Ghana

National Blood Service

GHANA

Collaboration Program with the Private Sector for Disseminating Japanese Technology for Prevention of Transfusion Transmitted Infections and Strengthening Safe Blood Supply System in Ghana

Final Report

December 2018

Japan International Cooperation Agency (JICA)
Terumo Corporation

OS
JR
18-056

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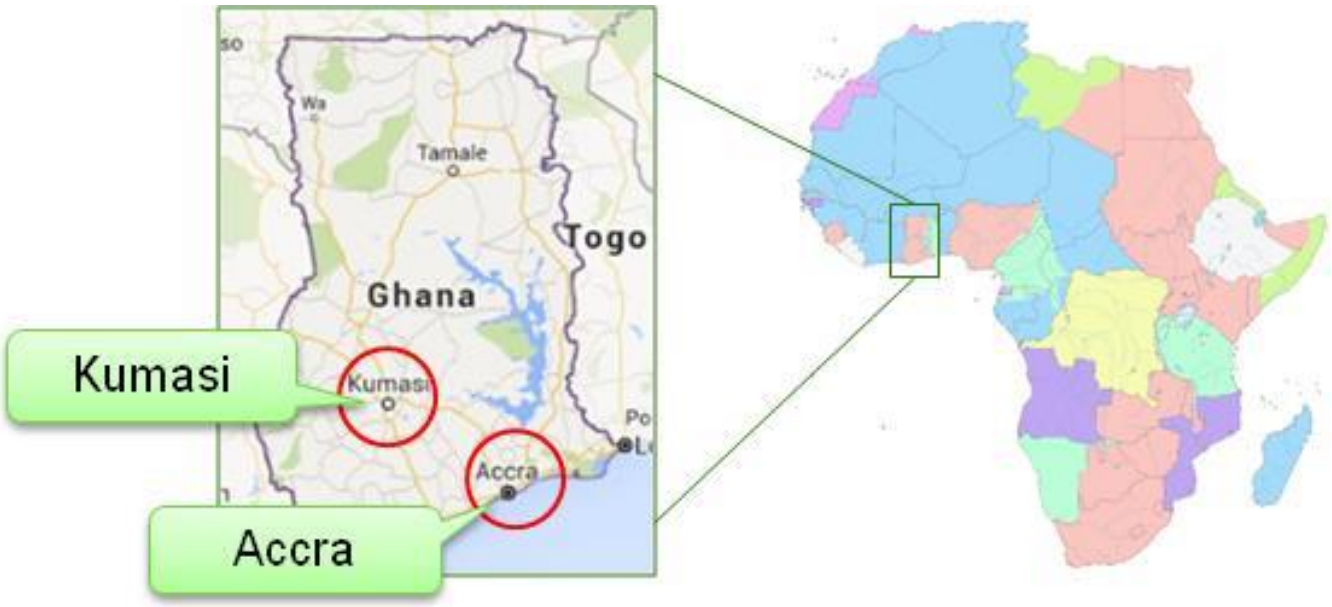


Abbreviation

Abbreviation	Formal Notation
AABB	American Association of Blood Banks
HV	HaemoVigilance
HIV	Human Immunodeficiency Virus
HCV	Hepatitis C Virus
KATH	Konfo-Anokye Teaching Hospital
KBTH	Koele-Bu Teaching Hospital
NBSG	National Blood Service of Ghana
SSA	Sub_Sahara Africa

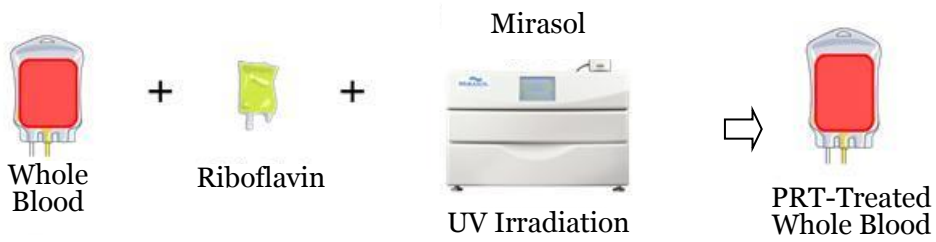
Chapter 1. Summary

1.1. Summary

It is difficult to introduce advanced medical technology into low and middle income countries without first securing a sufficient, safe, and sustainable blood supply.[1] Blood and blood components have been recently added to the list of the World Health Organization (WHO) essential medicines, and the WHO proposes the minimum required blood collections to be 10 units per 1000 inhabitants or about 1 percent of a country's population.[2] In sub-Saharan Africa (SSA), blood transfusions are indispensable, as they play a key role in the correction of anemia and the prevention of deaths, especially in pregnant women and children.[3] The clinical value of whole blood has been considered equal if not superior to blood components for the treatment of anemia caused by malaria, hemorrhage and trauma and is used currently in many countries in the region.[4] Yet unavailability of blood and provision of safe blood remain problematic in the region. High endemicity of transfusion-transmitted infection (TTI) in Ghana illustrates the problem: anti-HIV and hepatitis B surface antigen occur at a rate of 1.03 percent and 13.8 percent, respectively, in first-time donors, with similar values for replacement donors and a high prevalence of malaria parasitemia.[5,6,7] Improving blood safety and sustainability can enable a government to meet health targets, whether these are global goals, such as the UN sustainable development goals (SDG) or goals for antimicrobial resistance (AMR), or national goals for maternal health, child health, reduced disease transmission and greater possibilities for health tourism.[7,8] Priorities of intervention and the optimal allocation of resources vary from country to country, but integrating scientific, economic, ethical and social considerations into public heath priorities is fundamental for a good policy process. Surveillance procedures and hemovigilance systems are needed.[9]

