

# How to effectively report to SABRE and SHOT

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# Remit

- To explain how to successfully report to both MHRA and SHOT through the SABRE on-line reporting system
  - Background
  - Incident reporting and investigating system
  - What to report
  - The keys to successful reporting

# Leeds Teaching Hospitals



St James's University  
Hospital



The General Infirmary  
at Leeds

# Bradford Teaching Hospitals



Bradford Royal  
Infirmary

Leeds Teaching Hospitals  
Trust provides the  
Pathology services for  
Bradford Teaching  
Hospitals Foundation Trust

This includes the Blood  
Transfusion Laboratory

# Warning: Incident reporting involves lots of acronyms

- Examples of ones I may use
  - SHOT – Serious Hazards of Transfusion (UK)
  - MHRA - Medicines and Healthcare Products Regulatory Agency
  - BSQR – Blood Safety and Quality Regulations
  - SABRE – Serious Adverse Blood Reactions and Events (on line reporting system)
  - SAE – Serious Adverse Event
  - SAR – Serious Adverse Reaction

# The Danger of acronyms

- People don't always mean the same thing when using an acronym
  - MHRA
    - Michigan Hot Rod Association
    - Medicines and Healthcare Products Regulatory Agency
  - SHOT
    - Single-Hull Oil Tanker
    - Serious Hazards of Transfusion (UK)
  - SABRE
    - Somali Abyssinian Breed Rescue Education
    - Serious Adverse Blood Reactions and Events
  - GDAP
    - Growing Danger of Acronym Proliferation

# Background

- November 1996 – SHOT launched
  - Collect data on transfusion related deaths and major complications
  - Based at Manchester Blood Transfusion Centre
  - Anonymous
  - Voluntary
  - Produces annual reports on incidents and reactions which include recommendations on best practice and areas for further study

# Background

- **January 2003 - EU Directive 2002/98/EC:** setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
  - ...ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain...
  - ...introduce a set of organised surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions resulting from the collection of blood or blood components in order to prevent similar or equivalent events or reactions from occurring...

# Background

- **September 2005 - EU Directive 2005/61/EC:**  
implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and **notification of serious adverse reactions and events**
  - Article 5: Notification of serious adverse reactions
  - Article 6: Notification of serious adverse events
  - Reporting to the “Competent Authority” – the MHRA

# Background

- February 2005 – Blood Safety and Quality Regulations (SI 50/2005) *as amended*
- August 2006 - The Blood Safety and Quality (Amendment) Regulations 2006 (SI 2013/2006)
- Legal requirement to report Serious Adverse Blood Reactions and Events to the Competent Authority
- Criminal law

# The SABRE system



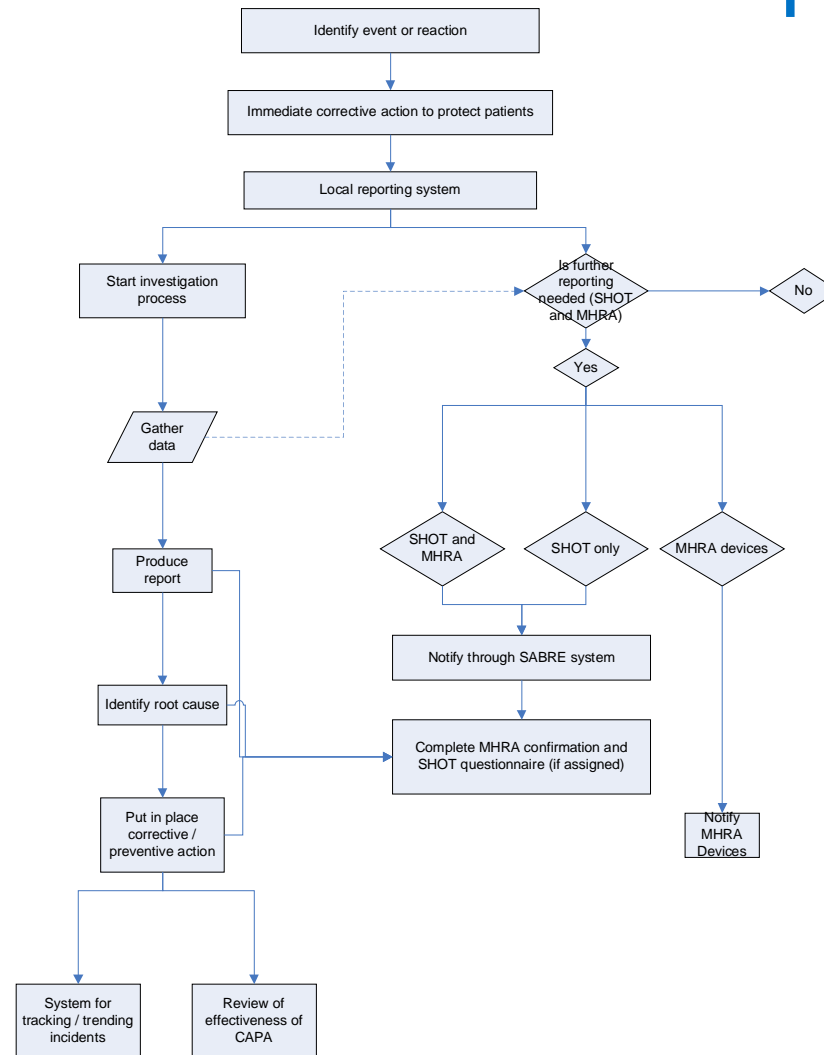
- On-line reporting system accessed through the MHRA's website
  - For reporting
    - Serious Adverse Reactions (SAR)
    - Serious Adverse Events (SAE)
    - Reporting to SHOT
  - Reporting to SHOT still remains voluntary but is required by HSC 2004/009 'Better Blood Transfusion'

