

*National Transfusion  
Advisory Group*



*NTAG*

**NOCA** National Office of  
Clinical Audit

# SHIFTING THE PARADIGM THROUGH QUALITY IMPROVEMENT

Dr Joan Power  
Consultant Haematologist  
Clinical Lead Advisor for Transfusion

# SHIFTING THE PARADIGM

Pre Transfusion crisis intervention

Blood Transfusion has strong legal framework for Quality and Haemovigilance (HV)

Arising from blood scandals and ensuing enquiries

Pathway needed now to develop national sustained cycle of Quality Healthcare improvement from this base



# SHIFTING THE PARADIGM

## Legal framework - EU Directives

(Mother Directive) 2002/98/EC

Setting standards of Quality And Safety for the collection, testing, processing, storage and distribution of human blood and blood components

SI 360 of 2005 European Communities *Quality and Safety of Human Blood and Blood Components* Regulations 2005

Second Technical (Daughter) Directive 2005/61/EC

*Traceability requirements and notification of Serious adverse reactions and events ( Haemovigilance)*

SI 547 of 2006 - AMLBB minimum requirements for use in conjunction with ISO 15189 standard

However does not include clinical SAE



# SHIFTING THE PARADIGM

Haemovigilance (mature) definition:

*“set of surveillance procedures covering the whole transfusion chain to collect & assess information on unexpected/undesirable effects*

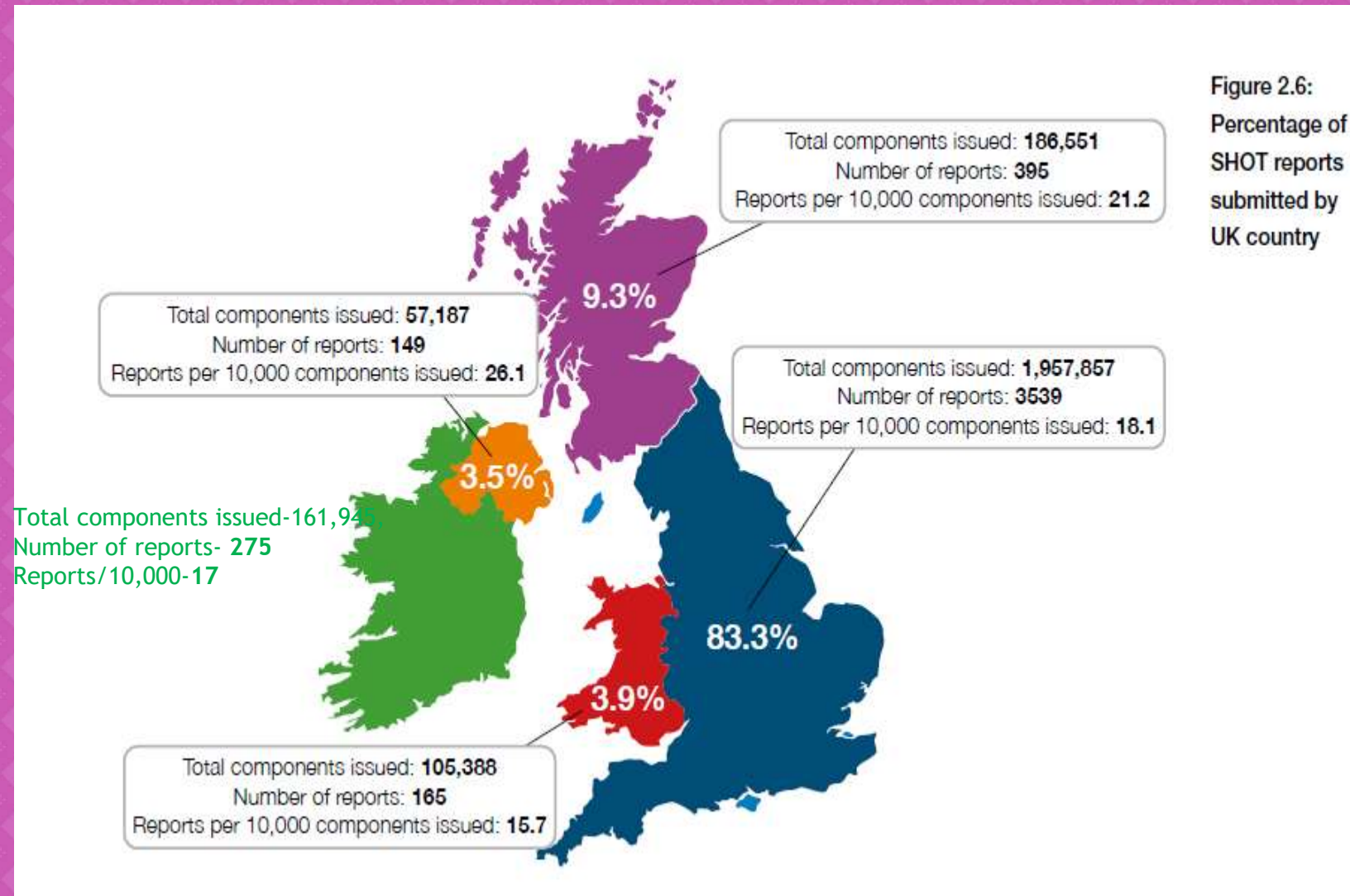
*Serious adverse events (SAE),  
Serious adverse reactions (SAR)  
resulting from the therapeutic use of  
labile blood components  
and to prevent their  
occurrence/recurrence”*

