients first and last name, hospital name and number, ABO and Rh type of recipient, date of compatibility test, name and signature of person who performed the compatibility test.	**Remains open** **Major** – the unit of blood is unidentifiable and there is a high risk it could be transfused to the incorrect patient.
8.2.4.1 Recipient's given name and surname.		Fail		
8.2.4.2 Hospital name and number.		Fail		
8.2.4.3 ABO and RhD type of recipient.		Fail		
8.2.4.4 Date of compatibility test.		Fail		
8.2.4.5 Name/signature of individual who performed the compatibility testing.		Fail		

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
8.2.5 The recipient's specimens are stored at +2°C to +6°C for at least 5 days after the transfusion.	Samples were found stored under the bench at room temperature	Fail	A dedicated sample fridge needs to be used to store samples for 5 days.	**Minor** – samples should be stored at 2-6°C to maintain integrity should further testing or investigations need to be done.
8.3.1 At the time a unit is issued, there shall be a final check of facility records and each unit of blood or blood component. Verification shall include:				
8.3.1.2 The intended recipient's two independent identifiers, as well as ABO group, and RhD type.		Pass		
8.3.1.3 The donation identification number, the donor ABO group, and, if required, the RhD type.		Pass		
8.3.1.5 The date and time of issue.		Pass		
8.3.1.6 Name/signature of individual who releases the blood component.		Pass		
8.3.1.7 Name/signature of individual taking delivery of the blood component, if applicable.	Crossmatch logs are not double checked or co-signed by the person collecting the blood.	Fail	Have a section in the log for the collector/nurse or lab staff to sign.	**Major** – increased risk of wrong blood to wrong patient.

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
8.3.1.8 Visual inspection of blood and blood component.	No record or discard log evidence to demonstrate this occurs.	Fail	Discard Log has now been developed – to be distributed by the NBTC document management team and put into use by the laboratory head.	**Major** – a clotted or haemolysed unit could be issued and transfused if not inspected prior to issue.
8.3.2 In the case of anomaly or error detection during the time of issue, the unit is withheld for further investigation and appropriate corrective and preventive action taken.	No records exist to log investigations or corrective actions.	Fail	Develop a log to monitor investigative steps and corrective actions.	**Major** – lack of traceability increases risk to patient outcomes.
8.4.1 Massive Transfusion:				
8.4.1.1 The facility has a procedure regarding compatibility testing when, within 24 hours, a patient has received an amount of blood or blood components approximating the patient's total blood volume.	Procedures don't exist to manage Massive transfusion	Fail	Develop procedures which describe the process for dealing with massive transfusion and emergency situations.	**Major** – risk of patient mortality from bleeding if crossmatch is not performed correctly in an emergency situation.
8.4.2 NEONATAL Transfusion (i.e. for inants under 4 months):				
8.4.2.1 Only anti-A and anti-B reagents are required to determine the neonatal ABO group. The RhD type is determined as previously described.	Procedures don't exist to manage transfusion of neonates.	Fail	Develop laboratory procedures for performing crossmatching for neonates.	Major – risk neonatal complications if crossmatching is not performed correctly

Accreditation Standard Assessed	Report Findings 22nd Jan, 2018	Pass /Fail	Recommendation / Evidence	Citation Classification / Status
8.4.2.1.1 ABO group compatible red cell components are issued.		Fail		
8.4.2.1.2 RhD compatible red cell components are issued.		Fail		
8.4.2.5 If a non-group O neonate is to receive ABO group specific red cells that are not compatible with the maternal ABO group, the neonate's specimen only is used for compatibility testing.		Fail		

Follow up Audit Report – From Findings at Kampong Cham BTC at Dec 2017 Audit

26th January, 2018

PART 1: CRITICAL NON CONFORMANCES

The following form part of the critical non-conformances found at Kampong Cham at time of audit. Corrective actions should be closed out **within a week** of reporting.

Critical Finding/Description	Accreditation standard reference	Recommendations for corrective action	Follow Up/Corrective Action Progress Audit **date*	Status **date*
Blood Storage				
A unit identified as positive for HBsAg was found in the blood fridge used to store untested blood. The unit had been collected and initially tested three days prior, and remained undiscarded. The label had been marked with a red cross to distinguish it as unusable. Non-compliance in following standard procedure, *TEC-SER-R002 - Single Assay Viral Testing Algorithm*	5.1.1 The facility has procedures for the appropriate segregation and quarantine of untested units or those waiting further testing.	Apply appropriate segregation measures for any units identified as initially reactive for any TTI. 1. Establish a dedicated and well signed area for quarantined reactive units, to be stored until confirmatory testing is complete. 2. Once test results are complete, and a TTI status has been reported, action the unit immediately (discard or put into stock). 3. Refresh staff to follow the algorithm, which states to quarantine initially reactive units immediately.		