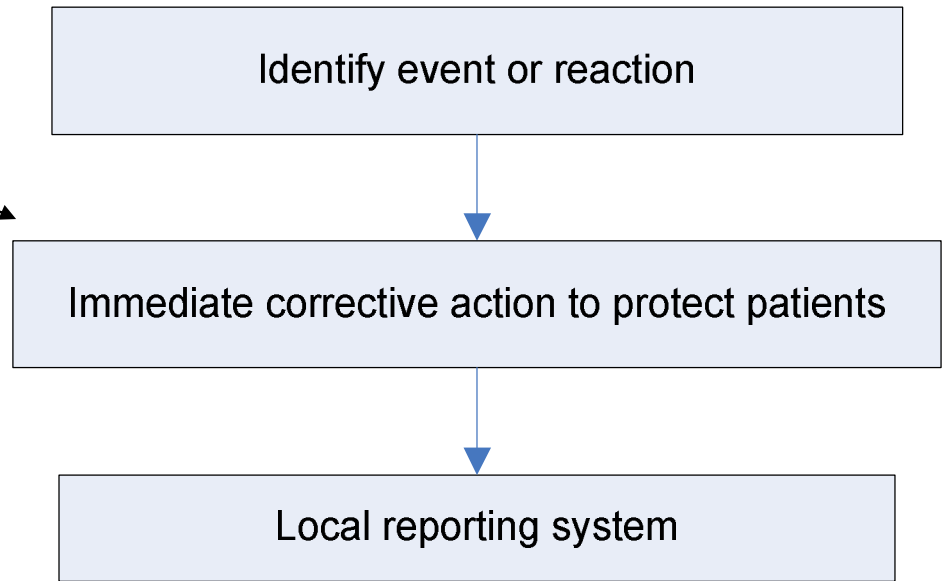
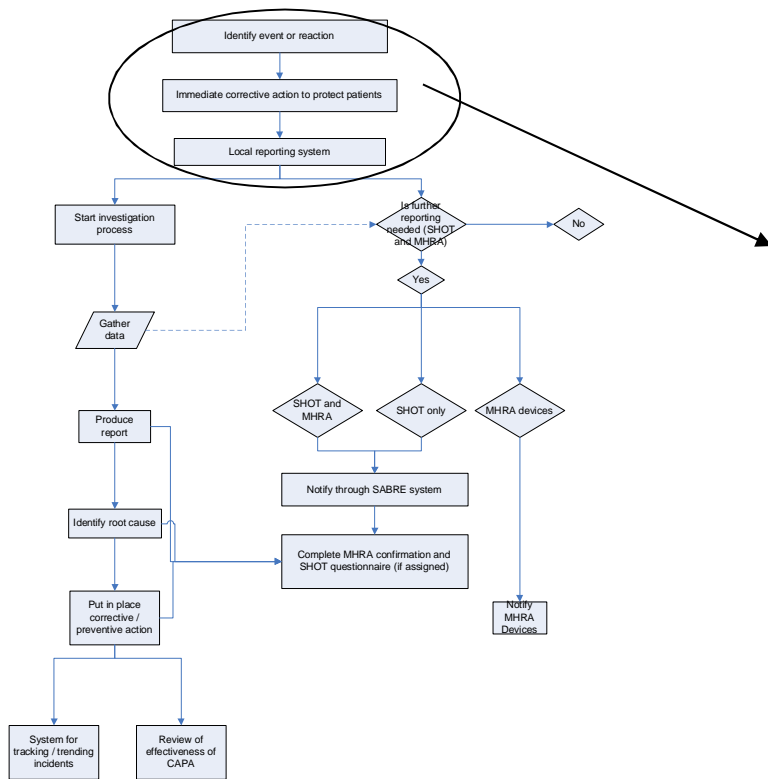
# Reporting

- 2007 SHOT report
  - Figures from both SHOT and MHRA show that a substantial number of hospitals, including some high users, are not sending reports. This is in breach of European and UK legislation
- Report from Blood Consultative Committee, January 2009
  - 45 laboratories had not reported any events or reactions to SABRE in a three year period
  - 5 of those were issuing in excess of 5000 units per year

