

Role of haemovigilance in optimal use of blood components

Georges Andreu

Institut National de la transfusion Sanguine

What Haemovigilance does cover ?

Adverse reactions and events plus traceability and donor epidemiology are analyzed in a growing number of countries through haemovigilance networks.

The whole transfusion chain is covered, and may be classified as follows (EU directive) :

Transfusion Process :

- Traceability of blood components
- Events (severe)

Recipients :

- Reactions (severe vs all)

Donors :

- Epidemiology
- Reactions (severe vs all)

Directive 2002/98/EC definitions

1. Serious adverse reaction :

- an unintended response in *donor* or in *patient* associated with the *collection* or *transfusion* of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity ;

2. Serious adverse event :

- any *untoward occurrence* associated with the collection, testing, processing, storage and distribution, of blood and 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

Haemovigilance workflow

Serious adverse reactions

Reporting establishment

- Rapid notification
- Confirmation notification
- Annual notification

Competent authority

- Annual report

Serious adverse events

Reporting establishment

- Rapid notification
- Confirmation notification
- Annual notification

Competent authority

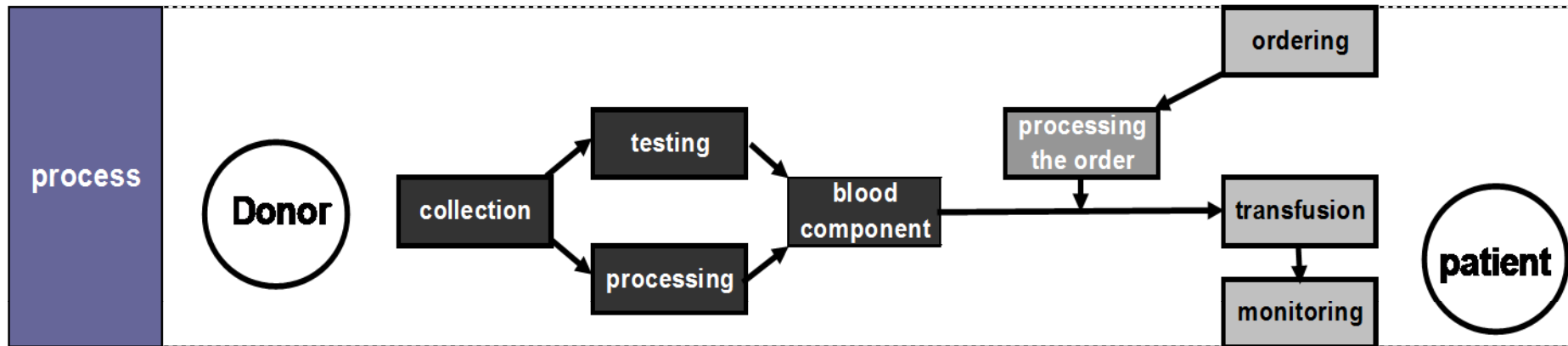
- Annual report

What Optimal Blood component Use is ?

Brian McLelland, 2008

1. Safe supply of blood component :
 - ✓ Right unit
 - ✓ To the right patient
 - ✓ At the right time
 - ✓ In the right conditions
2. Appropriate prescribing
 - ✓ Complies with guidelines + sound clinical conditions
3. With a benchmarked utilization
 - ✓ Within an acceptable range

<i>location</i>	<i>Blood establishment</i>	<i>blood establishment or Hospital blood bank</i>	<i>Hospital</i>
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Adverse reactions	all ?							all ?
	severe yes							severe yes
	y	y	y	y	y	y	y	y
adverse events	post donation info						transfusion monitoring yes	
							ordering ?	

