The Quality Conundrum

High Resource TM Standards in Low Resource Environments

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Case 1

- 29 yr old woman is 24 hours post home delivery and has increased vaginal bleeding.
- Goes to local hospital, assessed and sent by ambulance 100kms to national referral hospital.(KNH) Has increased bleeding all during transfer.
- Arrives at KNH with profuse vaginal bleeding & 3gm Hb.

More Case 1

- Samples sent to lab, patient prepped for emergency hysterectomy.
- PT and APTT do not clot at all.
- Lab ask me what to do. Just setting up Fibrinogen so not readily available.
- Can't call the floor - **no telephone !!**
- We go to the floor (2000 bed hospital) and patient has expired due to bleeding.

Even More Case 1

- What was the diagnosis ?
- Post Partum DIC
- PT & APTT did not clot since she had almost no fibrinogen (less than 100mg/dL later in day.
- Was not transfused since they had NO blood or blood products except at KNH.

Case 2

- 23 y.o. is admitted to Emory Midtown Hospital requiring emergency C section.
- Labs pre op show PT of 10.1 secs, APTT of 25.5seconds & Fibrinogen of 768mg/dL.
- Section is uneventful, but about 13 hours later she passes 1 litre of blood vaginally in 15 minutes and becomes hypotensive

More Case 2

- Labs are drawn and blood FFP, Cryo and Antithrombin are ordered.
- Presumptive Dx is DIC secondary to retained placental products.
- Labs show PT of 15.1 seconds, APTT of 42.4 seconds, fibrinogen of 219mg/dL,AT of 41% and D-dimer of 5225ng/mL

Even More Case 2

- Is transfused with RBCs, FFP, cryo and AT and has emergent D & C and stops bleeding, and stabilises hemodynamically.
- Post surgery labs, PT 13.6secs, APTT 34.5secs, Fibrinnogen 355mg/dL and Dimers of 8612ng/mL
- Patients survives without issues.

CASE 3

- Same Kenya patient arrives at rural hospital bleeding post home delivery.
- Too sick to transport.
- Blood Bank has 3 units of blood available, but no rapid HIV kits to test them. !
- What to do?
- Transfuse anyway since she might survive and worry about HIV later, or do nothing?

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ACCIDENT & EMERGENCY


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The Resource Conundrum

- He who has the resources medically can provide blood & blood products with minimal problems.
- Blood Needs are a well accepted component of medical care.
- Blood Safety is usually a national priority and the system is heavily regulated.

More Resource Conundrum

- Most low resource countries have no blood policy and usually little blood.
- Most blood is collected locally not in large Blood Centres.
- There is little appreciation that blood availability is important to advance medical care.
- Almost all blood is whole blood.

Blood Needs

- 12 million units drawn in the US for a population of 300 million.
- Georgia, population 12 million draws 40,000 units and produces FFP & Cryo. Almost no platelet production.
- Kenya, population 40 million draws about 30,000 units with almost no secondary processing.

Conundrums

- Are our standards useful in less developed countries?
- Do we need to customise them ?
- What can they afford?
- Who pays for anything.
- How can we help ! Can we !

Personal Experience

- PEPFAR sent me to Kenya to help write National Transfusion Service Guidelines.
- We sat in a hotel for a week & tried to emulate those AABB standards that were applicable.
- A basic document had been developed 3 years before.

More Personal Experience

- We wrote nice guidelines and produced a lovely document that was printed in a nice handbook.
- It contained very pertinent information.
- Nobody uses it !
- Effectively no national distribution!