Like many low- and middle-income countries, Ghana, the target area of this project, is burdened with an elevated risk of TTI in its blood supply. *Plasmodium* transmission by transfusion is up to 28 percent, and approximately 10 percent of blood collections in the country are bacterially contaminated.[6,10] Reports estimate the prevalence of viral markers in the Ghanaian donor population to be 1.03 to 1.1 percent for HIV, 13.8 to 14.9 percent for hepatitis B virus (HBV), 1.3 to 9.4 percent for hepatitis C virus (HCV) and as high as 55 percent for malaria.[11,12] As such, a mechanism for a stable supply of safe blood and transfusions is urgently required to reduce TTI, specifically in vulnerable patient populations, such as children and perinatal women.

Pathogen reduction of whole blood and blood components is a proactive approach to reduce TTI while preserving adequate cell and protein quality. The Mirasol® Pathogen Reduction Technology (PRT) system offered by Terumo BCT uses a combination of riboflavin (vitamin B2), a non-toxic, non-mutagenic compound, and a specific spectrum of ultraviolet (UV) light to inactivate viruses, bacteria, parasites, and white blood cells that may be present in collected blood products. Since its development in 2007, the range of its application has expanded from treatment of platelets and plasma to also include whole blood. In 2014, the African Investigation of the Mirasol System for Whole Blood (AIMS) study conducted in Ghana showed a reduction of 87 percent in the transmission of malaria while maintaining the efficacy of the transfused blood. The results were published in the medical journal *The Lancet* in 2016.[13] Mirasol acquired a CE mark in 2015 and approval of the Food and Drug Authority of Ghana in August 2016.



A hemovigilance (HV) system is considered an effective mechanism to establish and extend a safe and stable blood supply through transfusion monitoring. WHO recommends HV as a means to collect information on transfusion-related side effects, analyze the causes of such effects, and prevent the regeneration and recurrence of the effects for the continuous improvement of the quality and safety of all processes in blood preparation and transfusion.

The collaboration among Terumo Corporation, AABB, and the Japan International Cooperation Agency (JICA) aims at establishing a safe and sustainable blood supply in Ghana through a hemovigilance system that will help to improve transfusion practices and to establish and standardize the routine use of PRT, helping to reduce the risk of TTI from whole blood transfusions. Pathogen reduction with the Mirasol system for whole blood was implemented at the National Blood Service of Ghana (NBSG), and an HV system developed in coordination with AABB consulting services was implemented in Korle-Bu and Komfo Anokye Teaching Hospitals (KBTH and KATH) in Accra and Kumasi, respectively. Anemic obstetric patients and both adult and pediatric oncology patients were selected as beneficiaries of the transfusion of Mirasol-treated blood. Lastly, an output of the project is the appropriate budget allocation for the continued use of Mirasol and HV after the conclusion of this project. This project was implemented at the blood centers in the major cities of Accra and Kumasi under NBSG, which is responsible for the collection, treatment, and supply of blood for transfusion, and at KBTH and KATH under the supervision of the Ministry of Health of Ghana (MOH).

To establish Mirasol in routine use, eight participants from Accra and four from Kumasi were trained in operation and basic maintenance through a combination of lecture-based and hands-on training and passed a certification test. Late in the project, two operators from each blood center were trained to become trainers themselves to ensure continued use of Mirasol after the conclusion of the project. Additionally, engineers from the local distributor for Terumo Corporation were certified to maintain, inspect, and repair the system.

After the training activities mentioned above, a total of 971 units of Mirasol-treated, pathogen-reduced whole blood were used for transfusion in KBTH (517 bags) and KATH (454 bags) between May 2017 and October 2018. Table 1 shows the number of bags of Mirasol-treated whole blood used for transfusion by department. As transfusion of blood components (versus whole blood) was performed more frequently than anticipated, the frequency of Mirasol-treated whole blood transfusion was very small in the pediatric department. Approximately 30 units of Mirasol-treated whole blood per month were transfused on average in each of the two hospitals during the project period. Although this observation indicates that pathogen-reduced blood is used in a small fraction (less than 10 percent) of the transfusions performed in these hospitals, this project has proven for the first time in the world that it is possible to prepare PRT-treated whole blood and use it safely in transfusion on a routine basis without affecting the ordinary operation of a hospital.