Haemovigilance as a means for nonconformity management

Detailed clinical transfusion process-1

1. Ordering (at the clinical ward)

- Assess the need
- Inform the patient
- Complete the request form
- Take blood Sample
- Transport blood sample and request to Hospital Blood Bank (HBB) or Blood Establishment (BE)

2. Processing the order (at the HBB or BE)

- Request and Sample reception
- Pre-transfusion testing
- Select appropriate unit of blood component. In case appropriate unit is not available, order it to (another) Blood Establishment
- Issue the unit
- Transport of the unit to the requesting ward

Detailed clinical transfusion process-2

3. Transfusion (in clinical ward)

- Reception in clinical ward (and storage) of unit
- Pre-administration checks (including bedside tests)
- Administer the unit
- Record transfusion and report to HBB or BE (traceability)
- archiving for traceability (HBB or BE)

4. Monitoring (in clinical ward)

- Monitor the patient
- Monitor the transfusion
- Manage adverse reaction if any
- Report adverse reaction if any (a. ward to HBB or BE and b. HBB or BE to National Haemovigilance Registry)
- Record outcome (including reassessing the need)

Commonly considered Severe Adverse Events

1. Inappropriate blood component (BC transfused)
 - BC intended for another patient
 - Inappropriate BC specification
 - Inappropriate or unnecessary transfusion
 - Unsafe BC due to handling or storage error
 - Undertransfusion
 - No transfusion
2. Near Miss Events (BC not transfused) that could result in :
 - Wrong blood group result
 - Collection of inappropriate BC
 - Issue of inappropriate BC

Adverse events may lead to adverse reaction !

deaths after inappropriate BC transfusion

SHOT 2006 :

- Overdosage of platelet in 12mths old infant
- Overdosage of RCC in 80y old patient

France 2004 :

- ABO incompatibility
- Red cell incompatibility (anti FY1 + JK1)

Incidence of Adverse events and reactions

	UK 2006	France 03-05
Adverse Events (inappropriate BC)	1 / 7500 BC	1 / 18210 BC
Adverse Reactions	1 / 22000 BC	1 / 450 BC

Many factors make comparison useless :

- Notification of severe reactions vs all severities
- Policy of haemovigilance network :
 - France targeted only Adverse reactions until 2002
 - UK targeted inappropriate BC since 1996
 - None targeted inappropriate prescription nor no/under transfusion

Does Haemovigilance evaluate optimal use ?

Process

Haemovigilance

1. Ordering

- *Assess the need* Usually does not cover
- *Inform the patient* Usually does not cover
- Complete request form Yes (Adverse Event)
- Take blood Sample Yes (Adverse Event)
- Transport blood sample and request Yes (Adverse Event)

2. Processing the order

- Request and Sample reception Yes (Adverse Event)
- Pre-transfusion testing Yes (Adverse Event)
- Select appropriate unit of BC. Yes (Adverse Event)
- Issue the unit Yes (Adverse Event)
- Transport BC to the ward Yes (Adverse Event)

Does Haemovigilance evaluate optimal use ?

Process

Haemovigilance

3. Transfusion

- | | |
|-----------------------------------|---------------------|
| – Reception (and storage) of unit | Yes (Adverse Event) |
| – Pre-administration checks | Yes (Adverse Event) |
| – transfusion | Yes (Adverse Event) |
| – Record and report traceability | Yes (Traceability) |
| – archiving for traceability | Yes (Traceability) |