PART 2: OTHER FINDINGS

The following form part of other findings cited against each standard at Kampong Cham at time of audit, which can range in classification from *Major* to *Pass.* This follow up audit acts to check corrective actions implemented against the citations from previous report, and identifies any new non-conformances.

Accreditation Standard Assessed	Findings 11th Dec 2017	Pass /Fail	Recommendation / Evidence	Citation Classification	Status 26th Jan 2018
Section 2: Blood Donor Management					
2.1.2.1 There is a plan in development to encourage repeat (regular) donors.	4 events/year to celebrate regular donors to maintain retention. Records are maintained of regular donors.	Pass	Photo 1 Education materials to encourage return donation still in progress – to be distributed.	N/A	Maintained
2.2.1 Donor selection criteria are available and in use. Donors meet requirements with regard to age, weight, blood pressure, pulse and haemo-globin / haematocrit.	Donor Selection Guidelines (DSG) were available in the interview rooms. Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria.	Pass	Photo 2, 3 and 4	N/A	Maintained
2.2.2 Guidelines are in use for the deferral of potential donors who do not meet the selection criteria for medical and surgical conditions, medications and exposure to potential transfusion transmissible infections.	Donor Selection Guidelines were available in the interview rooms. Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria and high risk behaviour.	Pass	An approved medications list has now been added to the Donor Selection Guidelines. **NBTC activity** - Distribute the updated Donor Selection Guidelines with the Medications List added, accompanied with training.	N/A	**Changed from Intermediate to Pass**
2.3.1 A medical history questionnaire (in a language which is understood) is completed by each donor prior to donation. Donors are informed of any medically significant abnormality detected.	Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria and high risk behaviour.	Pass	Photo 6,7 and 8 Records are locked in a secured store room in a confidential manner.	N/A	Maintained

2.3.2 A private interview is conducted with each donor.	Room shows evidence of use and records	Pass	Photo 2,3 and 4	Practice was not observed as no donors were present at time of audit.	Maintained
2.4.2 Written consent is obtained from the donor prior to donation.	One DHQ was found without a signature	Pass	Photo 6, 7 and 8	N/A	**Changed from Intermediate to Pass**
2.4.3 There is a mechanism in place for the confidential exclusion of donation (CUE).	Not yet trained in CUE. It has been included in the Donor Counselling Guidelines (DCG) in the pre-donation counselling section. These have not yet been distributed as the translated version is still in review.	Fail	Donors currently are not informed as part of pre donation counselling that they can call the centre to exclude a potentially at risk unit. Recommend distribution and training of the DCG as soon as possible.	**Major** – may have impact on the safety of blood supply if at risk donors don't know to inform the BTC of any potential risk after donation.	**NATIONAL Remains Open** Will be closed out when the Donor Counselling Guidelines are distributed with training.
2.5.1 Donors counselled confidentially about any significant abnormality detected during testing.	Records for referral of HIV and Syphilis reactive donors only. No logs for Hep B and C donors counselled and referred. They do counsel and refer to local clinic/GP, but no SOP or records logged for the process.	Pass	Photo 13 Recommend adding a column to log to include Hep B and C donors counselled, and for donor to co-sign with the counsellor BTC staff.	N/A	**Changed from Major to Pass** Recommendat-ion applied.
2.5.2 When counselling services are not available, facility refers donors to appropriate external medical services					
Section 3: Collection of Blood from Donors					
3.1.1 Blood is collected using a closed system.	Site uses standard approved bags and collection systems.	Pass	N/A	N/A	Maintained

