Advancing Transfusion and Cellular Therapies Worldwide

Introducing a Cloud-Based Hemovigilance System for Data Collection and Analysis: Lessons Learned from the Hemovigilance Program in Ghana

Presenting Author: Srijana Rajbhandary, BDS, MPH (AABB)

Co-Authors: Barbee I. Whitaker, Patricia M. Knox, Marcia Cardoso, Shilo Wilkinson, Mono Masaki,

Stephanie Nealis, Shirley Owusu-Oforie, Diane P. de Coning, Justina K. Ansah, Lucy Asamoah-Akuoko, and Christine Bales

Disclosure

- I have no conflicts of interest to disclose
- This project was funded and supported by the Japan International Cooperation Agency (JICA) through its program to disseminate Japanese private technologies for economic, infrastructural, healthcare, scientific, and environmental development in developing countries by collaborating with private companies
- Terumo BCT, Inc. (TBCT) received the JICA grant for this project.

Project Goals

- Improve current transfusion practices by training local medical staff on Hemovigilance (HV)
- To develop a user-friendly data entry application with following capabilities:
  - Capture the paper based transfusion reaction form
  - Provide basic reports for timely analysis and evaluation
  - Centralize data from different hospitals with the aim to develop a national hemovigilance system
- Compare transfusion-related adverse reactions (TRAR) in patients who are transfused whole blood (WB) treated using TBCT's Mirasol Pathogen Reduction Technology (PRT) System and patients who received conventional WB transfusions.

Project Partners

TERUMOBCT
Unlocking the Potential of Blood

JICA ジャイカ

AABB
Advancing Transfusion and Cellular Therapies Worldwide

How did the project develop?

AABB Global Services +TERUMO

- AABB Consulting Services (AABBCS) has provided Technical Assistance to over 10 countries in Africa since 2004
- AABBCS and TBCT partnered with a plan to support convalescent plasma during the Ebola crisis – no funding could be attained
- The Ghana Hemovigilance project concept was initiated in the summer of 2016, after the JICA grant was awarded to TBCT

Assessment and Training

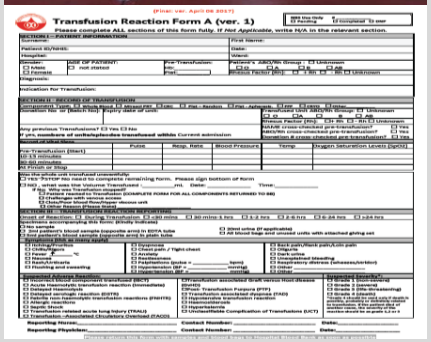
- April 2017- AABBCS conducted assessment of existing practices of National Blood Service, Ghana (NBSG)
- May 2017- Gaps were identified and the HV training was developed
- May 2017- 11-day training program conducted, incorporating lectures and practice sessions to teach NBSG and hospital staff about transfusion medicine and hemovigilance

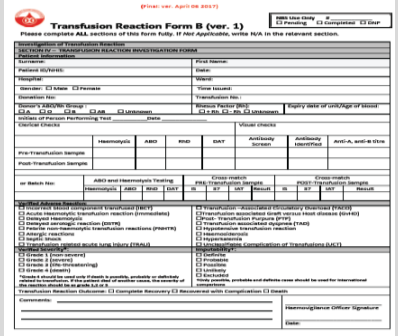
HV Infrastructure

- AABB Department of Research and AABBCS reviewed and enhanced NBSG's existing transfusion reaction form
- February 2017- AABB engaged Dovel Technologies, LLC to develop the HV infrastructure — a cloud-based data repository (portal) for electronic data capture, management, and analysis of transfusions and TRAR
- April 2017 -Training on the web-portal conducted through webinars
- June 2017- Reporting began