4. Monitoring

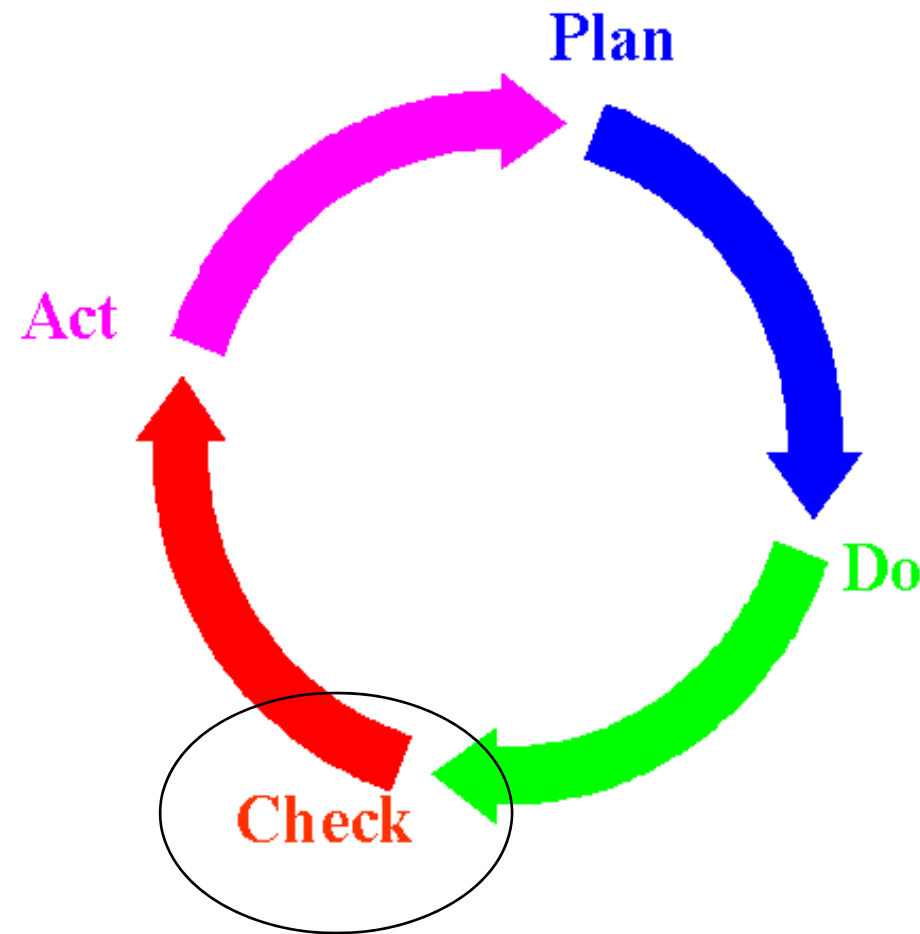
- | | |
|----------------------------------|------------------------|
| – Monitor the patient | Yes (Adverse Event) |
| – Monitor the transfusion | Yes (Adverse Event) |
| – Manage adverse reaction if any | Yes (Adverse Reaction) |
| – Report adverse reaction if any | Yes (Adverse Reaction) |
| – Record outcome | Yes (Adverse Event) |

Evaluation tools of optimal blood use

	audits	Haemovigilance	
<i>Safe supply of blood component :</i>			
Right unit		x	inappropriate BC
To the right patient		x	inappropriate BC
At the right time	x	poorly evaluated by haemovigilance	
In the right conditions		x	inappropriate BC
<i>Appropriate prescribing</i>			
Complies with guidelines + sound clinical conditions	x	poorly or not evaluated by haemovigilance	
<i>With a benchmarked utilization</i>			
Within an acceptable range	x	up to now not evaluated by haemovigilance	

Deming Wheel...

and the optimal use of blood components



Plan: prepare guidelines for blood components usage (safety, administrative, clinical)