Even More Experience

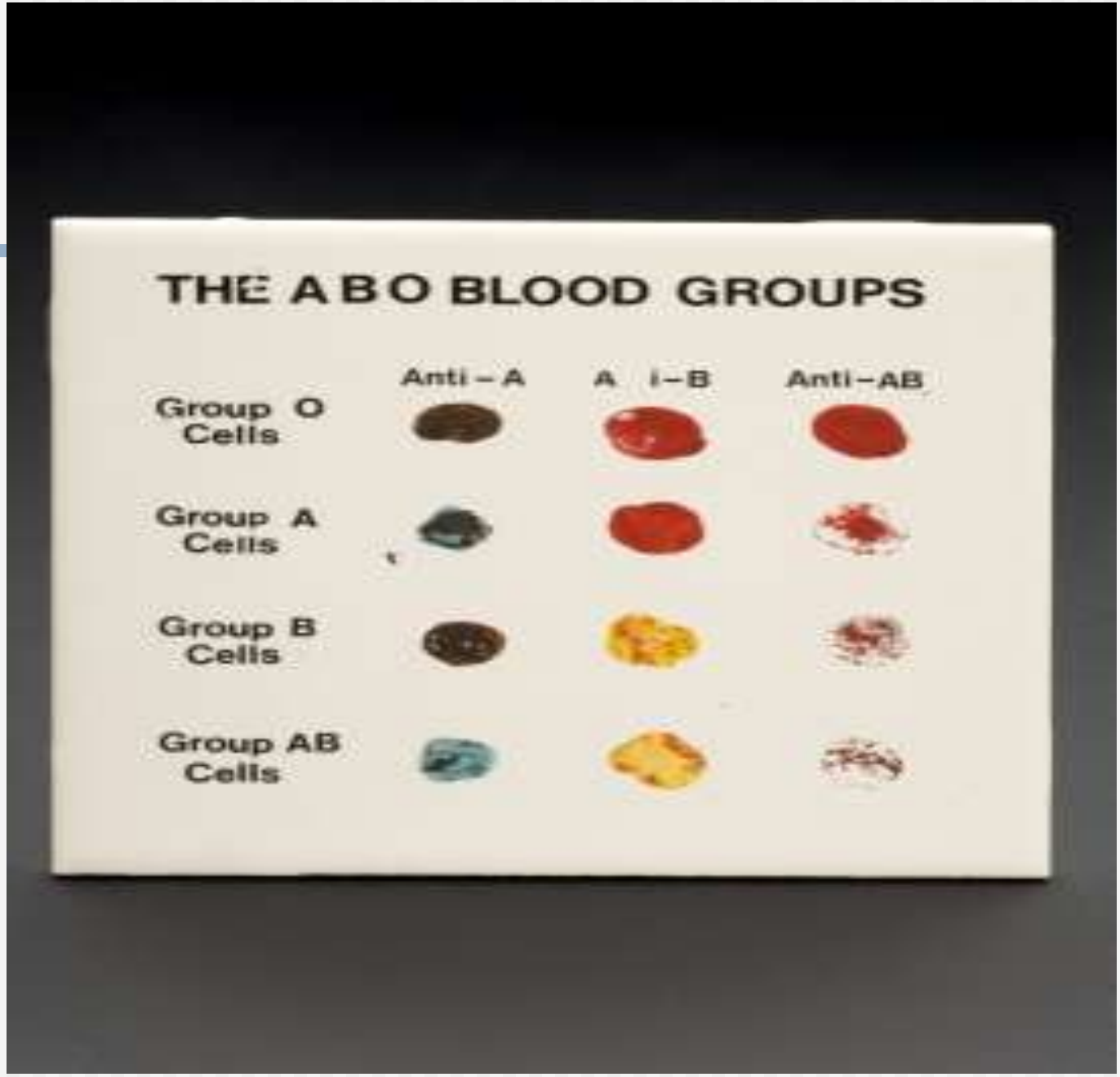
- Kenya has no central distribution of blood. It's all local
- Families bring their relatives to donate. Many don't' qualify
- The lab may have no HIV kits.
- Typing sera can come from anywhere that's cheap !

Tbilisi Experience

- Intermediate resource country.
- Well developed blood policy and stringent controls on reagents.
- No real national BTS.
- Both public and private draw sites.
- Most blood from paid donors.
- All Hepatitis/HIV negative

More Tbilisi Experience

- Donor typing done on tiles at donation.
- All tube labeling and processing done by hand.
- Effective monitoring and oversight.
- Some computerisation.
- All blood must be approved by TM specialist anywhere in the country !!