Table 1. Number of Mirasol-Treated Whole Blood Transfusions

Facility	Pediatric	Oncology	OB/GY	Total
KBTH	0	503	14	517
KATH	20	172	262	454
Total	20	675	276	971

As of October 2018

Efforts had been made to establish a HV system without material success in Ghana before the implementation of this project. Therefore, hemovigilance training was organized in consultation with an expert in HV with the assistance of the Japanese Red Cross Society. Seven key stakeholders from the NBSG and the teaching hospitals participated. The training was designed to increase the participants' understanding of the significance of HV, as well as to establish the system. Among the training subjects were the history of HV, establishment and implementation of procedures, introduction of a cloud-based system for data input and analysis, appointment of a HV coordinator to play a central role, and discussions about differences between Ghana and Japan. A hemovigilance inspection was conducted during the project period to confirm the participants' knowledge of techniques and processes, and problems found in the inspection were corrected as needed.

These activities led the nurses, doctors and senior management staff of KBTH and KATH to be fully aware of the significance and importance of HV and to declare their commitment to continue the HV activities as an essential component of safe and stable transfusion by September 2018. This suggests that one objective of this project, the establishment of a basic HV system, has been achieved. HV data were obtained on the transfusion of 792 bags of Mirasol-treated whole blood and 797 bags of untreated whole blood from the two hospitals by the end of August 2018. The collation and analysis of these data revealed that the incidence of transfusion-related adverse reactions was lower with transfusion of Mirasol-treated whole blood than with transfusion of untreated whole blood. This observation proves that safer transfusion has been achieved.

In addition to the activities to establish the routine use of Mirasol and an HV system mentioned above, Terumo negotiated with the MOH and NBSG on the future budget allocation for the continuous use of Mirasol after the conclusion of this project. In November 2017, NBSG submitted the "Draft Five-Year Plan for Mirasol System to Establish Safe Transfusion Medicine," which focused on the continued use of Mirasol and the extension of the HV system, to MOH. Meanwhile, Terumo BCT opened a branch office in Kenya in February 2018 in preparation for future business development in sub-Saharan Africa, including Ghana. Terumo BCT also continued to inform the MOH of the progress and output of this project and to negotiate with the MOH on the budget allocation. These activities led to the commitment by MOH in September 2018 to allocate budget of $20,000 USD in FY 2018 and $300,000 to $400,000 USD over the following five years to continue this project. If this budget is executed, two Mirasol systems will be installed in the Tamale Blood Center, the third center in Ghana, in 2020.

With Mirasol in routine use and an HV system in place in Ghana, the feasibility of establishing a stable supply of safe blood has been proven. Continuation of this project is helping to develop an environment with the potential to provision of high-quality healthcare services in Ghana.

Chapter 2. Outline of the Project

2.1. Activities in the Project

This project was implemented in accordance with the schedule shown below.

	Time/Period/Place	Activity	Purpose & Overview of Activity
1st Activity in Ghana	Feb. 2017 6 days Accra, Kumasi	HV Assessment	Formulate the HV implementation plan, confirm and evaluate the current process at each facility, and set the goal and analyze the gap towards it.
2nd Activity in Ghana	May 2017 1 day Accra	Kickoff Meeting	Sharing the overall outline, implementation plan, and target deliverables of this project, confirm process flow and role assignment. Visit major agencies such as the Ministry of Health and appeal the purpose and significance of this project.
	May 2017 9 days Accra, Kumasi	HV Training	Acquire knowledge and procedures to carry out HV mainly by nurses and doctors. Conduct HV training based on the plan.
	May/Jun 2017 14 days Accra, Kumasi	Mirasol Operator Training	Train operators to use the Mirasol system.
1st Activity in Japan	Jul. 2017 5 days Tokyo	HV Training	Conduct the lecture and discussion to exchange opinions on a transfusion safety management system including HV efforts in Japan. Assist with the establishment of a safe and sustainable blood supply system in Ghana through tours of the related facilities.
3rd Activity in Ghana	Oct. 2017 3 days Accra, Kumasi	HV Audit	Confirm that HV data is properly collected and take corrective action as necessary.
	Feb.2018 3 days Accra, Kumasi	HV Data Review	Discuss need for the final report to supply aggregated HV data and confirm the progress of the project.
4th Activity in Ghana	Oct. 2017, Mar. 2018 4 days Accra, Kumasi	Business Follow-Up	Report on the HV data summary to the Ministry of Health, Ghana FDA, and National Blood Bank Service Headquarters and discuss business continuity and budget plan after JICA project is over.
5th Activity in Ghana	Sep. 2018 1 day Accra	Handover Meeting	Sum up the results and accomplishments. Share ideas about the best way to proceed after the project handover.
	Sep. 2018 2 days Accra, Kumasi	HV Workshop	Share HV activities and data summary from throughout the project and discuss HV continuity in the future.
	Sept. 2018 4 days Accra, Kumasi	Mirasol Trainer Training	Train some operators of the Mirasol system to train future operations.