3.2.1 The venepuncture site is disinfected.	Sighted disinfecting site twice, as per collection SOP	Pass	N/A	N/A	Maintained
3.3 Blood specimens are collected at the same time as the blood collection. Specimens are labelled before the donation begins and are re-identified with the blood container immediately after filling.	Sighted at time of collection	Pass	N/A	N/A	Maintained
3.3.1 Each specimen is labelled using a system that enables traceability back to the donor and to the recipient/ patient.	Paperwork did not follow the donor to the bed so details could be checked with the donor.	Intermediate	Recommend following SOP by checking donor identity with the donor at the bedside.	**Minor** – donor container and specimen labelling occurs with donor at registration.	**Remains open** Was not observed at time of audit.
3.3.2 Integral pilot tubing is used for subsequent compatibility testing.	Site uses standard approved bags and collection systems with integral pilot sample pouches.	Pass	N/A	N/A	Maintained
3.4 The volume of blood collected is proportionate to the volume of anticoagulant.	Collection monitor is used to weigh the collection volume to within the specifications of the blood bags	Intermediate	Require equipment maintenance logs of the collection monitors with calibration and validation details	**Minor** – may affect the initial volume of the whole blood being collected.	**Remains open** No logs for equipment maintenance.
3.5 After collection, the blood is stored under conditions appropriate for the components to be made from it.	Blood is passed into a temperature controlled room for processing. Documented on the components log.	Pass	Photo 32 and 33	N/A	Maintained
3.6 Resources are available and personnel trained in the	SOPs were available upon request for collection processes	Pass	N/A	N/A	Maintained

management of donor reactions at mobile and fixed sites.	in the area the tasks are performed				
Section 4: Handling, Transportation and Storage					
4.1 Blood and blood components are handled, stored and transported in a manner that prevents damage, limits deterioration and meets specified requirements. 4.6.1 The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges. 7.1.1.1 All incoming blood and blood components are checked for component integrity, expiry date, group and temperature on receipt.	No SOPS or records were available to demonstrate how blood is packed, transported or received from mobiles.	Fail	Packing configuration SOPs and consignment forms should be implemented that capture packing time, donation numbers packed, unpacking time, checking of correct packing configuration and checking of units received	**Major** – lack of checking may result in out of temperature instances not being identified and can compromise blood safety.	**NATIONAL Remains Open** Container packing and checking SOPs to be developed based on validation data.
4.4.2 Refrigerators, freezers, and platelet incubators have their temperature either continuously monitored or monitored at least 3 times at	All temperature logs were up to date and included on all storage equipment sighted.	Pass	Photo 15 and 16	**OFI –** Standardised forms for temperature logging	**NATIONAL** Standardised Equipment and Room Temperature logs have now

regular time intervals over 24 hours.					been developed, to be distributed by the NBTC document management team.
4.4.4.1 There are designated storage areas for materials, in-process and final components.	Blood/red cells - sighted segregated storage areas, however not for when a sample is initially reactive. Plasma - untested is segregated from tested by freezer shelves only, as only one freezer works (photo 22). Reagents - in the critical store room are unsegregated between released vs unreleased kits. No quarantine SOP available.	Fail	Photo 19, 20 and 21 Create a dedicated storage space for units to be quarantined once identified as initially reactive and are during investigation. Place sign the shelf of the deep freezer for plasma segregation between untested and tested units. Add signage in the critical store room to distinguish between released reagents (acceptance criteria passed) vs unreleased reagents. Develop a record form which outlines the acceptance criteria for reagents so they can be signed off before placing in the designated released area/shelf. Develop a quarantine SOP to manage required segregation.	**Major** - a lack of clearly marked segregation can lead to confusion on which products are ok for use and may result in untested or quarantine blood products or reagents being released/used in error.	**Changed from Major to Critical Remains Open** Refer to *Part 1: Critical Non Conformances* for blood unit quarantining. Critical store room still requires segregated areas and appropriate reagent and consumable logging.

4.5.1 The alarm is set to activate under conditions that will allow timely action to be taken before blood or blood components reach an unacceptable temperature.	Alarm set points were observed set as required	Inter medi ate	Photo 23 Develop log for alarm actions and SOP on how to action out of limits alarms.	**Minor –** failing to action an alarm may result in loss of cold chain and storage requirements.	**NATIONAL Remains open** Alarms set correctly. Requires a national SOP for managing alarms.
Section 5: Testing of Donated Blood					
5.1.2 Discrepancies are resolved before the unit is released from quarantine and made available for transfusion.	No records of investigative process or results for donor TTI testing or blood grouping. Incompatibility records available showing positive crossmatches.	Pass	Photo 31 Algorithms were available. All discrepancies should be recorded including steps taken for their resolution. Siem Reap will offer KCM their forms as a standard record form to use.	**Minor** – while investigations are done according to the available algorithms, it is not currently being recorded.	**Changed from Intermediate to Pass** New form in use to log all test results according to algorithm.
5.2.1.3 The RhD type is determined with anti-D reagent. If blood is initially typed as RhD negative it is further tested to detect weak D. When the test for weak D is positive, the unit is labelled as Rh positive. When the tests for RhD and weak D are negative, the unit is labelled as Rh negative.	No weak D performed - no recording fields for weak D investigation - grouping is done all from the unit (tube segment, not donor)	Pass	Commence testing for Weak D on units initially grouped as RhD negative, to determine the final conclusive Rhesus status. Record the results on the donor grouping worksheet.	N/A	**Changed from Major to Pass** SOP for Weak D was referenced.
5.2.2. Group O donations shall be tested for ABO antibodies of a high titre and whole blood	No titre testing is done at this site	Fail	Implement a testing method to detect and label high titre	**Minor –** Group specific units are currently	**NATIONAL Remains open**