*With mandatory and voluntary elements*



# SHIFTING THE PARADIGM

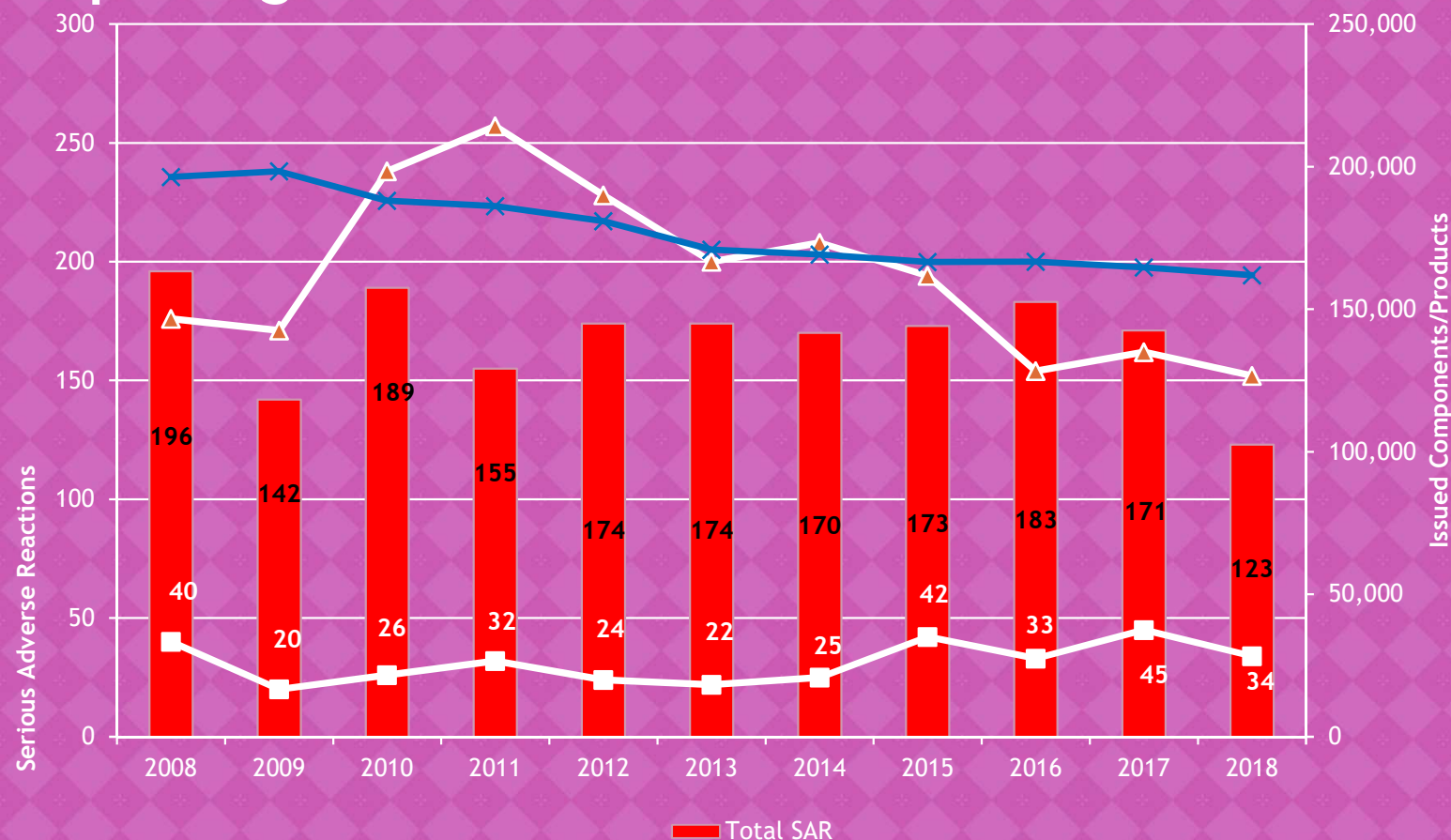
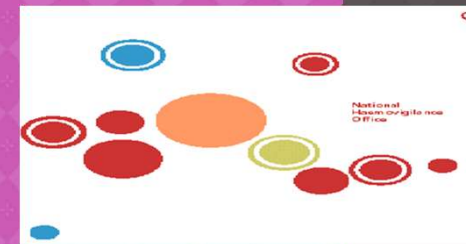
UK HV system 'Serious Hazards of Transfusion' *SHOT*