# Successful reporting

# Understand the whole process





# Knowing about the incident

- If you don't know about it you won't be able to report it
- Need a simple local reporting system
  - Simple reporting form
  - Encourage self reporting of 'events' in the laboratory
    - Avoid the blame game
  - Encourage reporting of suspected reactions by clinical areas to the laboratory or hospital transfusion team
    - Make it easy for them to report to the lab
    - Make it easy for the lab staff to deal with

# TIRF – Transfusion incident and reaction form

Complete the form in full if necessary continue overleaf. If attaching other documents please attach securely							
Please circle site							
Blood Transfusion							
	BRI	CAH	LGI	SCFT	SJUH	St L	WGH
incident: please select	Clinical incident			Non-clinical incident			
	Time (24hr clock)						
location : Include room N <sup>o</sup> if known							
Patient/Staff member/Other persons/ Sample involved (Complete in full or attach request form copy)							
DOB. / /							
LN <sup>o</sup> or NHS N <sup>o</sup> Staff N <sup>o</sup> :				Ward:			
number(s)							
state for reactions only		Tick				Tick	
- Red cell reaction sent to ward				Form 2 – Platelets / plasma reaction sent to ward			
state for all incidents – do not request or complete an IRI form (HTT will decide)							
of all implicated units requested							
naming ward staff: name and contact details:							
time reported to BB							
of senior staff (BB) reported to							
what happened: brief details (state facts if assumptions say so) Include names and contact details of Witness(es) (if any)							
Continue overleaf if necessary							
Please give brief details of any immediate remedial action taken:(Please state if no action taken)							
Continue overleaf if necessary							
Form completed by							
Signature				Date			
Incident reviewed by							
Signature				Date			
Comments including actions taken or initiated							
Continue overleaf if necessary							

If this is a transfusion reaction forward this completed form to the HTT at LGI (fax to 23318) and send a copy to the Quality Manager. If a laboratory incident please forward to the Quality Manager (LGI fax number 25540)

# Transfusion reaction ward forms

## Form 1 – Transfusion reaction to red cells

A possible transfusion reaction has been reported for this patient: please complete actions detailed on this form. Please note urticarial and minor febrile (temp rise of less than 1.5°C) reactions with no other symptoms do not need investigating

Patient name	
DOB	
Hospital Number	
Ward/Hospital	

- Please return all used and unused units of any blood product administered in previous 24 hours
- Please send samples as listed in table below
- Please arrange for the patient to have a chest X ray if they suffered from breathing difficulties during the reaction

Samples needed	Tests to be performed / requested	Laboratory in which tests performed	Tick once sent
Clotted (1x 6ml Red top, lack inner)	Group, antibody screen, re-crossmatch	Blood Bank	
:DTA (1x 6ml Pink top)	DAT		
:DTA (4ml purple top)	Full blood count (FBC)	Haematology	
Blood cultures	Blood cultures	Microbiology	
First urine passed post transfusion (sterile universal container)	Urobilin Urobilinogen Urine bilirubin	Biochemistry	
Clotted (1x red top, lack inner)	Serum immunoglobulins	Immunology	
Clotted (1x red top, lack inner)	Mast cell tryptase - to be taken <ul style="list-style-type: none"> <li>• Immediately</li> <li>• @4 hours</li> <li>• @24 hours</li> </ul>	Immunology	

If you have any queries please contact Blood Bank on: LGI: 23398 SJUH: 65559  
Or the Hospital transfusion team on 23984 or 67657

## Form 2 – Transfusion Reaction to Platelets / Plasma / Cryoprecipitate

A possible transfusion reaction has been reported for this patient: please complete actions detailed on this form. Please note urticarial and minor febrile (temp rise of less than 1.5°C) reactions with no other symptoms do not need investigating

Patient name	
DOB	
Hospital Number	
Ward/Hospital	

- Please return all used and unused units of any blood product administered in previous 24 hours
- Please send samples as listed in table below
- Please arrange for the patient to have a chest X ray if they suffered from breathing difficulties during the reaction

Samples needed	Tests to be performed / requested	Laboratory in which tests performed	Tick once sent
Clotted (2 x 6ml red top, lack inner)	National Blood service H and I testing – HTT will advise if needed	Blood Bank	
:DTA (2 x 6ml pink top)			
Blood cultures	Blood cultures	Microbiology	
Clotted (1x red top, lack inner)	Serum immunoglobulins	Immunology	
:DTA (4ml purple top)	Full blood count (FBC)	Haematology	
Clotted (1x red top, lack inner)	Mast cell tryptase - to be taken <ul style="list-style-type: none"> <li>• Immediately</li> <li>• @4 hours</li> <li>• @24 hours</li> </ul>	Immunology	