Chapter 3. Overall Evaluation of the Project (Evaluation of the Outputs of Project Implementation)

3.1 Outputs of the Project (Contribution to the Target Cities, Regions and Country)

3.1.1. Establishment and Standardization of Routine Use of the Mirasol Pathogen Reduction System in the Blood Centers

1) Record of Use

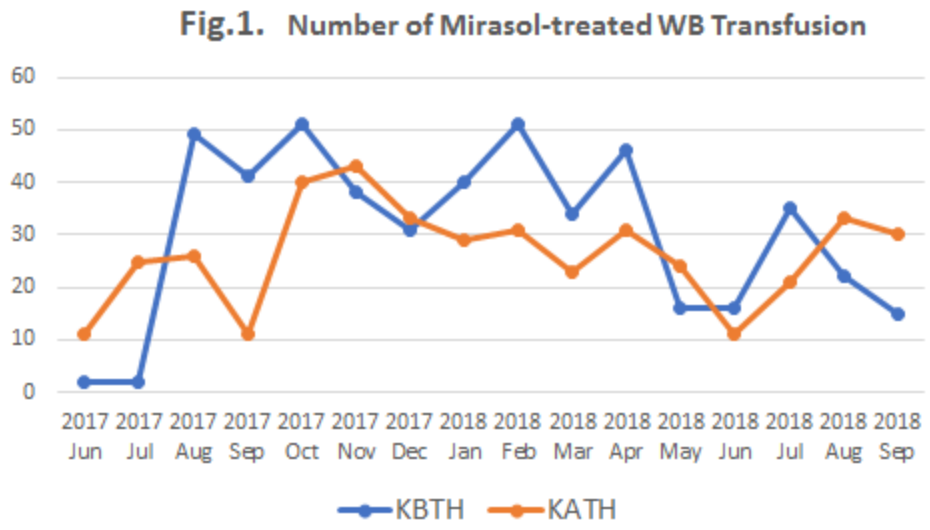
A total of 971 units of Mirasol-treated pathogen-reduced whole blood (WB) were used for transfusion in *Korle-Bu Teaching Hospital* (KBTH) (517 bags) and Komfo Anokye Teaching Hospital (KATH) (454 bags) between May 2017 and October 2018. Table 2 shows the number of bags of Mirasol-treated whole blood used for transfusion by department. Fig. 1 shows the change in the numbers of the bags of transfused Mirasol-treated whole blood per month in the two hospitals. Approximately 30 bags per month of Mirasol-treated whole blood were used for transfusion in each hospital except during the beginning of the project period. The number of Mirasol-treated whole blood units transfused during this project accounted for 1.4 percent of all transfusions in the two hospitals and 3.8 percent of the transfusions in the obstetrics/ gynecology (OB/GY) and pediatric departments of KATH. These numbers show that only a small fraction of blood used for transfusion was pathogen-reduced. However, this project has proven that it is possible to prepare PRT-treated whole blood and use it safely in transfusion on a routine basis without affecting the ordinary operation of a hospital.

In the original plan, 67 percent and 58 percent of the blood used for transfusion in KBTH and KATH, respectively, was expected to be Mirasol-treated whole blood. In reality, transfusion practices at both hospitals changed dramatically, resulting in less than 10 percent of transfusions using Mirasol-treated whole blood. One reason was that the pediatric departments rapidly adopted transfusion of red blood cell components instead of whole blood. Another reason was that the OB/GY department of KBTH collected more blood than was expected, and therefore the need for Mirasol-treated whole blood supplied by NBSG was less. Neither of these reasons was due to the Mirasol treatment itself.

Table 2. Number of Mirasol-Treated Whole Blood Transfusions

Facility	Pediatric	Oncology	OB/GY	Total
KBTH	0	503	14	517
KATH	20	172	262	454
Total	20	675	276	971

As of October 2018



2) Implementation of Training and Its Outputs

Training was a key area of focus for this project and necessary to establishing routine use of PRT. Lectures and hands-on instruction were provided to those individuals who would be Mirasol operators, and all operators were trained by the same Terumo BCT representative to ensure a uniform transfer of knowledge. Certificates were issued to those who passed the examination. This training methodology effectively motivated the participants and proved successful in building strong competency in the operation of Mirasol.

A total of 12 participants, eight from KBTH and four from KATH, became certified Mirasol operators. Mirasol operational training was also provided to an engineer of the local distributor for Terumo BCT. Additionally, to support the continued use of the Mirasol PRT system after the conclusion of the project, two individuals from each of the two blood centers were educated to become Mirasol trainers, thus building the capacity to support training of new operators, as needed. These activities led to the routine and continued use of Mirasol at both blood centers.

3) Establishment of a Maintenance System

An engineer in charge of technical support at Arcoa, the distributor of medical equipment for Terumo BCT in Ghana, was instructed on the periodic inspection and repair of the Mirasol system at a Terumo BCT facility in Europe and received operational training similar to the training provided to the blood center operators mentioned earlier. In addition, this individual trained two other engineers so that they could conduct the periodic inspection and repair in the event of absence. It was decided that assistance from the Mirasol Operation Support Team of Terumo BCT Europe was to be requested when highly sophisticated repair work was required. During the 15-month project period in which the Mirasol system was in use, troubleshooting was required to address a malfunction of UV lamps and clamps, blackout of the display screen, and false alarm activation. The Arcoa technical support engineer restored the system with troubleshooting procedures and replacement of parts. Because more than one Mirasol system was installed in each center, such troubles never developed into serious problems that interfered with the blood supply.