Project concept

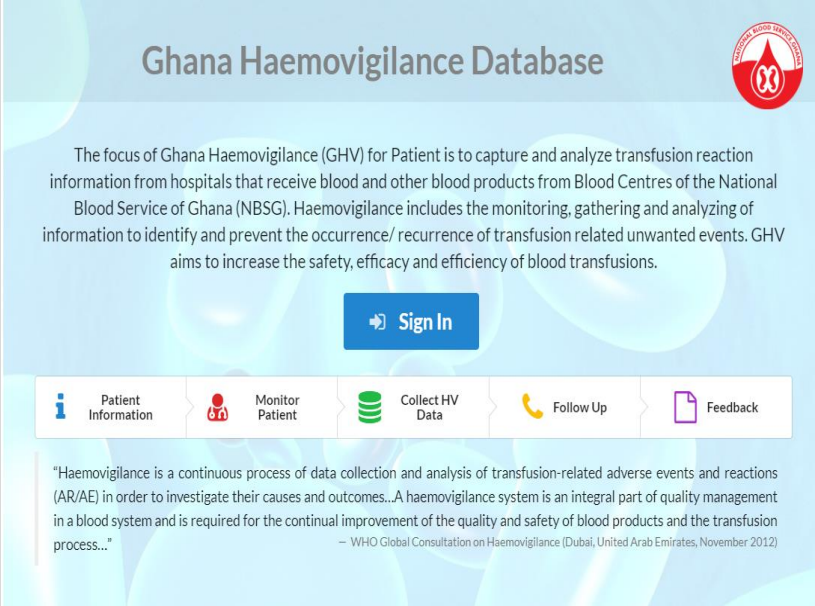
Develop Local Partnerships


Transfusion Reaction Form A (ver. 1)