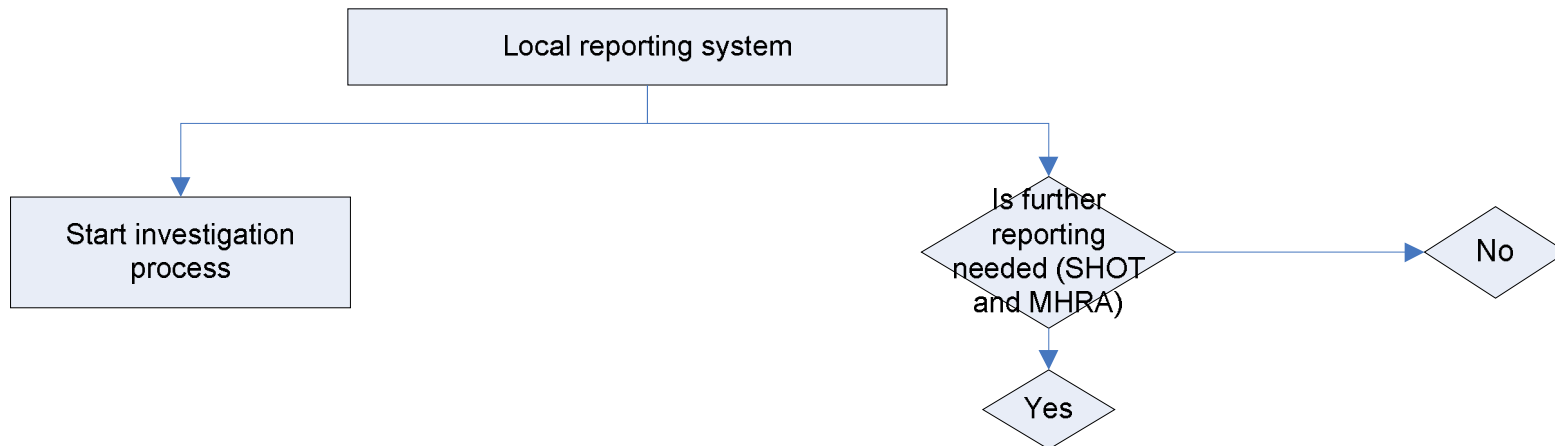
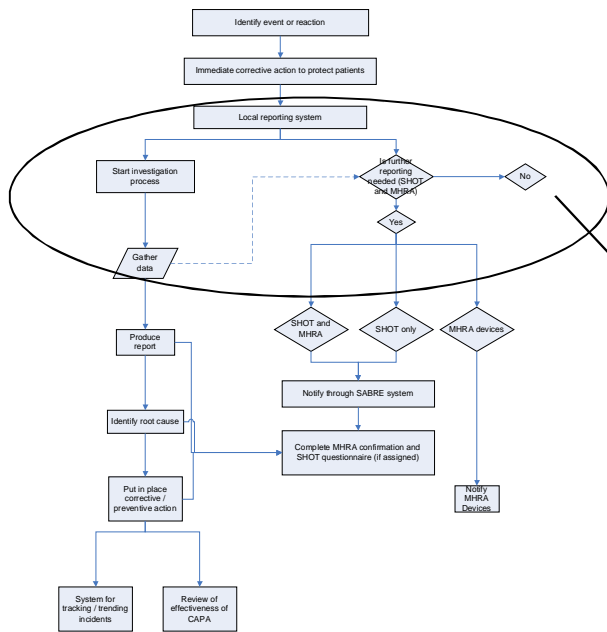
If you have any queries please contact Blood Bank on: LGI: 23398 SJUH: 65559  
Or the Hospital transfusion team on 23984 or 67657

Note for lab staff: do not send NBS samples until discussed with HTT

# Immediate corrective action

- This is what you do immediately following an event or reaction to protect this patient and other patients
- Have a system in place to ensure this happens
  - Empowering staff
  - Training staff
  - Having a system to escalate more serious incidents
- Examples
  - Suspected ABO HTR – informing appropriate medical staff (Haematologist / Renal Medicine Specialist) – *protecting this patient*
  - Red cell transfusion reaction – recall of other units issued for this patient; *protecting this patient*
  - Suspected bacterial reaction – inform the National Blood Service; *protecting other patients*
  - Blood fridge failure – quarantine units from fridge; *protecting other patients*

# The next stage – Further reporting and investigation



# Further reporting / investigation

- These will probably start at around the same time
- MHRA expect reporting within 7 days
  - You may have time to start investigating before further reporting
- If you are unsure about whether an incident is reportable, ask the SABRE team or SHOT

# Deciding what you need to report further

- What constitutes a **Serious** Adverse Reaction
  - Definition '*an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is **fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity***'
  - Also need reporting to SHOT

# Deciding what you need to report further

- What constitutes a **Serious** Adverse Event
  - *'any untoward occurrence associated with the **collection, testing, processing, storage and distribution**, of blood or blood components that **might** lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.'*
  - Errors in the laboratory, or in storage and distribution that are not picked up by the normal laboratory quality system checks
  - It includes near-miss events
  - Reporting to SHOT; these will be either
    - Incorrect blood component transfused (IBCT)
    - Right blood, right patient
    - Or Near miss, testing, storage or distribution