# SHIFTING THE PARADIGM

Irish HV system- NHO

Reporting trends 2008-2018



Róisín Brady

Deaths	TACO	Age >69	Clinical Error related
9	9	8	3 (dilute sample-wrong Hb, rate too fast, 2 units transfused where 1 prescribed)

# SHIFTING THE PARADIGM

## NHO- 2020 SAE/SAR TRENDS

Total Reports (inc anti-D Ig events) - 219

TACO - 30 (14%)

age	18-50	51-70	>70
N=	2	8	20

Clinical outcome	Death possibly related	Serious sequelae	Minor sequelae
N=	1	2	3

Following single unit transfused
N=17

Error associated	
N=2	4 units transfused for prescription of 3 2 units administered too quickly



# SHIFTING THE PARADIGM

## WBIT

WBIT 2020	EBTS in hospital	MNCMS in hospital	Total electronic system
N=79	55	18	In hospital 73
(N=48 2019)	EBTS in use 36	MNCMS in use 15	In use 51

Site of first error	labelling	sampling	Admission clerking	other
N=	38	23	5	1

COVID-19 related	Remote labelling	Distraction at labelling	transposition	Error in handwritten sample
N=7	3	1	1	2

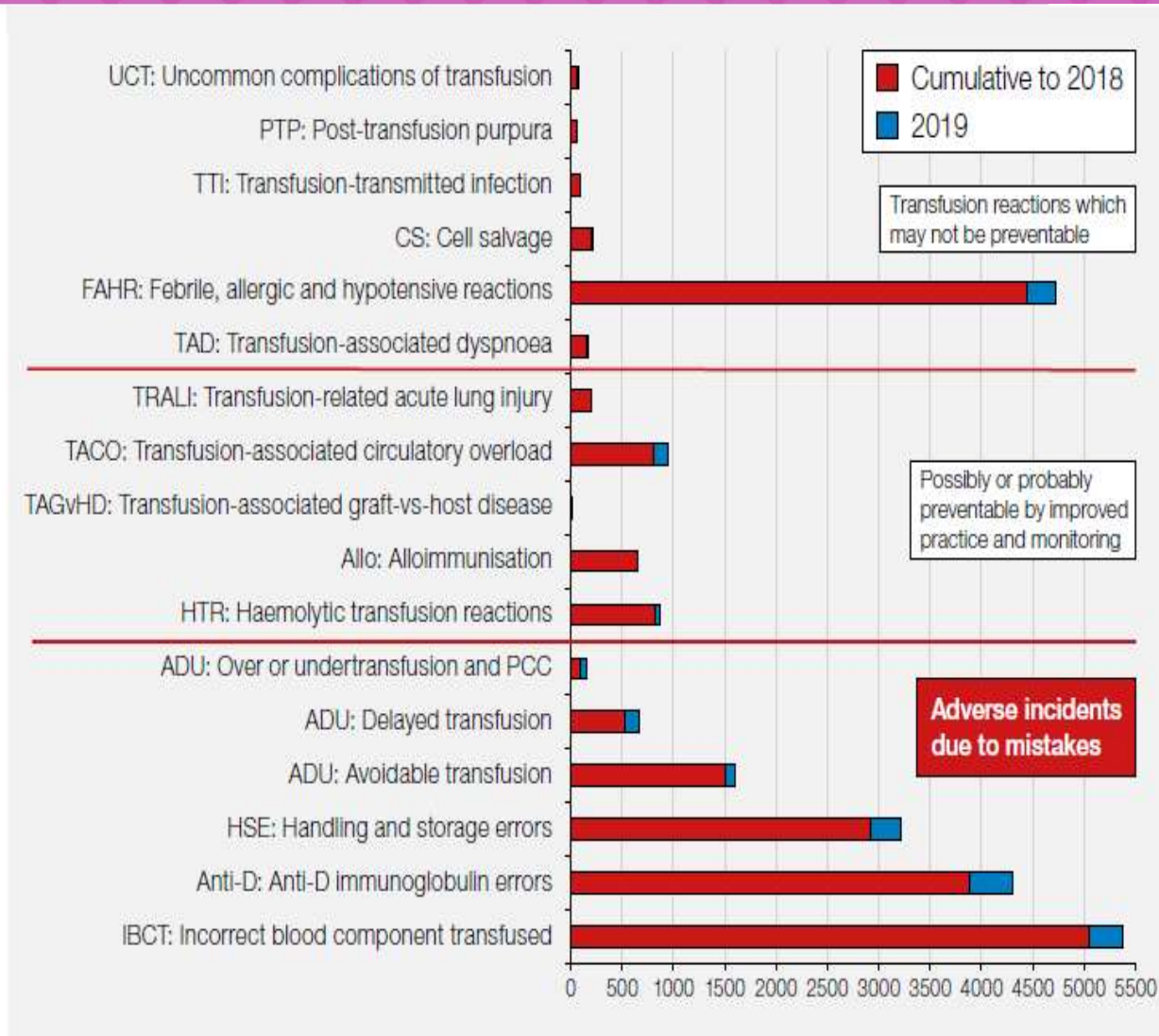
18 potentially ABO incompatible



# SHIFTING THE PARADIGM

Figure 3.5:  
Cumulative data for  
SHOT categories  
1996-2019 n=23341

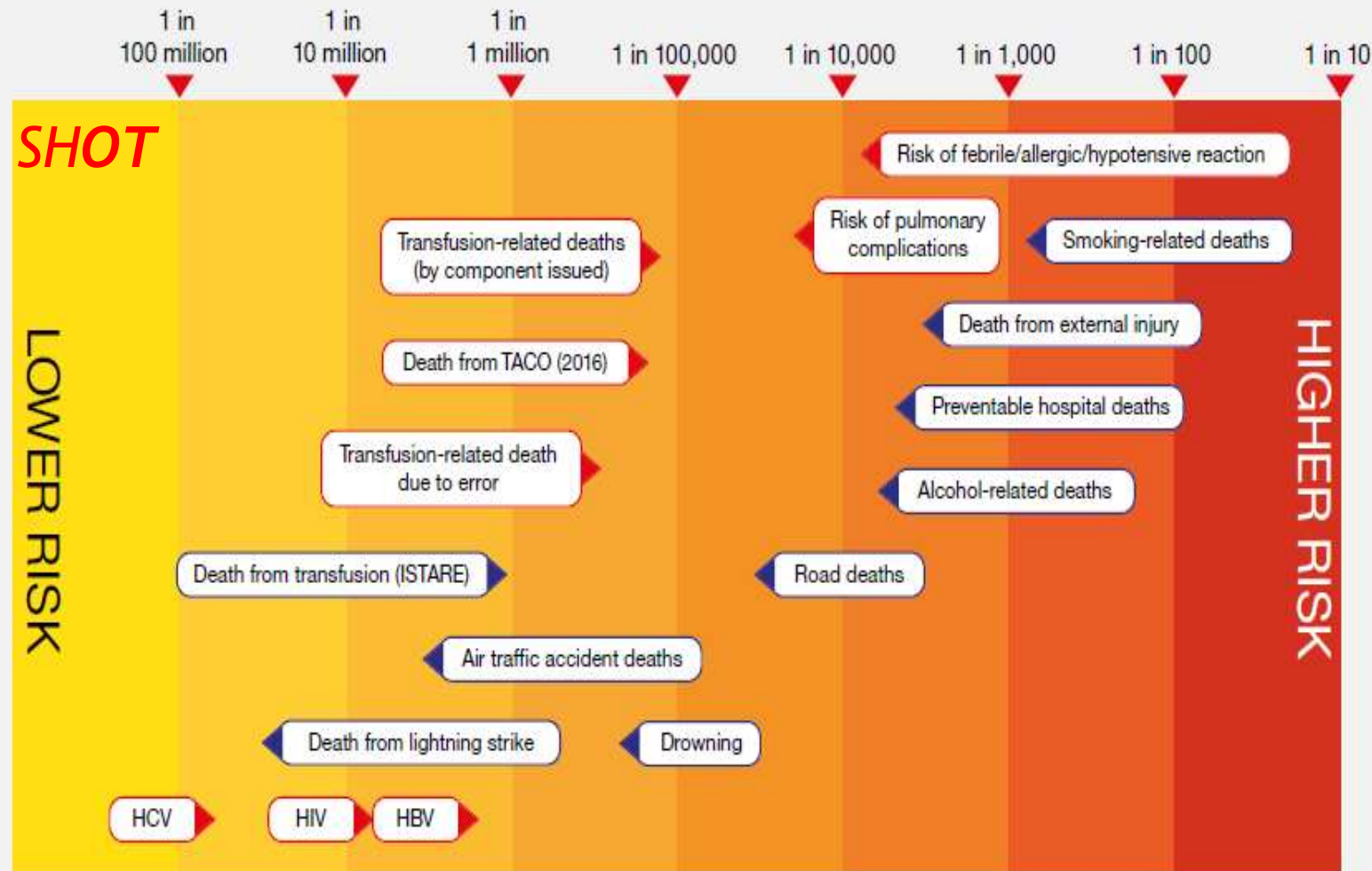
**SHOT**



\*Data on alloimmunisation has not been collected since 2015

# SHIFTING THE PARADIGM

Approximate risks associated with transfusion compared with other life activities: UK data (log scale)



Sources of data: Many of these are found online in the UK office for national statistics. Red outline indicates SHOT data, blue outline indicates data from other sources. ISTARE is the International Haemovigilance Network database for the surveillance of adverse reactions and events in donor and recipients. Viral transmissions denote risk of infection, not deaths. HCV=hepatitis C virus; HIV=human immunodeficiency virus; HBV=hepatitis B virus. A full list of sources is available in supplementary information on the SHOT website [www.shotuk.org](http://www.shotuk.org).