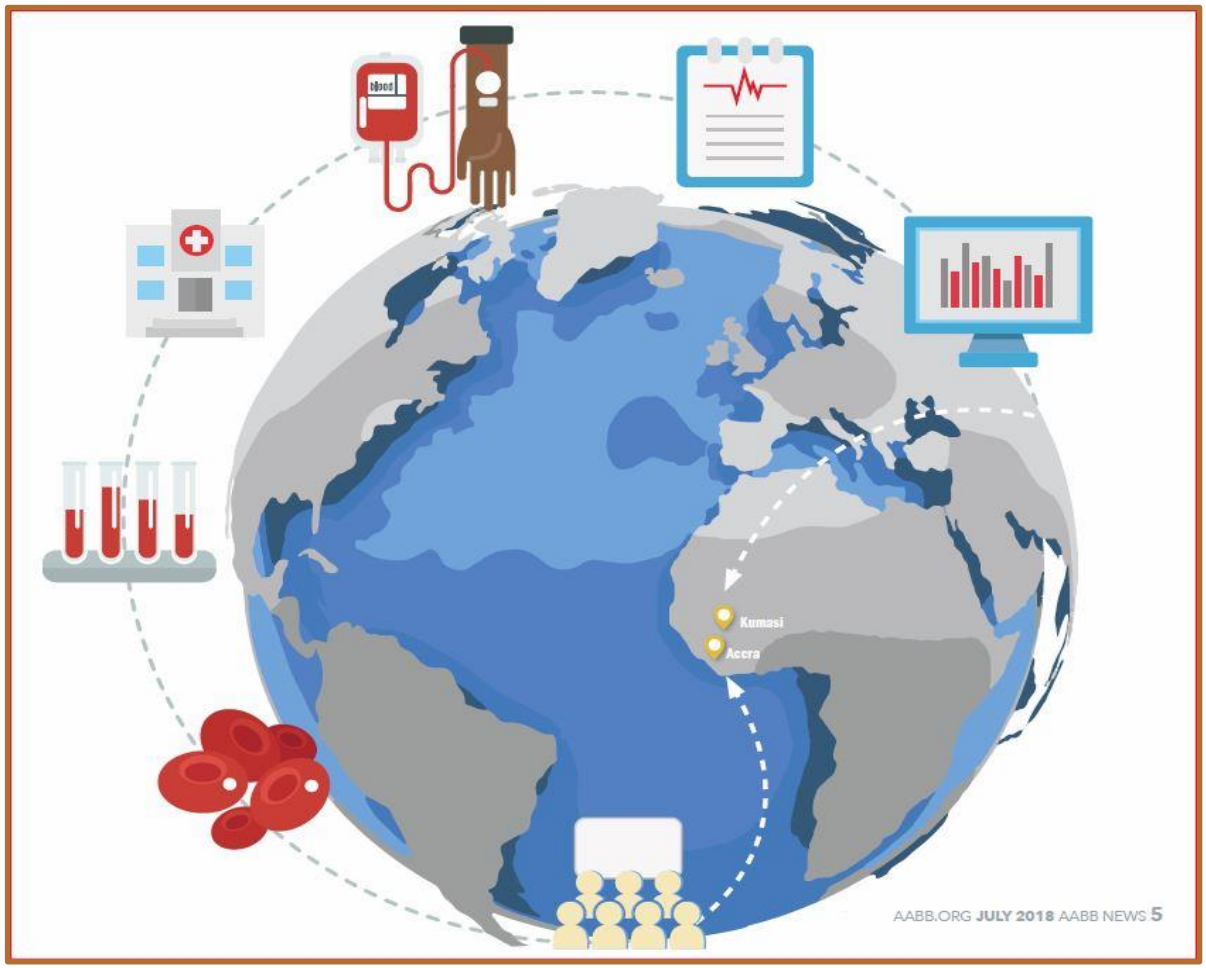

Transfusion Reaction Form B (ver. 1)

- Train local staff - “Train trainers”
  - empowerment + sustainability
- Enhance the existing transfusion reaction form
  - don’t reinvent the wheel

Provide Sustainable Infrastructure



- Develop a user-friendly hemovigilance infrastructure
- Long Term Goal
  – hand over the infrastructure to NBSG



Cloud Based Hemovigilance System

**Picture Source: July 2018, AABB NEWS*

Basic Features

- 2 Participating hospitals
  - Korle Bu Teaching Hospital (Accra)
  - Komfo Anokye Teaching Hospital (Kumasi)
- 2 parallel sites
  - Staging Test site
  - Live site
- 4 levels of access

Role	Access	Availability
System Admin	View, edit and download entire database, all reports and forms from 2 hospitals + Control all user accounts	NBSG staff, AABB staff and vendor only
Site Admin	View, edit and download database, reports and forms from individual hospital + Control individual hospital user accounts	Hospital staff
Data Manager	View, edit and download database, reports and forms from individual hospital	Hospital staff
Data Reviewer	View reports and forms from individual hospital	Hospital staff + TBCT staff

Ghana Haemovigilance Database

The focus of Ghana Haemovigilance (GHV) for Patient is to capture and analyze transfusion reaction information from hospitals that receive blood and other blood products from Blood Centres of the National Blood Service of Ghana (NBSG). Haemovigilance includes the monitoring, gathering and analyzing of information to identify and prevent the occurrence/ recurrence of transfusion related unwanted events. GHV aims to increase the safety, efficacy and efficiency of blood transfusions.

Sign In

Patient Information | Monitor Patient | Collect HV Data | Follow Up | Feedback

"Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse events and reactions (AR/AE) in order to investigate their causes and outcomes...A haemovigilance system is an integral part of quality management in a blood system and is required for the continual improvement of the quality and safety of blood products and the transfusion process..."

— WHO Global Consultation on Haemovigilance (Dubai, United Arab Emirates, November 2012)

Funded by IICA TERUMO TERUMOBCT

Ghana Haemovigilance Database

AABB : AABB Administrator (System Admin) Sign Out

- Home
- Transfusion Forms 0
- Forms with Reaction 0
- Incomplete Forms 0
- Add New Form
- Reports
- Change Password
- User Accounts 10
- Add New User
- Activity Log
- Data Export

Welcome, AABB Administrator !