# Serious Adverse Events (Yes or No?)

- Non irradiated component issued to Hodgkin's Disease patient; error made in lab. Error detected after transfusion started
  - YES SAE
  - Also report to SHOT as IBCT
- Non irradiated component issued to Hodgkin's Disease patient; error made in lab. Error detected on ward before transfusion started
  - YES SAE. Error was not detected as part of the laboratory's quality system
  - Also report to SHOT as Near miss
- Non irradiated component issued to Hodgkin's Disease patient; lab unaware of diagnosis, found on ward after transfusion.
  - NO not SAE. Error was outside the laboratory's control
  - Report to SHOT only as IBCT

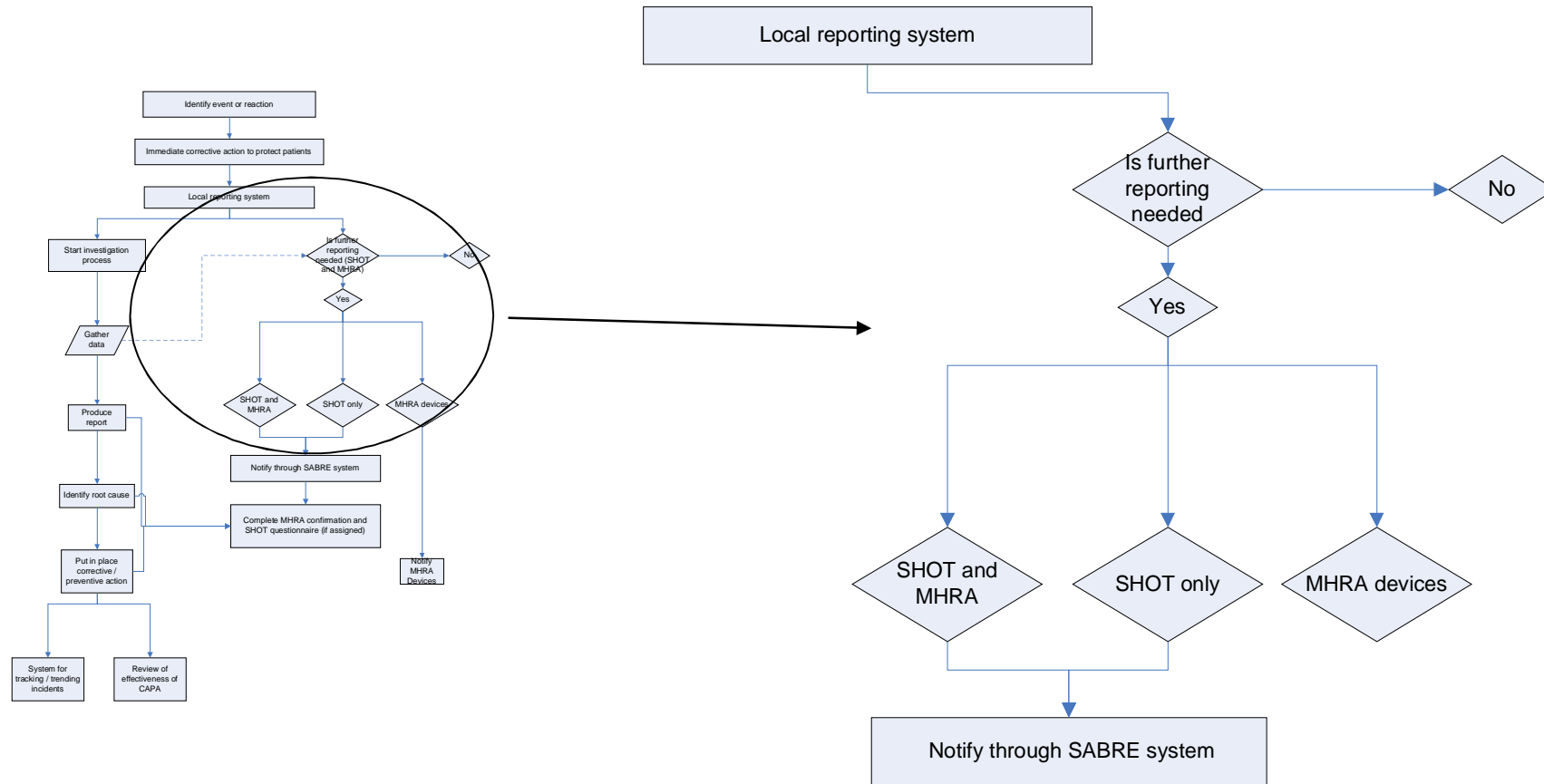
# Serious Adverse Events (Yes or No?)