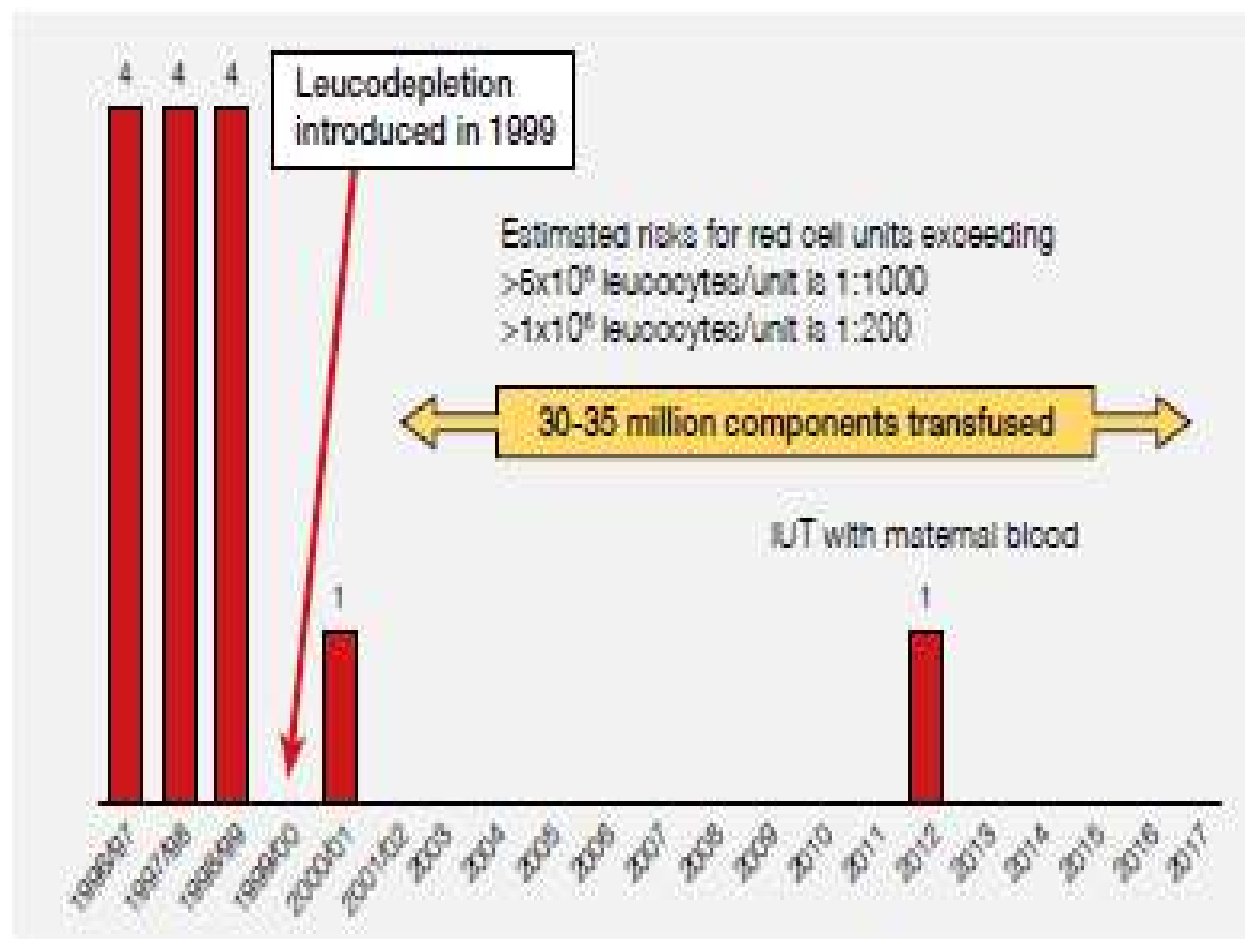


# SHIFTING THE PARADIGM

## LEARNING FROM ADVERSE EVENTS -CHANGES IN THE BLOOD CENTRE

Figure 3.5:  
Cases of transfusion-  
associated graft-  
versus-host disease  
reported to SHOT  
since 1996