AABB

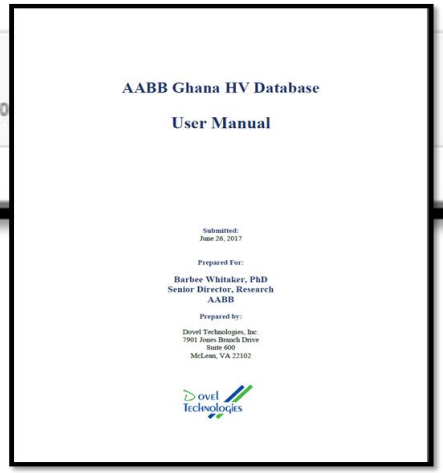
	All Transfusion Forms	Forms with Reaction	Incomplete Forms
Hospital Totals:	0	0	0
Your Totals:	0	0	0

Haemovigilance Questions? Contact
Email: Marcia.Cardoso@terumobct.com or
Email: Shilo.Wilkinson@terumobct.com

Mirasol Questions? Contact Mr. Daniel Owusu, ARCOA Ghana Ltd
Tel: 0302-782203
Email: daniel.arcoa@gmail.com

Ghana Haemovigilance Database User Manual

This User Manual provides step-by step instructions on maintaining and managing the various functio



AABB Ghana HV Database

User Manual

Submitted:
June 26, 2017

Prepared For:

Barbee Whitaker, PhD
Senior Director, Research
AABB

Prepared by:

Dovel Technologies, Inc.
7901 Jones Branch Drive
Suite 600
McLean, VA 22102

Dovel Technologies

Paper Data Entry Form (A &B)

(Final: ver. April 06 2017)

Transfusion Reaction Form A (ver. 1)

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

(Final: ver. April 06 2017)

Transfusion Reaction Form B (ver. 1)

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

Electronic Data Entry Form (1)

Home

Transfusion Forms 1440

Forms with Reaction 71

Incomplete Forms 4

Add New Form

Reports

Change Password

User Accounts 17

Add New User

Activity Log

Data Export

Transfusion Reaction Form A Add

SECTION I: PATIENT INFORMATION

Patient ID/NHIS: *
Enter Patient ID/NHIS

Date of Transfusion: *

Gender: *
Male Female

Age of Patient: **

not stated

Hospital:
All Hospitals

Ward:
Enter Ward Name

Pre-Transfusion

Hemoglobin (Hb) Level:
0.0 to 20.0

Platelet Count:

Patient's ABO/Rh

ABO Group: *
O A B AB Unknown

Rhesus Factor (Rh): *
+Rh -Rh Unknown

Diagnosis:

Indication for Transfusion:

SECTION II: RECORD OF TRANSFUSION

Component Type: *
Whole Blood CRC Platelet-Random Platelet-Apheresis FFP CRYO Other

Mirasol PRT

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Electronic Data Entry Form (2)

Transfusion Reaction Form B

SECTION IV: TRANSFUSION REACTION INVESTIGATION FORM

Patient ID/NHIS:
Donation No:
Hospital: ALL

Transfusion Date:
Expiry Date of Unit:
Ward:

Patient Gender:
Patient Age:
Patient ABO/Rh:
Transfused Unit ABO/Rh:

Time Component Issued: --:-- -- hh:mm am/pm

Transfusion No.:

Verified Adverse Reaction: **

- Incorrect blood component transfused (IBCT)
- Acute Haemolytic transfusion reaction (Immediate)
- Delayed Haemolysis
- Delayed serologic reaction (DSTR)
- Febrile non-haemolytic transfusion reactions (FNHTR)
- Allergic reactions
- Septic Shock
- Transfusion related acute lung injury (TRALI)
- NONE
- Transfusion –Associated Circulatory Overload (TACO)
- Transfusion associated Graft versus Host disease (TAGvHD)
- Post- Transfusion Purpura (PTP)
- Transfusion associated dyspnea (TAD)
- Hypotensive transfusion reaction
- Haemosiderosis
- Hyperkalemia
- Unclassifiable Complication of Transfusions (UCT)

Verified Severity:

Grade 1 (non-severe) Grade 2 (severe) Grade 3 (life-threatening) Grade 4 (death)

Imputability:

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Transfusion related acute lung injury (TRALI)

Unclassifiable Complication of Transfusions (UCT)

None

Verified Severity:*

Grade 1 (non-

h)

Imputability:*

Definite

Transfusion Reac

Complete Rec

Comments:

Was lab verificat

ed and dated by Haemovigilance Officer?*

Yes No

Yes No

Mark this Form complete and submit it.