units found to contain high titre allo-agglutinins shall be labelled as such and issued only to group O patients.			Group O units for whole blood and plasma. To minimise risk, issuing group identical plasma products to Group O patients addresses this issue.	used for patients, so the risk of reaction is low, regardless of titre results.	Requires an additional procedure for testing.
5.2.3. Serum or plasma from donors is tested for unexpected antibodies using a method known to detect clinically significant antibodies. When these are detected, plasma from these units is not used for transfusion.	Currently only immediate spin crossmatching is being performed on FFP units for transfusion	Pass	Implement full minor crossmatch for the issue of compatible FFP units, to detect clinically significant unexpected antibodies which may be present in the donor plasma.	N/A	**Changed from Major to Pass** Plasma is now being fully crossmatched.
Section 6: Blood Component Production					
6.1.1 Blood components are separated from whole blood no more than 24 hours after collection.	Blood Components record form is being used which outlines the traceability of unit from collection to storage	Pass	Photo 32 and 33 Require logging the time of final storage on the components log form.	N/A	**Changed from Minor to Pass** Times have been added to the Blood Components Record Form
6.1.2 The expiry date of any component is calculated by considering the day of donation as day zero.		Pass	Photo 34	N/A	Maintained
6.3.3.2 Trace any unit of blood or component from source to final disposition and recheck		Pass	Photo 32 and 33 Use of components log and then issue logs when crossmatched	N/A	Maintained

records applying to the specific unit.			can trace any unit from collection to issue.		
6.3.5.1 Name of the component.	The name of the component type was not on the blood unit	Fail	Photo 35 Include the component type/name on the unit	**Minor** – may not distinguish between red cells and whole blood.	**Remains open** Units did not have component type on label
6.3.5.2 The unique numeric or alphanumeric identification.		Pass	Photo 35		Maintained
6.3.5.3 The date of collection of the blood or component from the donor.		Pass	Photo 35		Maintained
6.3.5.6 Storage and transport temperature.	Included on the bag label	Pass	Photo 35 Should be included on a printed label if they move to printed labels	**OFI** – to be included on printed label if move to using printed labels, according to component type.	Maintained
6.3.5.7 Expiry date, and time where appropriate.		Pass	Photo 35	**OFI** – include time of expiry	Maintained
6.3.5.8 The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required).		Pass	Photo 35		Maintained
6.3.5.9 Name of the facility.	Included on the barcode donation ID label	Pass	Photo 35		Maintained
Section 7: Receipt, Ordering, Selection and Issuing of Blood and Blood Components					

7.2.1 All requests for blood are authorized by a medical practitioner or other authorized healthcare professional.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2 The request form for blood or blood components accompanies the recipient's blood specimens, is legible and includes the following information:		Pass			Maintained
7.2.2.1 Recipient's given name and surname.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2.2 Hospital number (or second identifier, if not available).		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2.3 Date of birth, sex, hospital, ward.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2.4 Name of individual ordering blood.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2.7 Date and time the blood is required.	No required date and time – blood is only requested when immediately required.	Pass	Photo 32, 33, 39 and 40		**Changed from Intermediate to Pass**
7.2.2.9 Name and signature of the individual completing request form.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.2.10 Date and time the request form was completed.		Pass	Photo 32, 33, 39 and 40		Maintained
7.2.3.1 Recipient's given name and surname.		Pass			Maintained