**SHOT**



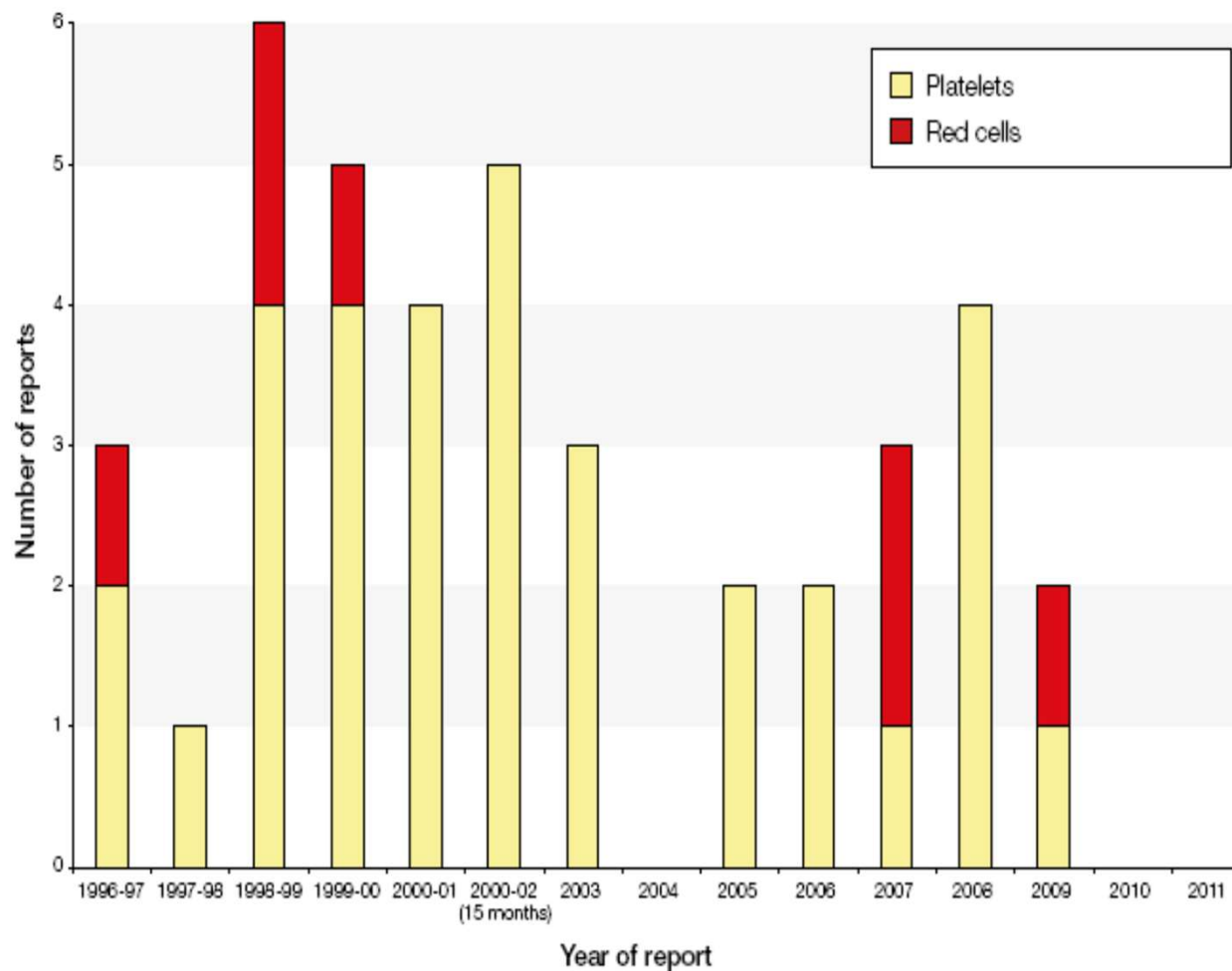
IUT=intravascular transfusion.