4) Reaction of the Users

Although there was initial concern about whether individuals in charge of blood preparation in the blood centers could use Mirasol without affecting their daily operations, the training provided and the establishment of the maintenance system by the local distributor led to smooth adoption and routine use.

Operators from both blood centers rated Mirasol "very acceptable" (the second-best score in a five-point evaluation) for overall usability. The seven operators were interviewed on the usability of the Mirasol equipment, disposables, and accessory devices, including the Terumo welders and tube sealers. They evaluated the Mirasol system highest on its ease of use and the minimal number of operation steps necessary for PRT treatment.

Suggestions for improvement that the operators presented will be taken into consideration for future product development efforts and include the reduction of treatment time and simultaneous UV treatment of multiple bags.

3.1.2. Establishment and Standardization of Hemovigilance (HV) in the Hospitals

1) Result of the collation and analysis of HV data

Table 3 shows the numbers of bags of blood used for transfusion by department in each facility in which HV data were collected during this project.

Table 3. Number of Transfusions

Facility	Pediatrics		Oncology		OB/GY		Total	
	Mirasol treated	Untreated	Mirasol treated	Untreated	Mirasol treated	Untreated	Mirasol treated	Untreated
KBTH	0	0	503	411	14	2	517	413
KATH	20	32	172	155	262	476	454	663
Total	20	32	675	566	276	478	971	1076

As of 25 October 2018

HV data were obtained from the 971 transfused units of Mirasol-treated whole blood and 1,076 units of untreated whole blood by the end of October 2018. All data were entered into the cloud-based system established in this project and were collated and analyzed by the system. Table 4 shows the incidence of transfusion-related adverse reactions among the patients who received Mirasol-treated and untreated whole blood as of the end of July 2018. Incidence for patients who received Mirasol-treated whole blood was lower than that for patients who received untreated blood, proving that the project objective to improve the safety of blood transfusions has been achieved.

Table 4. Summary of Transfusion Reactions

	Untreated	Mirasol-Treated	Total
Acute hemolytic transfusion reaction (immediate)	1	0	1
Allergic reactions	11	5	16
Febrile non-hemolytic transfusion reaction (FNHTR)	22	12	34
Febrile non-hemolytic transfusion reaction (FNHTR), Allergic reaction	1	-	1
Transfusion-associated circulatory overload (TACO)	1	3	4
Unclassifiable complication of transfusion (UCT)	10	11	21
Grand total of reactions	46	31	77
None	797	792	1589
Frequency of transfusion reactions (Mirasol-treated)		**3.76%**	
Frequency of transfusion reactions (Untreated)	**5.46%**		

As of July 2018

2) Establishment of HV system

Efforts had been made to establish a HV system in Ghana without success before the implementation of this project. Therefore, an HV assessment was conducted in the beginning of the project, and a training program was prepared based on both theoretical and practical aspects of HV and included lectures, hands-on clinical practice sessions at selected wards, and online webinars for software demonstration. AABB Consulting Services (AABB CS) was employed to develop the HV system and to support the HV training and implementation. ISBT working definitions were invaluable during training sessions and throughout the project.

The interactive training implemented in accordance with this program was designed to increase the participants' understanding of the significance of HV. Among the training subjects were the implementation of HV, establishment of standardized HV procedures to be used in both hospitals, and appointment of an HV coordinator who was to play the central role in HV. The Transfusion Sheet A used for recording the condition of patients during transfusion in the two hospitals is shown in Attachment 1. The data entered into this sheet were input into the cloud-based system developed for this project. A full-time individual was employed to analyze the entered data during the project period to ensure data collection met the stated requirements. Many health workers of the two hospitals said that the continued practice of measurement and observation of the vital signs of patients during transfusion had improved their awareness of the safety of transfusion and patient care. It is a great achievement of this project that staff of the hospitals voiced their support without solicitation to continue the HV activities with patients in the pediatric, OB/GY, and oncology departments and to extend to other departments.

Based on the idea that it was essential to gain the support of all groups of hospital staff—senior managers, doctors in the field, and nurses—to establish and routinize the HV system, the activities listed below were implemented in this project in a way similar to the Plan-Do-Check-Act (PDCA) cycle. These activities had led to the full understanding of the significance and importance of HV by all staff involved at KBTH and KATH and led them to declare that they would continue implementing the activities as an essential component in performing transfusion in a safe and stable environment. One of the objectives of this project—to establish a basic HV

system—is considered to have been achieved with the creation of the HV system, including such activities as the preparation of a standardized HV recording sheet and introduction of a cloud-based data entry and analysis system, and with the support of involved hospital staff.

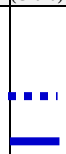
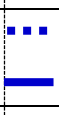
Hemovigilance activities included:

- February 2017: HV assessment
- May 2017: Training on HV
- July 2017: Training in Japan (training and discussion on HV at the Japan Red Cross Society)
- October 2017: HV inspection
- February 2018: Review of HV data
- September 2018: Workshop on HV

3) Legislation to provide an adequate, sustainable and safe blood supply

The mandate of the National Blood Service Ghana is to ensure an effective and coordinated national approach to the provision of safe, adequate, and efficacious blood and blood products, making it timely, accessible and affordable to all patients requiring blood transfusion therapy in both public and private healthcare institutions in the country. The MOH in collaboration with NBSG is working on a bill to back the provision of blood services to health facilities in the country. The bill, when passed, will ensure safer blood transfusion by health professionals in both public and private health facilities.