7.2.3.3 Name of hospital and ward.	No other information contained on sample tubes other than name and age of patient.	Pass	Further training of nurses and communication with the HTC is recommended to meet minimum labelling requirements. Rejection of samples should also be enforced, with sample acceptance criteria included in the crossmatching SOP.	**Major** – no assurance that the sample belongs to the correct patient, who will be transfused with units of blood.	**Changed from Fail to Pass**
7.2.3.4 Date taken.		Fail			**Remains open** Patient samples are still being insufficiently labelled
7.2.3.5 Name or signature of individual taking the blood specimen.		Fail			
7.2.4 The request form and blood specimens which are received in the laboratory are reviewed. In case of discrepancy, incomplete forms, unsuitable specimens, or doubt, the specimen is not used; a new specimen and request form is requested and used.	No records showing rejection or request for new samples	Fail	Further training of nurses and communication with the HTC is recommended to meet minimum labelling requirements. Rejection of samples should also be enforced, with sample acceptance criteria included in the crossmatching SOP.	**Major** – no assurance that the sample belongs to the correct patient, who will be transfused with units of blood.	**NATIONAL Remains open** No formal process to log the management of incorrectly labelled samples
7.3.1.1 Recipients receive whole blood and red blood cell-containing components which are ABO compatible.	Records available showing compatibility and issue. Records also available showing incompatibility and not issued.	Pass	Photo 41	N/A	Maintained
Section 8: Compatibility Testing					
8.2.3 A blood transfusion record is completed for each recipient and includes all units of blood or components issued, indicating the:		Pass	Photo 41		Maintained
8.2.3.1 Recipient's name.		Pass		N/A	Maintained

8.2.3.2 Hospital identification number.		Pass		N/A	Maintained
8.2.3.3 Recipient ABO group and RhD type, if applicable.		Pass		N/A	Maintained
8.2.3.5 Donor ABO group and RhD type.		Pass		N/A	Maintained
8.2.3.7 Name/signature of the individual who performed the compatibility testing.		Pass		N/A	Maintained
8.2.3.8 Date of issue for transfusion.		Pass		N/A	Maintained
8.2.4 A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:	Labels are not currently attached to issued blood bags.	Intermediate	KCM should introduce printed labels for issued blood packs using the recently received zebra printers. The label should include: recipients first and last name, hospital name and number, ABO and Rh type of recipient, date of compatibility test, name and signature of person who performed the compatibility test.	**Minor** – Patient details hand written on the unit label.	**NATIONAL Changed from Major to Minor Intermediate Remains open** Requires a standard process for labelling crossmatched units

Follow up Audit Report – From Findings at Siem Reap BTC at Dec 2017 Audit

29th January, 2018

PART 1: CRITICAL NON CONFORMANCES

No critical non-conformances were identified during the assessment of Siem Reap Blood Centre.

PART 2: OTHER FINDINGS

The following form part of other findings cited against each standard at Siem Reap at time of audit, which can range in classification from *Major* to *Pass.* This follow up audit acts to check corrective actions implemented against the citations from previous report, and identifies any new non-conformances.

Accreditation Standard Assessed	Findings 15th Dec 2017	Pass /Fail	Recommendation / Evidence	Citation Classification	Status 29th Jan 2018
Section 2: Blood Donor Management					
2.1.2.1 There is a plan in development to encourage repeat (regular) donors.	Log book of regular donors, and information pamphlets to aid their return.	Pass	Photo 1-4	N/A	Maintained
2.2.1 Donor selection criteria are available and in use. Donors meet requirements with regard to age, weight, blood pressure, pulse and haemo-globin / haematocrit.	Donor Selection Guidelines (DSG) were available in the interview rooms. Includes summary of donation criteria on the desk. Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria.	Pass	Photo 5-6	N/A	Maintained

2.2.2 Guidelines are in use for the deferral of potential donors who do not meet the selection criteria for medical and surgical conditions, medications and exposure to potential transfusion transmissible infections.	Donor Selection Guidelines were available in the interview rooms. Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria and high risk behaviour.	Pass	An approved medications list has now been added to the Donor Selection Guidelines. **NBTC activity** - Distribute the updated Donor Selection Guidelines with the Medications List added, accompanied with training.	N/A	**Changed from Intermediate to Pass**
2.3.1 A medical history questionnaire (in a language which is understood) is completed by each donor prior to donation. Donors are informed of any medically significant abnormality detected.	DHQ completed, with donor refreshments voucher. Donor Health Questionnaires (DHQ) showed evidence of recording health check criteria and high risk behaviour.	Pass	Photos 9-13	N/A	Maintained
2.3.2 A private interview is conducted with each donor.	Room shows evidence of use and records. Room observed being used during audit, and stations assigned	Pass	Photo 14 and 15	N/A	Maintained
2.4.2 Written consent is obtained from the donor prior to donation.		Pass	Photos 9-13	N/A	Maintained
2.4.3 There is a mechanism in place for the confidential exclusion of donation (CUE).	Not yet trained in CUE. It has been included in the Donor Counselling Guidelines (DCG) in the pre-donation counselling section. These have not yet been distributed as the translated version is still in review.	Fail	Donors currently are not informed as part of pre donation counselling that they can call the centre to exclude a potentially at risk unit. Recommend distribution and training of the DCG as soon as possible.	**Major** – may have impact on the safety of blood supply if at risk donors don't know to inform the BTC	**NATIONAL Remains Open** Will be closed out when the Donor Counselling Guidelines are