THE ABO BLOOD GROUPS
Anti – A
A i – B
Anti – AB
Group O Cells
Group A Cells
Group B Cells
Group AB Cells

QC in the "Real World"

- In high resource countries we are obsessive about "quality" in all aspects of Blood Banking.
- We have more "paper" procedures than the Federal Government.
- We have regulations everywhere & about everything !
- We probably inspect toilet paper in the Blood Bank and have an SOP about it's size !

U.S. BB & TS Oversight

- Typically Blood Banks & hospital based Transfusion Services have different regulatory standards.
- Hospital TS operate under CLIA 88 licenses.
- Both AABB & CAP have deemed status to inspect and approve TS functions including QC.

Role of FDA

- Ultimate regulator for Blood Bank practices. Can inspect at any time!
- Need to approve all equipment, reagents, blood products, drugs, devices used in Blood Banking practices
- Require to have all serious adverse effects of transfusion reported quickly to them.
- Not always your best friend!

Role of WHO

- Many developing countries look to WHO for “guidance” on many aspects of medical practice.
- Big focus on infectious diseases
- TM not a big area for them.
- The ISBT is also important and more relevant than AABB in low resource countries

QC involves

- Equipment
- Reagents
- Blood Components
- Therapeutic Factor Products
- Personnel (proficiency/staff competency)
- Processes (SOPs & Standardisation)
- Administrative & Medical oversight.

Examples in TM/QC

- In the US all BB/TM facilities must use outside provided QC material to validate all testing procedures.
- Ex. DAT testing, antibody identification.
- These can then be compared nationally.
- Can not be done by the same technical staff for every survey, but must be rotated to “prove” competence by all staff.

More QC Issues

- The fact that all equipment /reagents are “approved” by the FDA provides some degree of expected performance by labs.
- Manufacturers who find or are notified by labs of problems in reagents must report this to the FDA or face censure, fines or be closed down.

QC in Lower Resource Areas

- QC cost significant time and money for BB/TMS in the US. As much as 20% of the reagent budget goes to QC requirements.
- These costs can be passed on users/patients as part of their healthcare bill.

QC in Lower Resource Areas

- The ability to pass on QC costs is not always easy or even feasible with limited resources.
- It is often attractive to use reagents or equipment from low cost countries like India or China because they are much cheaper, but may have limited or no “approval”

QC in Lower Resource Areas

- This is not to say that all of these reagents are bad.
- Some Indian BB reagents are good but do not meet FDA standards for potency. Maybe the FDA standards are too high?
- Some countries place no controls on importation of medical equipment.

QC in Lower Resource Areas

- Standardisation is a key component of good QC practices.
- This includes SOP (AABB)
- Reagents (FDA or CE marked)
- Technical staff licensure & training
- Medical staff training.(BB boarded)

Who Controls & Who Pays?

- Many countries have government tenders as their mechanism for equipment & reagent purchases.
- There is often little or no input from any labs users as to what they really need or want.
- Price is usually the over riding consideration. (low must be best !)

Who Controls & who Pays?

- Centralised Blood Banks tend to use similar equipment & reagents which provides better QC opportunities.
- Hospital based TM services often are quite different and may use lab group buying by vendors with very different instrument/reagents.

Who controls & who pays?

- Does a country even have a national source of QC (usually cheaper)
- Buying from CAP or EU/WHO sources is often very expensive.
- Who oversees the results of external QC ?
- Who deals with QC failures and what tolerances for variability are allowed

Who controls & who pays?

- Is there any accountability?
- Are there any ramifications ?

  (inspection, oversight, closure !)
- What is reasonable in a lower resource country? (anything !!)
- How do good QC programmes evolve ? (Nepotism!)

Personnel Experience !

- Lab in low resource country says they get very variable results on testing using their blood typing sera.
- Reagents are from other low resource country with little information about expected titre or potency.
- Importing distributor was diluting the antisera to make more money. No import restrictions & no government standards.

Personnel Experience !

- No accountability for the distributor.
- Who is responsible for any oversight to prevent this ?
- This was two years ago & nothing has changed !
- TM is still not perceived as being important in the big picture.

Crotalus horridus

timber rattlesnake

Practice & QC Risks

- Many times poor QC implementation will cause obvious issues.
- Eventually somebody in these countries will sue the hospital/BB
- Any help/support we give is useful.
- That snake may come back to bite you in the butt !!