Save Only

Save & Submit

Cancel

Reset

Validation Failed

Donation/Batch No: is required
Rhesus Factor (Rh): is required
Rhesus Factor (Rh): is required
Was the whole unit transfused uneventfully: is required

OK

Incomplete Forms

Add New Form

Reports

Show 10 entries

Search:

Status	Transfusion Date	Patient ID/NHIS	Donation No.	PRT	Component Type
⚠	01 Feb 2018	3130/99520001	ST6587/59		FFP
✔	30 Jan 2018	1592/99460000	XY1018/51		FFP
✔			91		Platelet-Apheresis
✔			67		Platelet-Apheresis
✔			54		CRYO
✔			55		CRYO
⚠			58		Platelet-Apheresis
✔			71		CRC
✔			54		FFP
✔	15 Jan 2018	4665/99487000	ST7868/12		CRC

Saved

The Transfusion form for patient 4921/99461900 is saved.

OK

Showing 1 to 10 of 346 entries

Previous 1 2 3 4 5 ... 35 Next

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Verified Severity:

- (●) Grade 1 (non-severe)
- ( ) Grade 2 (severe)
- ( ) Grade 3 (life-threatening)
- ( ) Grade 4 (death)

Imputability:

- ( ) Definite
- ( ) Probable
- (●) Possible
- ( ) Unlikely
- ( ) Excluded

Transfusion Reaction Outcome:

- ( ) Complete Recovery
- (●) Recovered with Complication
- ( ) Death

Comments:

Was lab verification complete? **

- (●) Yes
- ( ) No
- ( ) N/A

Is Form B signed and dated by Haemovigilance Officer? **

- (●) Yes
- ( ) No

[x] Mark this Form complete and submit it.

Save Only | Save & Submit | Cancel | Delete

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Version: 1.0.2 (June, 2017)

Add New Form

Reports

Show 10 entries

Search:

Status	Transfusion Date	Patient ID/NHIS	Donation No.	PRT	Component Type
⚠	01 Feb 2018	3130/99520001	ST6587/59		FFP
✔	30 Jan 2018	1592/99460000	XY1018/51		FFP
✔			91		Platelet-Apheresis
✔			67		Platelet-Apheresis
✔			54		CRYO
✔			55		CRYO
⚠			58		Platelet-Apheresis
✔			71		CRC
✔			4		FFP
✔			2		CRC

Showing 1 to 10 of 346 entries

Previous 1 2 3 4 5 ... 35 Next

Submitted

The Transfusion form for patient ABC/001 is marked complete and submitted.

OK

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Form List

Ghana Haemovigilance Database STAGING TEST SITE Korle Bu Teaching Hospital (KBTH) : Data Manager (Data Manager) Sign Out

- Home
- Transfusion Forms 454
- Forms with Reaction 68
- Incomplete Forms 79
- Add New Form
- Reports
- Change Password

Transfusion Reaction Forms for Korle Bu Teaching Hospital (KBTH)

+ Add New Form

List of all Transfusion Forms

Highlighted rows mark your Forms. ✔ Submitted | ⚠ Incomplete | ⊙ Forms with Reactions | ☑ Mirasol PRT

Show 10 entries Search:

Status	Transfusion Date	Patient ID/NHIS	Donation No.	PRT	Component Type
✔ ⊙	12 Jun 2017	TEST CASE 003/12/06	June		FFP
✔ ⊙	12 Jun 2017	TEST CASE 004/12/06	JUNE		Platelet-Apheresis
✔	30 Jan 2017	6611/99353300	AB3945/45	☑	Whole Blood
✔	29 Jan 2017	1806/99887200	ST7226/42	☑	Whole Blood
✔	27 Jan 2017	6180/99679400	MB4101/12	☑	Whole Blood
⚠	26 Jan 2017	5518/99524300	LT8508/81		Whole Blood
⚠	26 Jan 2017	8205/99710200	PP7261/19		CRYO
✔	26 Jan 2017	3197/99597300	GH3754/49	☑	Whole Blood
✔	25 Jan 2017	5856/99712600	GH1022/73		CRYO
✔	25 Jan 2017	9864/99860800	GH5357/87		FFP