				of any potential risk after donation.	distributed with training.
2.5.1 Donors counselled confidentially about any significant abnormality detected during testing.	Room used for private counselling. Record forms available at request of all donors referred.	Pass	Photo 16 and 17, and 18-22	N/A	Maintained
2.5.2 When counselling services are not available, facility refers donors to appropriate external medical services					Maintained
Section 3: Collection of Blood from Donors					
3.1.1 Blood is collected using a closed system.	Site uses standard approved bags and collection systems.	Pass	Photo 23-24 extra - cleaning records sighted, photo 25	N/A	Maintained
3.2.1 The venepuncture site is disinfected.	Sighted disinfecting site twice, as per collection SOP	Pass	Photo 28	N/A	Maintained
3.3 Blood specimens are collected at the same time as the blood collection. Specimens are labelled before the donation begins and are re-identified with the blood container immediately after filling.	Paperwork did not follow the donor to the bed so details could be checked with the donor. Tubes were pre labelled at the bedside	Pass	Recommend following SOP by checking donor identity with the donor at the bedside. Check about the requirement for pre-labelling tubes, and update SOP as required	N/A	**Changed from Minor to Pass** Observed at time of audit.
3.3.1 Each specimen is labelled using a system that enables traceability back to the donor and to the recipient/ patient.	No labelling for the tile grouping during donor registration and health check. Tube is labelled before collection	Pass	Photo 26 and 29 Label tile used to group the donor with donor details and reagent name, to minimise the risk of donor group mismatch.	N/A	**Changed from Minor to Pass** Have a new tile with permanent

					reagent labelling. They label with the donor number when tile grouping – observed at time of audit.
3.3.2 Integral pilot tubing is used for subsequent compatibility testing.	Site uses standard approved bags and collection systems with integral pilot sample pouches.	Pass	Photo 30	N/A	Maintained
3.4 The volume of blood collected is proportionate to the volume of anticoagulant.	Collection monitor is used to weigh the collection volume to within the specifications of the blood bags	Intermediate	Photo 31 Require equipment maintenance logs of the collection monitors with calibration and validation details	**Minor** – may affect the initial volume of the whole blood being collected.	**Remains open** No logs for equipment maintenance.
3.5 After collection, the blood is stored under conditions appropriate for the components to be made from it.	Blood is passed into a temperature controlled room for processing. Documented on the components log.	Pass	Photo 44	N/A	Maintained
3.6 Resources are available and personnel trained in the management of donor reactions at mobile and fixed sites.	SOPs were available upon request for collection processes in the area the tasks are performed	Pass	Photo 27	N/A	Maintained
Section 4: Handling, Transportation and Storage					
4.1 Blood and blood components are handled, stored and transported in a manner that prevents damage,	No SOPS or records were available to demonstrate how blood is packed, transported or received from mobiles.	Fail	Packing configuration SOPs and consignment forms should be implemented that capture packing time, donation numbers packed, unpacking time, checking	**Major** – lack of checking may result in out of temperature instances not	**NATIONAL Remains Open** Container packing and checking SOPs

limits deterioration and meets specified requirements. 4.6.1 The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges. 7.1.1.1 All incoming blood and blood components are checked for component integrity, expiry date, group and temperature on receipt.			of correct packing configuration and checking of units received	being identified and can compromise blood safety.	to be developed based on validation data.
4.4.2 Refrigerators, freezers, and platelet incubators have their temperature either continuously monitored or monitored at least 3 times at regular time intervals over 24 hours.	All temperature logs were up to date and included on all storage equipment sighted.	Pass	Photo 32	**OFI –** Standardised forms for temperature logging	**NATIONAL** Standardised Equipment and Room Temperature logs have now been developed, to be distributed by the NBTC document management team.