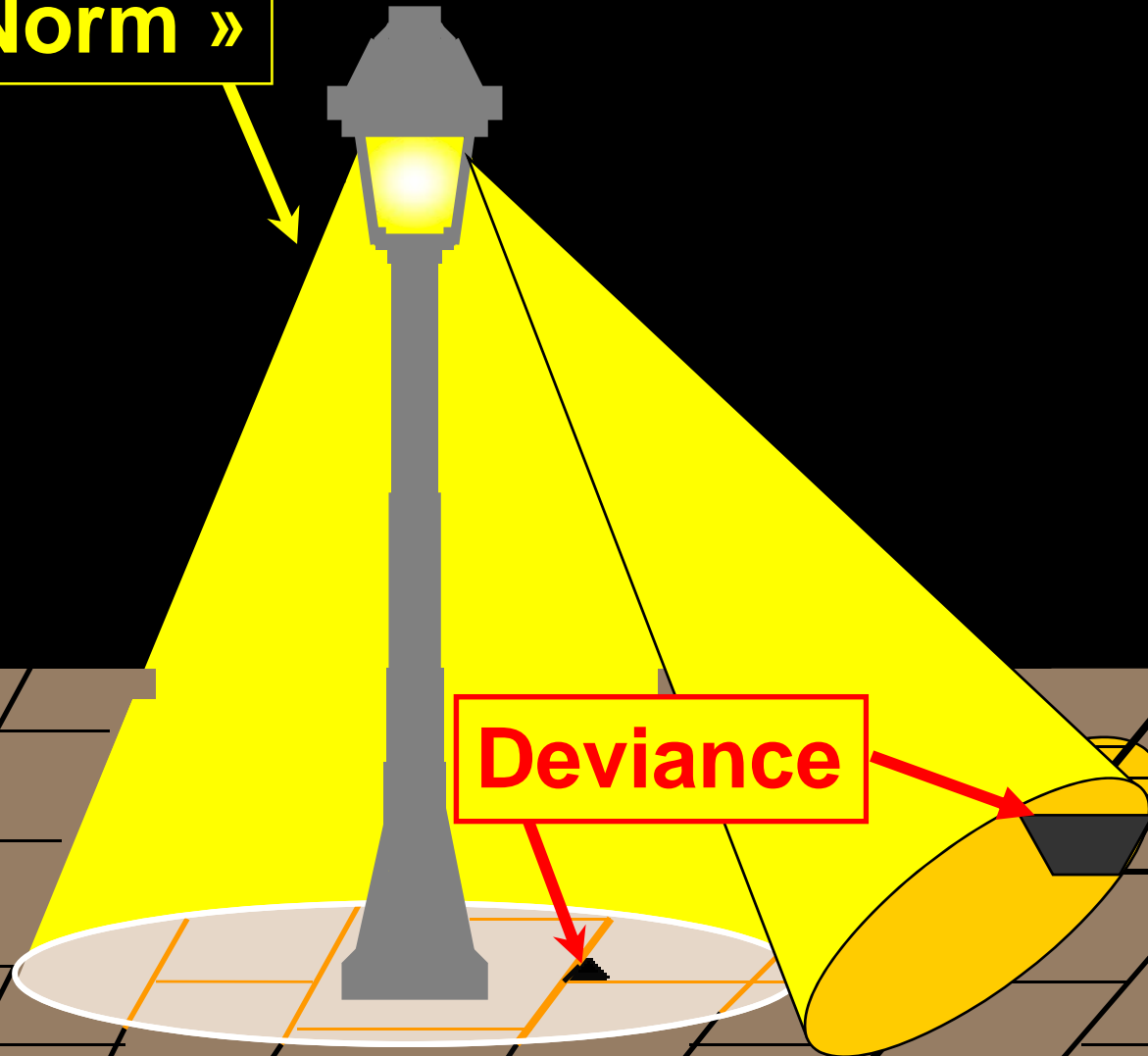
Do: real life in clinical settings and Blood establishments

Check: develop indicators of guidelines compliance, including from Haemovigilance data

Act: Decide what actions are required to correct any problems and/or move onto the next stage.

expanding the scope of hemovigilance

« Norm »



Deviance

deviance



conclusion

- Haemovigilance is an important contributor to the evaluation of optimal use of blood components, as providing information
- However,
 - methods to catch and to notify some critical adverse events (e.g. deleterious effects of delayed or under/no transfusion) are poorly implemented and will require development ;
 - Audit methods are probably more adapted to analyze and measure some critical factors of optimal use of blood components (e.g. non compliance with clinical guidelines).