3.2. Output of This Project (for Business Development), Remaining Challenges, and Proposed Solutions

#	Task	Activity Plan & Actual						Accomplishment & Evaluation		Issues/Challenge & Solutions
		1st (Ghana)	2nd (Ghana)	1st (Japan)	3rd (Ghana	4th (Ghana)	5th (Ghana)			
1	HemovigilanceAssessment							Completed	Baseline assessment of current situation and issues/challenges in Accra & Kumasi. Based on initial assessment, AABB Consulting Services developed hemovigilance database and training plan.	
2	Creation of Education & Environment Hemovigilance Implementation							Completed	Installed and operated hemovigilance database in Accra & Kumasi. Created unified documents and process for both teaching hospitals. Performed awareness about hemovigilance.	
3	Creation of Mirasol Operator Training & Environment							Completed	Certified 12 Mirasol operators in Accra and Kumasi. Established Mirasol maintenance service system by local distributor (Arcoa).	
4	Key Opinion Leader (KOL) Enlightenment							Completed	Secured Ghanaian KOLs' awareness about the significance of hemovigilance through an educational session with JRC. Found helpful solutions using JRC suggestion.	
5	Hemovigilance Follow-Up							Remaining Issues	Proved that Mirasol-treated WB transfusion was safe and lowered transfusion-related adverse events. Continued monthly hemovigilance data summary and analysis.	1) Health economic analysis. 2) Improved recognition and awareness about hemovigilance at KBTH. 3) Ghana FDA approval of Mirasol-treated RBC, increase usage at pediatric department.
6	Business Follow-Up							Completed	Secured commitment of budget to purchase Mirasol by MOH.	4) Budget approval and execution. 5) Legislation of hemovigilance.
7	Handover							Completed	Trained 4 Mirasol trainers. (Accra 2, Kumasi 2)	

3.2.1. Outputs of This Project (for Business Development)

Key outputs of this project to support the continued use of Mirasol PRT and HV in Ghana include:

- In October 2017, NBSG confirmed that Mirasol and HV could be used continuously in a lower-middle-income country like Ghana and could contribute sufficiently to the safe and stable blood supply.
- In November 2017, NBSG prepared the "Draft Five-Year Plan for Mirasol System to Establish Safe Transfusion Medicine," focused on the continued use of Mirasol and extension of the HV system and submitted the draft to MOH in November 2017.
- In September 2018, during the handover meeting, the Chief Director of the Ministry of Health (MOH) provided commitment to funding.

Coverage of this commitment by the Business Ghana news agency is excerpted below:

> *The Japan International Cooperation Agency (JICA) on Wednesday, handed over the Ghana Blood Safety Programme, to the Ministry of Health (MOH) at a ceremony in Accra for its sustainability.*
>
> *The event, was to formally bring to an end the JICA project on the routine use of the Terumo BCT Mirasol Pathogen Reduction Technology (PRT) System, and the implementation of a Haemovigilance programme in Ghana.*
>
> *Dr Justina Kordai Ansah, the Chief Executive Officer of the National Blood Service Ghana (NBSG), said the programme, followed the licencing of the Mirasol Whole Blood (WB) system for use by the Ghana Food and Drug Authority in August 2016, after the African Investigation of the Mirasol System (AIMS) study was completed in Kumasi in 2014.*
>
> *The project was then adopted for sponsorship by JICA in collaboration with the Terumo Corporation of Japan, to support sustainable Blood Safety by reducing the risk of transfusion reaction with the implementation of the Mirasol WB system in conjunction with the creation of an infrastructure for Hemovigilance programme.*
>
> *The Technology, she said, ensured protection against a broad number of pathogens including HIV, hepatitis and malaria, and the NBSG has since been able to implement the Mirasol PRT technology in the Southern and Central Blood Centres to provide safer blood for vulnerable patients both at the Korle-Bu and Okomfo Anokye Teaching Hospitals.*
>
> *She said the objective of the NBSG was to provide a reliable, adequate and safe supply of blood nationwide, as the MOH worked on a Blood Service bill, to back the provision of blood services in the country.*
>
> *Dr Ansah said the programme, had seen the significant training of a number of Ghanaian healthcare professionals in both Ghana and in Japan for sustainability.*
>
> *Nana Kwabena Agyei, the Chief Director of the Ministry of Health (MOH), representing Mr Kwaku Agyemen-Manu, the Minister, commended the NBSG for conceiving the idea and engaging various partners and stakeholders to bring it to fruition.*
>
> *He admitted that the safety, availability and affordability of blood was key to effective health care delivery and the attainment of Universal Health Coverage, and appealed to the public to support voluntary blood donations to enable the NBSG achieve 100 per cent voluntary unpaid donations by the end of 2020.*

He stated saying blood and its components have been recently added to the seventh edition of the Standard Treatment Guidelines and Essential Medicines List in Ghana as recommended by the WHO, and pledged the Ministry's commitment to championing the use of technologies for improving health services across the country, with limited risk of infections that could be transmitted through a blood transfusion.