Showing 1 to 10 of 454 entries

Previous 1 2 3 4 5 ... 46 Next

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Reports (1)

Ghana Haemovigilance Database

AABB : AABB Administrator (Systen

- Home
- Transfusion Forms 1440
- Forms with Reaction 71
- Incomplete Forms 4
- Add New Form
- Reports
- Change Password
- User Accounts 17
- Add New User
- Activity Log
- Data Export

Transfusion Reaction Severity Report Data refreshed 2018-06-30 at 03:29:08

100% search report

Start Date: 2017-06-30 End Date: 2018-06-30 Hospital: all

Apply Reset

Transfusion Reaction Severity Report

Report Date Range: 30 Jun 2017 - 30 Jun 2018 and Hospital : all

Verified Reaction Type	Grade 1 (non-severe)	Grade 2 (severe)	Total
Acute Haemolytic transfusion reaction (Immediate)	0	1	1
Allergic reactions	11	1	12
Febrile non-haemolytic transfusion reactions (FNHTR)	31	0	31
Transfusion –Associated Circulatory Overload (TACO)	1	3	4
Unclassifiable Complication of Transfusions (UCT)	16	3	19
Total	59	8	67

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Reports (2)

Ghana Haemovigilance Database STAGING TEST SITE Komfo Anokye Teaching Hospital (KATH) : Herrod Guthrie (Data Manager) Sign Out

- Home
- Transfusion Forms 346
- Forms with Reaction 58
- Incomplete Forms 69
- Add New Form
- Reports
- Change Password

Transfusion Reaction Component Report Data refreshed 2017-06-14 at 19:55:29

100% search report

Start Date: 2016-06-14 End Date: 2017-06-11 Hospital: Komfo Anokye Teaching Hc

Apply Reset

Transfusion Reaction Component Report

Report Date Range: 14 Jun 2016 - 11 Jun 2017 and Hospital : Komfo Anokye Teaching Hospital (KATH)

Note: The PRT for all components is calculated. At time of implementation, PRT for component types other than WB should have a 0.

Verified Reaction Type	Whole Blood			Platelet-Random		Platelet-Apheresis		FFP		CRYO		CRC		Total Component Type
	NoPRT	+PRT	Total	NoPRT	Total	NoPRT	Total	NoPRT	Total	NoPRT	Total	NoPRT	Total	
Acute Haemolytic transfusion reaction (Immediate)	0	0	0	0	0	1	1	0	0	0	0	0	0	1
Allergic reactions	1	1	2	0	0	0	0	0	0	0	0	0	0	2
Delayed serologic reaction (DSTR)	0	0	0	1	1	0	0	0	0	0	0	1	1	2
Febrile non-haemolytic transfusion reactions (FNHTR)	0	1	1	0	0	0	0	0	0	0	0	0	0	1
Haemosiderosis	0	0	0	0	0	0	0	0	0	1	1	0	0	1
Hyperkalemia	0	0	0	1	1	0	0	1	1	0	0	0	0	2
Hypotensive transfusion reaction	0	1	1	0	0	1	1	0	0	0	0	0	0	2
Incorrect blood component	0	1	1	0	0	0	0	1	1	0	0	0	0	2

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Reports (3)

Ghana Haemovigilance Database — STAGING TEST SITE — Korle Bu Teaching Hospital (KBTH) : Data Manager (Data Manager) — Sign Out

- Home
- Transfusion Forms 455
- Forms with Reaction 69
- Incomplete Forms 79
- Add New Form
- Reports
- Change Password

Sign and Symptoms Report — Data refreshed 2017-06-14 at 19:16:35

100% — search report

P_START_DATE	P_END_DATE	P_HOSPITAL
2016-06-14	2017-06-14	Korle Bu Teaching Hospital

Apply — Reset

Sign and Symptoms Report

Report Date Range: 14 Jun 2016 - 14 Jun 2017 and Hospital : Korle Bu Teaching Hospital (KBTH)