4.4.4.1 There are designated storage areas for materials, in-process and final components.	No extra freezer for plasma, use the bottom drawer for during testing, however not labelled, needs labelling. Reagents - in the critical store room are unsegregated between released vs unreleased kits. No quarantine SOP available.	Fail	Photo 33-36 Photo 41 - stock record sheets, given to hospital daily. Place sign the shelf of the deep freezer for plasma segregation between untested and tested units. Add signage in the critical store room to distinguish between released reagents (acceptance criteria passed) vs unreleased reagents. Develop a record form which outlines the acceptance criteria for reagents so they can be signed off before placing in the designated released area/shelf. Develop a quarantine SOP to manage required segregation.	**Minor –** Partially addressed. Lack of clearly marked segregation can lead to confusion on which products are ok for use and may result in untested or quarantine blood products or reagents being released/used in error.	**Changed from Major to Minor Remains open** Freezer segregation was addressed, and they have sufficient segregation of red cells. Critical store room still requires segregated areas and appropriate reagent and consumable logging.
4.5.1 The alarm is set to activate under conditions that will allow timely action to be taken before blood or blood components reach an unacceptable temperature.	Alarm set points were observed set as required	Intermediate	Photo 37 Develop log for alarm actions and SOP on how to action out of limits alarms.	**Minor –** failing to action an alarm may result in loss of cold chain and storage requirements.	**NATIONAL Remains open** Alarms set correctly. Requires a national SOP for managing alarms.
Section 5: Testing of Donated Blood					

5.1.2 Discrepancies are resolved before the unit is released from quarantine and made available for transfusion.	No records of investigative process or results for donor blood grouping. TTI investigative forms are used, mapping to algorithm results. Need to log discrepant blood group results for patients too, and have an investigations log	Pass	Photo 38-40, and Photos 50-51 Algorithms were available. Will add section to current worksheets for investigation of discrepant blood groups for donors and patients.	N/A	**Changed from Intermediate to Pass** New form in use to log all test results according to algorithm.
5.2.1.3 The RhD type is determined with anti-D reagent. If blood is initially typed as RhD negative it is further tested to detect weak D. When the test for weak D is positive, the unit is labelled as Rh positive. When the tests for RhD and weak D are negative, the unit is labelled as Rh negative.	No weak D performed - no recording fields for weak D investigation	Fail	Photo 42 - not recorded, possibly not performed Commence testing for Weak D on units initially grouped as RhD negative, to determine the final conclusive Rhesus status. Record the results on the donor grouping worksheet.	**Major –** a potentially Rh pos unit could be labelled as a Rh Neg and given to a Rh Neg patient, who may then go on to develop Anti-D.	**Remains open** Still no evidence of testing for Weak D
5.2.2. Group O donations shall be tested for ABO antibodies of a high titre i and whole blood units found to contain high titre allo-agglutinins shall be labelled as such and issued only to group O patients.	No titre testing is done at this site	Fail	Implement a testing method to detect and label high titre Group O units for whole blood and plasma. To minimise risk, issuing group identical plasma products to Group O patients addresses this issue.	**Minor –** Group specific units are currently used for patients, so the risk of reaction is low, regardless of titre results.	**NATIONAL Remains open** Requires an additional procedure for testing.
5.2.3. Serum or plasma from donors is tested for unexpected	Full crossmatching is being performed on FFP units for	Pass	Photo 43	N/A	Maintained

antibodies using a method known to detect clinically significant antibodies. When these are detected, plasma from these units is not used for transfusion.	transfusion, which will detect clinically significant unexpected antibodies that may be present in the donor plasma against patient red cells.				
Section 6: Blood Component Production					
6.1.1 Blood components are separated from whole blood no more than 24 hours after collection.	Blood Components record form is being used with times from collection to processing.	Pass	Photo 44	N/A	Maintained
6.1.2 The expiry date of any component is calculated by considering the day of donation as day zero.		Pass	Photo 44 and 46	N/A	Maintained
6.3.3.2 Trace any unit of blood or component from source to final disposition and recheck records applying to the specific unit.	Use of components log and then issue logs when crossmatched can trace any unit from collection to issue.	Pass	Photo 44	N/A	Maintained
6.3.5.1 Name of the component.		Pass	Photo 50	N/A	Maintained
6.3.5.2 The unique numeric or alphanumeric identification.		Pass	Photo 50	N/A	Maintained
6.3.5.3 The date of collection of the blood or component from the donor.		Pass	Photo 50	N/A	Maintained
6.3.5.6 Storage and transport temperature.	Included on the bag label	Pass	Photo 50	**OFI** – to be included on printed label if	Maintained