- Expired unit of blood not removed from issue fridge by lab staff.  
Taken to ward but not transfused
  - YES SAE. Laboratory has responsibility for removing expired units and failed to do this
  - Also report to SHOT as a near miss
- Ward removes a unit from fridge and returns it 45 minutes later.  
Laboratory is alerted by tracking system and recalls unit
  - NO Not SAE. Error was picked up as part of the laboratory's quality system
  - Not reportable to SHOT
- Ward removes unit from fridge but does not commence transfusion for 45 minutes. 15 minutes after start of transfusion member of ward staff realises that donation was out of fridge more than 30 minutes before commencing transfusion and contacts lab for advice.
  - NO not SAE. 30 minute rule only applies to returning blood to storage. Transfusion should be completed within 4 hours
  - Not reportable to SHOT

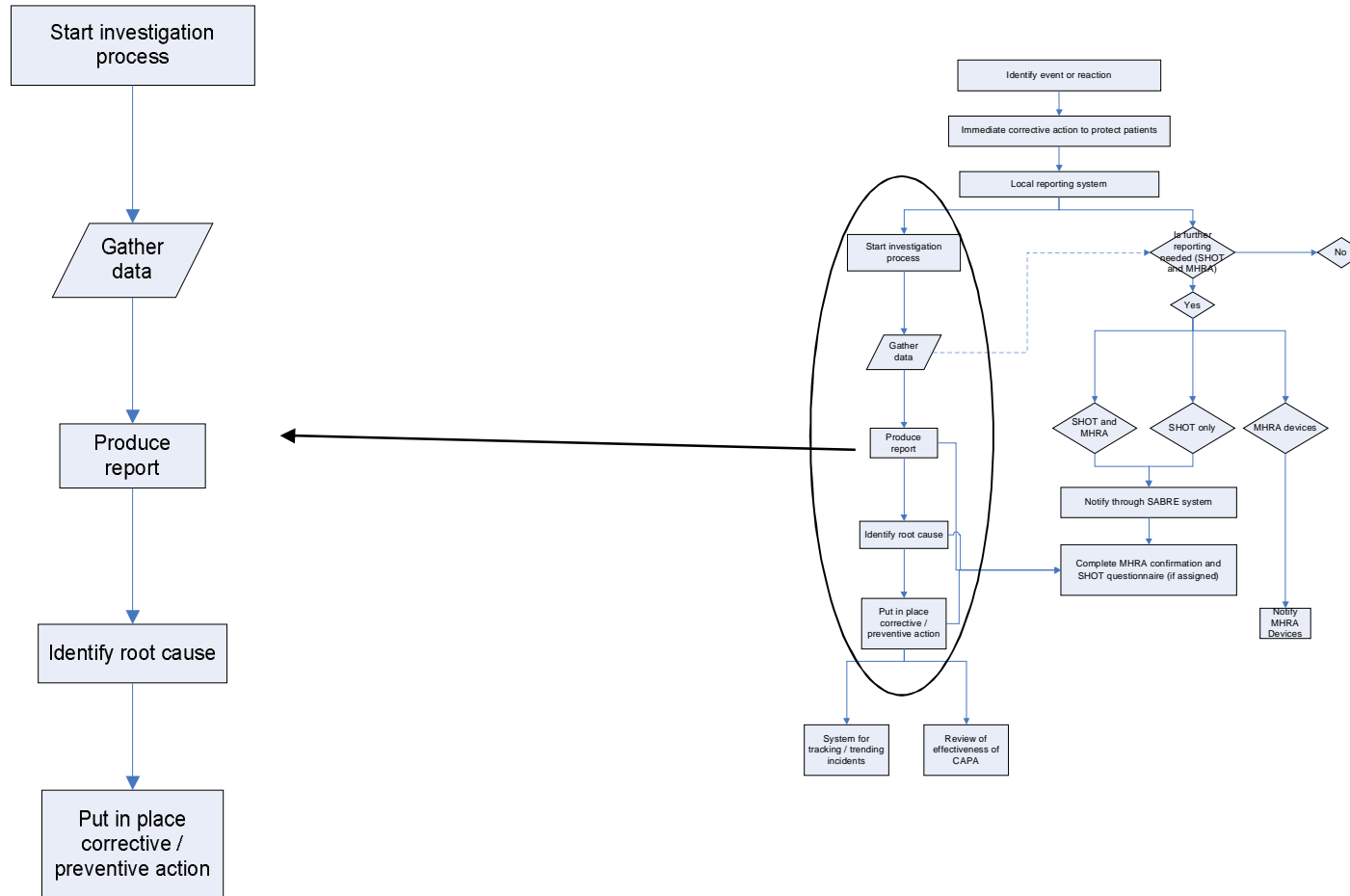
# Serious Adverse Events (Yes or No?)

- Nurse collects blood for patient A from blood fridge and transfuses it to patient B. No bedside check performed
  - Not an SAE – error occurred in clinical area
  - No transfusion reaction
    - Report to SHOT only as IBCT
  - Transfusion reaction
    - Report to MHRA as SAR
    - Report to SHOT as IBCT / Haemolytic transfusion reaction
- Further scenarios are available on the SHOT website  
<http://www.shotuk.org/SABRESCENARIOS&SOLUTIONS.pdf>

# Further reporting



# Investigation



# Investigation - Serious adverse reaction

- Gather information do determine
  - What type of reaction was it?
    - Don't always believe the type of reaction that was initially reported
    - Reaction types are not always easy to determine.
    - SHOT and MHRA have different categories – familiarise yourself with them