Date of Transfusion	Patient (D/H/HS)	Donation No or (Batch No)	Suspected Reaction Type	Verified Reaction Type	Itching/Pruritus	Chills/Rigors	Fever	Nausea	Rash/Urticaria	Flushing and sweating	Dyspnoea	Chest pain / Tight chest	Anxiety	Restlessness	Palpitations	Hypertension	Hypotension	Back pain/Flank pain/Loin pain	Oliguria	Dark urine	Unexplained bleeding	Respiratory distress (wheezes/stridor)	Fever (°C)	Palpitations (bpm)	Hypotension (mm hg)	Hypertension (mm hg)	Other (Text)	Other (Text)
20 Jun 2016	921 3/9 997 960 0	PP75 25/ 50	Transfusion related acute lung injury (TRA	Transfusion associated Graft versus Host							Yes																	

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Reports (4)

Ghana Haemovigilance Database STAGING TEST SITE Korle Bu Teaching Hospital (KBTH) : Data Manager (Data Manager) Sign Out

- Home
- Transfusion Forms 455
- Forms with Reaction 69
- Incomplete Forms 79
- Add New Form
- Reports
- Change Password

Line Listing Report Data refreshed 2017-06-14 at 19:17:18

100% search report

P_START_DATE: 2016-06-14

P_END_DATE: 2017-06-14

P_HOSPITAL: Korle Bu Teaching Hospital

Apply Reset

Line Listing Report

Report Date Range: 14 Jun 2016 - 14 Jun 2017 and Hospital : Korle Bu Teaching Hospital (KBTH)

Incomplete?	Transfusion Date	Patient ID	Gender	Age at Transfusion	Patient Unit ABO/Rh	Hospital	Ward	Indication for Transfusion	Component Type	PRT	Transfused Unit ABO/Rh	Onset of Reaction	Adverse Reactions Suspected	Adverse Reactions Verified	Severity of Reaction Suspected	Severity of Reaction Verified	Imputability of Reaction	Reaction Outcome
	14 Jun 2016	14656/ 99679 100	Female	69	AB -	Korle Bu Teaching Hospital (KBTH)		leukemia	Platelets-Random	No	U +							
Yes	15 Jun 2016	7704/ 99930 700	Female	25	AB +	Korle Bu Teaching Hospital		N/A	Whole Blood	Yes	U +							

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Version: 1.0.1 (June, 2017)

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Data Centralization

- Currently data from 2 hospitals are being reported
- Site coordinators responsible for data transfer from paper form to the web portal
- Individual hospital data available to
  - Site Admin
  - Data Manager
  - Data reviewer
- Data from both hospitals available to System Admin only

Preliminary Results

Category	Number reported
Total complete forms recorded	1,436
Forms with verified reactions	71
Febrile non-hemolytic transfusion reactions (FNHTR)	34
Unclassifiable Complication of Transfusions (UCT)	20
Allergic reactions	12
Transfusion –Associated Circulatory Overload (TACO)	4
Acute Hemolytic transfusion reaction (Immediate)	1

* Reaction rate /1,000 WB transfusion: Overall rate(49.4/1,000), FNHTR rate (23.7/1,000), UCT rate (13.9/1,000) , Allergic rate (8.4/1,000), TACO rate (2.8/1,000), AHTR rate (0.7/1,000)

Lessons Learned

- Don’t reinvent the wheel, simplify the wheel
- ISBT working definitions invaluable
- HV training and introduction of the hemovigilance system has improved monitoring and evaluation
- Easier to train on a simple system
- Completion of the data base earlier in the project would have been an advantage
- It is possible to use a simple cloud-based web portal to centralize hemovigilance data from different hospitals
- Training the trainers (local medical staff) is the key to sustainability
- Easily accessible & timely reports help in real-time analysis and evaluation
- Reports from the system can be used for educational purposes

Future…

- Capture 3,200 transfusion records within the funded project period
- NBSG oversee the cloud-based hemovigilance infrastructure, after the funded period ends
- Similar programs can be expanded to other sites to establish user-friendly national hemovigilance systems

THANK YOU!!

For questions: srajbhandary@aabb.org