			Should be included on a printed label if they move to printed labels	move to using printed labels, according to component type.	
6.3.5.7 Expiry date, and time where appropriate.		Pass	Photo 50	**OFI** – include time of expiry	Maintained
6.3.5.8 The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required).		Pass	Photo 50	N/A	Maintained
6.3.5.9 Name of the facility.		Pass	Photo 50	N/A	Maintained
Section 7: Receipt, Ordering, Selection and Issuing of Blood and Blood Components					
7.2.1 All requests for blood are authorized by a medical practitioner or other authorized healthcare professional.		Pass	Photo 47	N/A	Maintained
7.2.2 The request form for blood or blood components accompanies the recipient's blood specimens, is legible and includes the following information:		Pass		N/A	Maintained
7.2.2.1 Recipient's given name and surname.		Pass	Photo 47	N/A	Maintained
7.2.2.2 Hospital number (or second identifier, if not available).		Pass	Photo 47	N/A	Maintained

7.2.2.3 Date of birth, sex, hospital, ward.		Pass	Photo 47	N/A	Maintained
7.2.2.4 Name of individual ordering blood.		Pass	Photo 47	N/A	Maintained
7.2.2.7 Date and time the blood is required.	No required date and time – blood is only requested when immediately required.	Pass	Photo 47	N/A	**Changed from Intermediate to Pass**
7.2.2.9 Name and signature of the individual completing request form.		Pass	Photo 47	N/A	Maintained
7.2.2.10 Date and time the request form was completed.		Pass	Photo 47	N/A	Maintained
7.2.3.1 Recipient's given name and surname.	Small form on the request form with nurse details collecting the sample - for id and traceability purposes	Pass	Photo 47 and 49	N/A	Maintained
7.2.3.3 Name of hospital and ward.		Pass			Maintained
7.2.3.4 Date taken.		Pass			Maintained
7.2.3.5 Name or signature of individual taking the blood specimen.		Pass			Maintained
7.2.4 The request form and blood specimens which are received in the laboratory are reviewed. In case of discrepancy, incomplete forms, unsuitable specimens, or doubt, the specimen is not used; a new specimen and request form is requested and used.	Reject samples, now the forms mean the nurses collect and label properly. Rejection is less and less. No record form. But should be in crossmatching SOP about sample acceptance criteria. To be included in crossmatch SOPs	Intermediate	Sample acceptance criteria to be included in the crossmatching SOP.	N/A	**NATIONAL Remains open** No formal process to log the management of incorrectly labelled samples

7.3.1.1 Recipients receive whole blood and red blood cell-containing components which are ABO compatible.	Records available showing compatibility and issue. Records also available showing incompatibility and not issued.	Pass	Photo 47	N/A	Maintained
Section 8: Compatibility Testing					
8.2.3 A blood transfusion record is completed for each recipient and includes all units of blood or components issued, indicating the:		Pass		N/A	Maintained
8.2.3.1 Recipient's name.		Pass		N/A	Maintained
8.2.3.2 Hospital identification number.		Pass		N/A	Maintained
8.2.3.3 Recipient ABO group and RhD type, if applicable.		Pass		N/A	Maintained
8.2.3.5 Donor ABO group and RhD type.		Pass		N/A	Maintained
8.2.3.7 Name/signature of the individual who performed the compatibility testing.		Pass		N/A	Maintained
8.2.3.8 Date of issue for transfusion.		Pass		N/A	Maintained
8.2.4 A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:	Labels are not currently attached to issued blood bags.	Intermediate	SR should introduce printed labels for issued blood packs using the recently received zebra printers. The label should include: recipients first and last name, hospital name and number, ABO and Rh type of recipient, date of compatibility test, name and	**Minor** – Patient details hand written on a paper towel and attached to the unit.	**NATIONAL Changed from Major to Minor Intermediate Remains open** Requires a standard process for

			signature of person who performed the compatibility test.		labelling crossmatched units

PROJECT TEAM CONTACT DETAILS

Australian Red Cross Blood Service

290 Wellington Street, Perth Western Australia, 6000

Email: internationalservices@redcrossblood.org.au