# Investigation - Serious adverse reaction

- SHOT
  - Acute Transfusion Reaction
  - Haemolytic Transfusion Reaction (delayed or acute)
  - Transfusion Related Acute Lung Injury
  - Transfusion Transmitted Infection
  - Post Transfusion Purpura
  - Transfusion Associated Graft v Host Disease
  - Transfusion Associated Circulatory Overload
- MHRA
  - Anaphylaxis / hypersensitivity
  - Immunological haemolysis due to ABO incompatibility
  - Immunological haemolysis due to other allo-antibody
  - Non-immunological haemolysis
  - Transfusion related acute lung injury
  - Transfusion-transmitted bacterial infection
  - Transfusion-transmitted viral infection (HBV)
  - Transfusion-transmitted viral infection (HCV)
  - Transfusion-transmitted viral infection (HIV-1/2)
  - Transfusion-transmitted viral infection, Other (Specify)
  - Transfusion-transmitted parasitological infection (Malaria)
  - Transfusion-transmitted parasitological infection, Other (Specify)
  - Post-transfusion purpura
  - Graft versus host disease
  - Other serious reaction(s) (Specify)

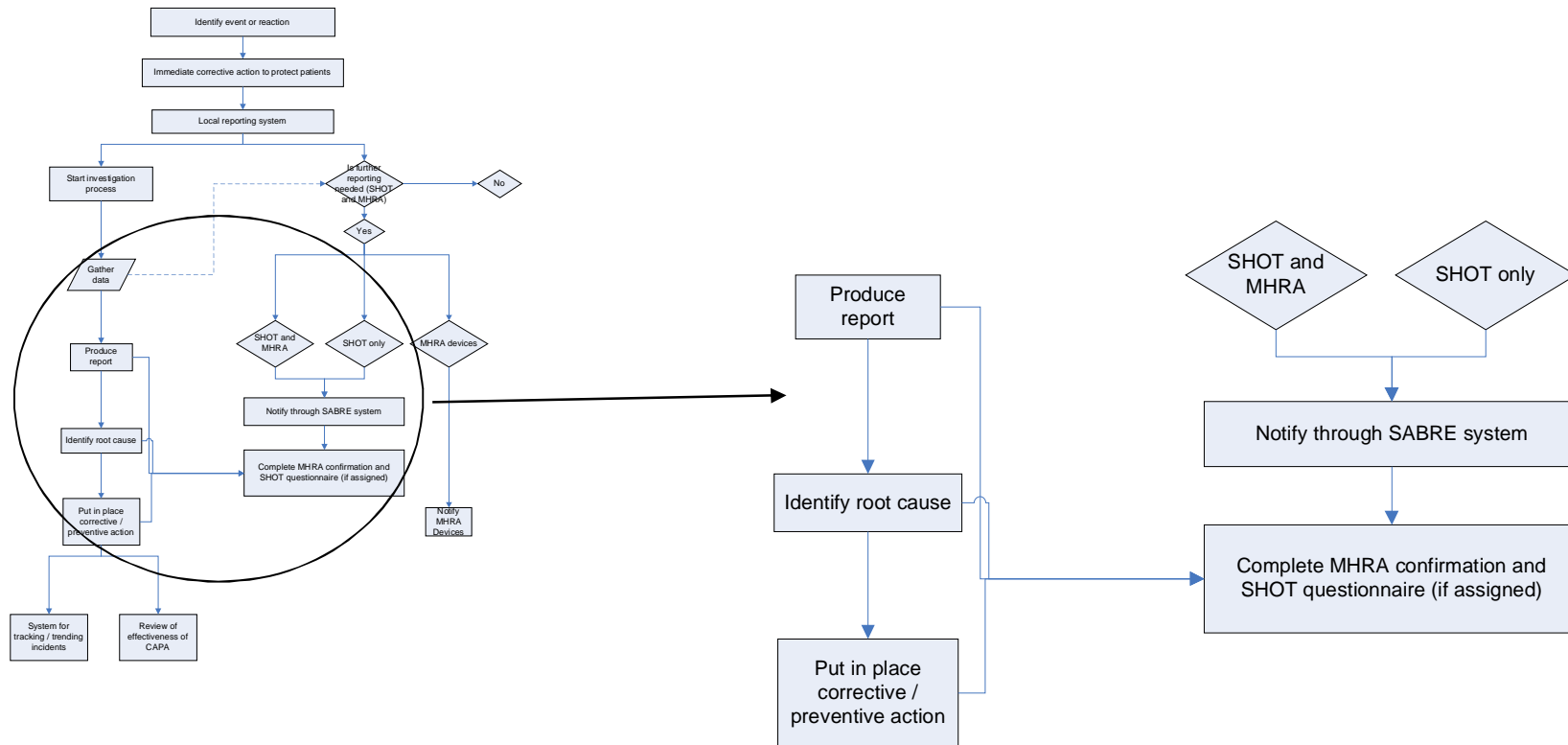
# Investigation - Serious adverse reaction

- Gather information do determine
  - Imputability
    - How likely was the transfusion the cause of the patient's symptoms?
- When gathering the information gather what you need to complete the appropriate shot questionnaire