Nana Agyei said the Ministry was committed to purchasing 20,000-dollar worth of disposables in 2018, to sustain the programme, and proceed to expand the programme in 2019 to include; the Northern Zonal blood centres in Tamale, he said.

He also said a budget of between 300,000 and 400,000 dollars per year, would be allocated for the next five years, to purchase equipment, disposables and provide maintenance for the installed equipment to support the sustainability of the programme.

Nana Agyei said Ghana currently collected approximately 6.1 units of whole blood for every 1,000 inhabitants, which was just a little over the current estimated minimal need recommended by the WHO, saying up to 50 per cent of those who received blood transfusions were pregnant women, postpartum women, children and infants.

Therefore improving blood safety and sustainability could enable the government meet health targets, including global goals, such as the United Nations Sustainable Development Goals (SDGs), antimicrobial Resistance (AMR), and national goals such as maternal and child health, reduction in transmission of malaria and other communicable diseases or enabling the possibilities of health tourism.

Mr Koji Tomita, the Deputy Chief of Mission Counsellor at the Japan Embassy, and Mr Shin Kuroda, the Advisor of Terumo Corporation in Japan, thanked the collaborators for the success of the project and urged NBSG to ensure the proper maintenance of the equipment for safe, effective, and efficient blood supply to Ghanaians.

Mr Tomita assured Ghana of the sustained support from the Japanese Government both in the health and other sectors of the country.

Ms Maki Ozawa, Senior Representative of JICA, said the project was not to merely introduce Japanese equipment to Ghana, but promote blood safety using well developed technology which had been scientifically proven to be effective.[14]

3.2.2. Challenges and Proposed Solutions

1) Budget approval and implementation

The most important outcome of this project is to ensure sufficient operational funds to provide a larger number of patients with safe blood for transfusion through the continued use of Mirasol and HV. Routine meetings between Terumo BCT, NBSG, and MOH will continue to support budget allocation discussions, including further discussions about the health economic assessment of the Mirasol PRT system for whole blood in Ghana.

2) Extension of the use of Mirasol for red blood cell preparation

Conventional whole blood transfusion is being replaced by transfusion of red blood cell (RBC) components in the pediatric and oncology departments in Ghana. The replacement has been completed in the pediatric department of

KBTH. Currently, Mirasol treatment is approved by the Ghanaian FDA only for whole blood. Therefore, a CE mark for RBCs derived from Mirasol-treated WB, followed by approval by the Ghanaian FDA, is needed so these additional patients can receive Mirasol-treated RBCs. Efforts are underway to explore the use of RBCs derived from Mirasol-treated WB. Once sufficient evidence is developed, Terumo BCT will seek Ghana FDA approval.

3) Health economic assessment of Mirasol PRT in Ghana

Terumo BCT has partnered with W. Alton Russell (Stanford University) and Dr. Brian Custer (Vitalant Research Institute, University of California San Francisco) to develop a health economic assessment of the Mirasol PRT for whole blood in Ghana. The consultants have developed a Microsoft Excel-based tool to estimate how many transfusion-related adverse events would be averted over the course of a year if Mirasol were implemented nationally. The seven transfusion-associated adverse events modeled are HIV, HCV, HBV, syphilis, malaria, sepsis/bacteria, and febrile non-hemolytic transfusion reactions.

The model uses estimates of the residual risk of each transfusion-related adverse event with untreated and PRT-treated whole blood to project the difference in the number of adverse events in transfused patients in Ghana. Epidemiological parameters are estimated from AIMS clinical trial data, from other literature, and in consultation with individuals at KATH. KATH is also providing estimates of the health system cost associated with each type of adverse event. Using these data, the project will provide results in terms of the accrued financial savings over one year to the health system in Ghana resulting from reduced transfusion-associated adverse events from treating whole blood donations with PRT. Results of the analysis will be reported in a manner that will facilitate the development of a manuscript(s) for publication with our partners at KATH.

4) Improvement of communication between blood center and hospitals

It can be challenging to develop a hemovigilance system that benefits both the hospital and the blood center, because blood is collected in the blood center, but transfusion monitoring occurs on the wards by hospital staff. To succeed, the transfusion committee must communicate regularly, receiving updates about transfusion reaction rates and creating a process to improve practices. The challenges from this project are to improve the communication between the two organizations so they both benefit from the value of using Mirasol and the HV system. Differences between the two blood centers and their correlating hospitals are physical location, maturity of the transfusion committees, size of wards, and experience using Mirasol, which vary greatly between KBTH and KATH. In KATH, the nurses and doctors have had extensive experience with Mirasol since the initiation of the AIMS study in 2014 and were motivated to continue to use Mirasol in conjunction with an HV system. There is also a transfusion committee in KATH, which includes the department that was using whole blood transfusion. The maturity of the transfusion committee in KATH has benefitted the project. Meanwhile, in KBTH in Accra there has been movement forward to form a transfusion committee within the hospital; as an example, at the handover meeting, the CEO of KBTH announced that HV activities should be strengthened in the hospital.