# Investigation - Serious Adverse Event

- Gather information
- Determine root cause. Use the SHOT/NPSA toolkits
  - <http://www.shotuk.org/RCA%20toolkit.pdf>
- Put in place corrective and preventive action
- If it is an IBCT gather the information you will need to complete a questionnaire

# Bringing it all together



# Confirmation on SABRE system

- Use your reports to complete the confirmation section of the SAE/SAR reporting
- Complete SHOT questionnaire – if one is allocated
- MHRA expect completion of investigation and confirmation *normally* within 30 days.
  - Extending beyond 30 days should be on a case by case basis. E.g. TRALI investigations which may take months if many donors are involved

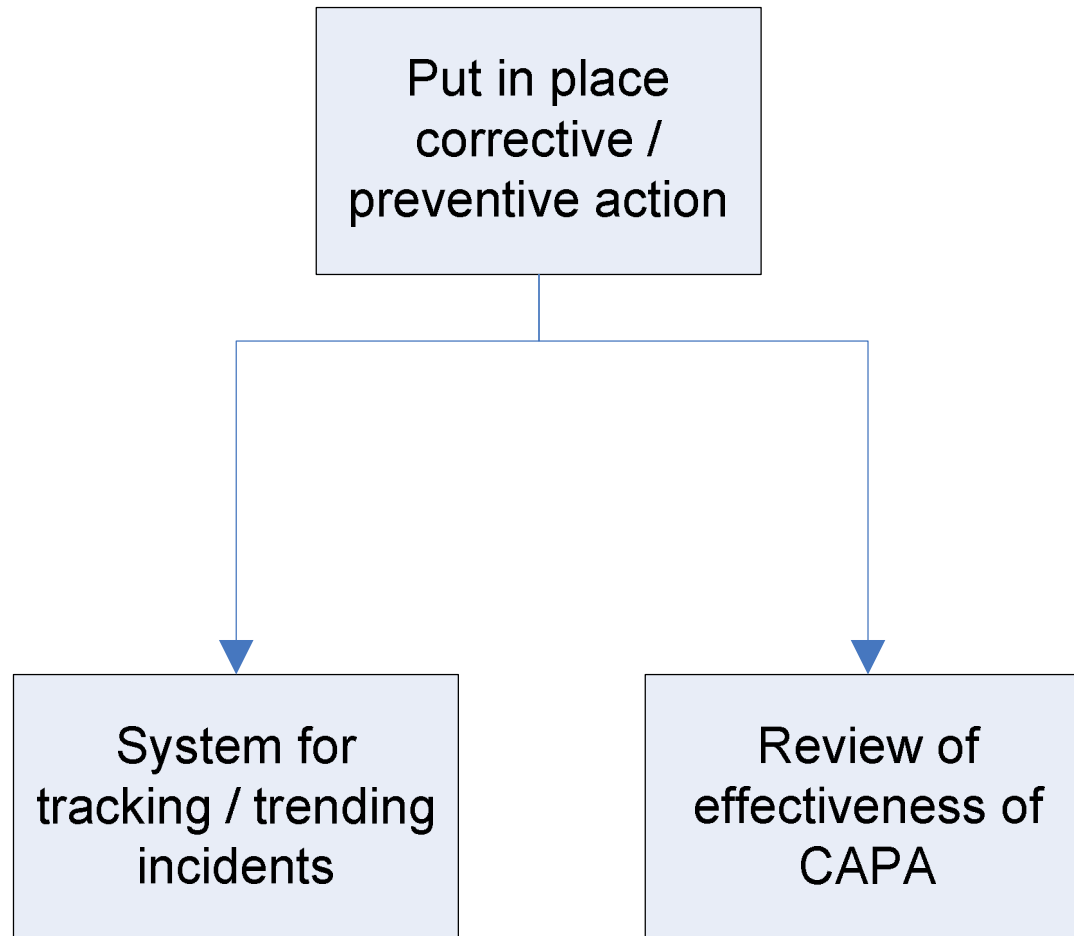
# Keys to making it all work successfully

- To understand the *whole process* for management of incidents and non-conformances
- Have a robust local system for identifying and reporting incidents
- Empower key personnel to investigate and report on SABRE.
- Make sure the reporting is done by someone who understands the incident
  - SAR – needs clinical /HTT input
  - SAE – needs to be done by someone who understands laboratory quality processes

# Keys to making it all work successfully

- Don't worry about reporting events to MHRA
  - It will not result in immediate inspection (*usually*)
  - Detecting and reporting incidents is a sign of a functioning quality management system.

# Food for thought



# Acknowledgements

- SHOT
- Leeds Teaching Hospitals Blood Transfusion Lab staff and Hospital Transfusion Team

# And Finally...

Enjoy failure and learn from it. You can never learn  
from success

James Dyson

I claim to be a simple individual liable to err like  
any other fellow mortal. I own, however, that I  
have humility enough to confess my errors and  
to retrace my steps.

Mohandas K Ghandi