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Attachment 1

(Final: ver. April 06 2017)

Transfusion Reaction Form A (ver. 1)

NBS Use Only #_____
☐ Pending ☐ Completed ☐ DNP

Please complete **ALL** sections of this form fully. If *Not Applicable*, write N/A in the relevant section.

SECTION I – PATIENT INFORMATION

Surname:			First Name:
Patient ID/NHIS:			Date:
Hospital:			Ward:
Gender: ☐ Male ☐ Female	AGE OF PATIENT: ☐ not stated	Pre-Transfusion: Hb:_____ Plat:_____	Patient's ABO/Rh Group : ☐ Unknown ☐ O ☐ A ☐ B ☐ AB Rhesus Factor (Rh): ☐ + Rh ☐ - Rh ☐ Unknown
Diagnosis:			
Indication for Transfusion:			

SECTION II - RECORD OF TRANSFUSION

Component Type: ☐ Whole Blood ☐ Mirasol PRT ☐ CRC ☐ Plat – Random ☐ Plat - Apheresis. ☐ FFP ☐ CRYO ☐ Other_____

Donation No or (Batch No):	Expiry date of unit:	Transfused Unit ABO/Rh Group: ☐ Unknown ☐ O ☐A ☐ B ☐ AB Rhesus Factor (Rh): ☐+ Rh ☐ - Rh ☐ Unknown
Any previous Transfusions? ☐ Yes ☐ No If yes, numbers of units/episodes transfused within Current admission		NAME cross-checked pre-transfusion? ☐ Yes ABO/Rh cross-checked pre-transfusion? ☐ Yes Donation # cross-checked pre-transfusion? ☐ Yes

Record of Vital Signs

	Pulse	Resp. Rate	Blood Pressure	Temp	Oxygen Saturation Levels (SpO2)
Pre-Transfusion (Start)					
10-15 minutes					
30-60 hour					
At Finish or Stop					

Was the whole unit transfused uneventfully:

☐ YES→STOP No need to complete remaining form. Please sign bottom of form

☐ NO , what was the Volume Transfused :_____mL Date: _____ Time:_____

If No: Why was Transfusion stopped?

- ☐ Patient reacted to Transfusion (COMPLETE FORM FOR ALL COMPONENTS RETURNED TO BB)
- ☐ Challenges with venous access
- ☐ Clots/Poor blood flow/Hyper viscous unit
- ☐ Other Reason (Please State) _____

SECTION III – TRANSFUSION REACTION REPORTING

Onset of Reaction: ☐ During Transfusion ☐ <30 mins ☐ 30 mins-1 hrs ☐ 1-2 hrs ☐ 2-6 hrs ☐ 6-24 hrs ☐ >24 hrs

Specimens accompanying this form: (Kindly indicate)

- ☐ No sample
- ☐ 2ml patient's blood sample (opposite arm) in EDTA tube
- ☐ 5ml patient's blood sample (opposite arm) in plain tube
- ☐ 20ml urine (if applicable)
- ☐ All blood bags and unused units with attached giving set

Symptoms (tick as many apply)

☐ Itching/Pruritus	☐ Dyspnoea	☐ Back pain/flank pain/Loin pain
☐ Chills/Rigors	☐ Chest pain / Tight chest	☐ Oliguria
☐ Fever ↑_____ °C	☐ Anxiety	☐ Dark urine
☐ Nausea	☐ Restlessness	☐ Unexplained bleeding
☐ Rash/Urticaria	☐ Palpitations (pulse = _____ bpm)	☐ Respiratory distress (wheezes/stridor)
☐ Flushing and sweating	☐ Hypotension (BP = _____ mmHg)	☐ Other _____
	☐ Hypertension (BP = _____ mmHg)	☐ Other _____

Suspected Adverse Reaction:		Suspected Severity*:
☐ Incorrect blood component transfused (IBCT)	☐Transfusion associated Graft versus Host disease (GvHD)	☐ Grade 1 (non-severe)
☐ Acute Haemolytic transfusion reaction (Immediate)	☐Post- Transfusion Purpura (PTP)	☐ Grade 2 (severe)
☐ Delayed Haemolysis	☐ Transfusion associated dyspnea (TAD)	☐ Grade 3 (life-threatening)
☐ Delayed serologic reaction (DSTR)	☐ Hypotensive transfusion reaction	☐ Grade 4 (death)
☐ Febrile non-haemolytic transfusion reactions (FNHTR)	☐ Haemosiderosis	*Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1,2 or 3
☐ Allergic reactions	☐ Hyperkalemia	
☐ Septic Shock	☐ Unclassifiable Complication of Transfusions (UCT)	
☐ Transfusion related acute lung injury (TRALI)		
☐ Transfusion –Associated Circulatory Overload (TACO)		

Reporting Nurse:_____ **Contact Number:** _____ **Date:**_____

Reporting Physician:_____ **Contact Number:** _____ **Date:**_____

Please return this form with samples and blood bags to Hospital Blood Bank as soon as possible