# SHIFTING THE PARADIGM

Learning from Adverse Events  
-changes in the blood centre

Figure 20.1  
Number of bacterial  
TTI incidents, by  
year of report  
and type of  
unit transfused  
(Scotland included  
from 10/1998)

**SHOT**



Venepuncture site decontamination,  
deviation 1st 30 ml donation, enhanced testing



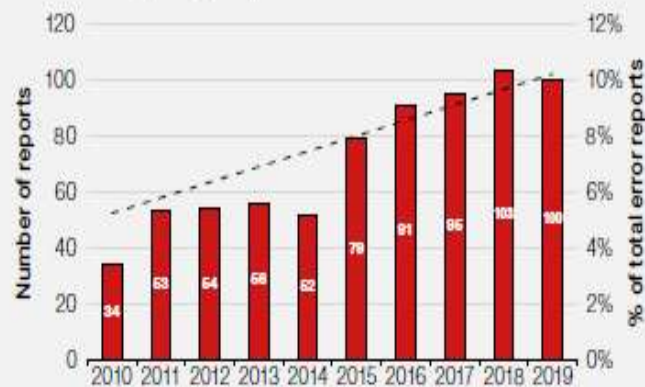
# SHIFTING THE PARADIGM

## Trends in Clinical errors - interventions needed

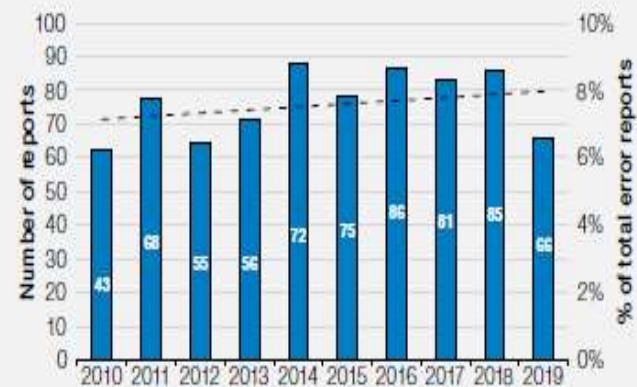
Figure 2.7:  
Trend of error  
reports from  
different  
departments

**SHOT**

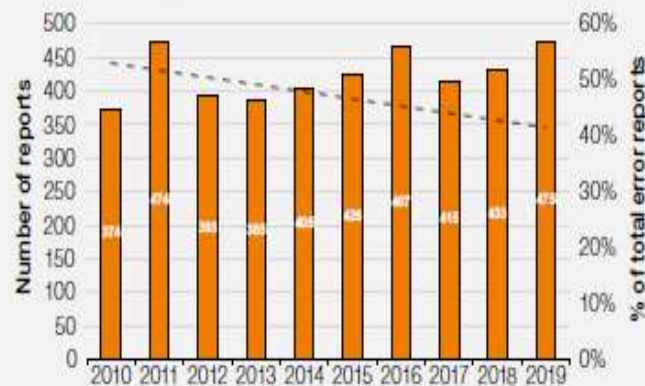
a. Emergency departments



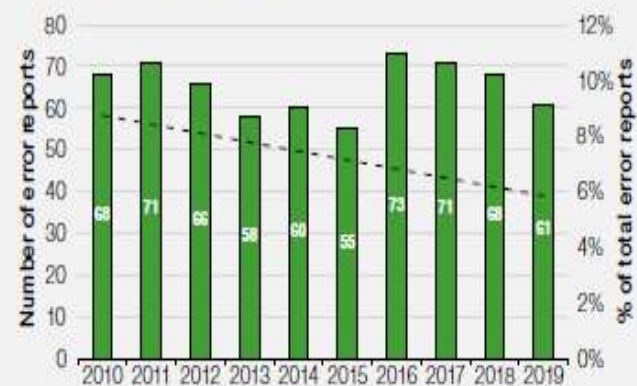
b. Theatres



c. General wards



d. Adult critical care



# SHIFTING THE PARADIGM

Developing a National Framework

Clinical lead advisor appointed - Sept 2019

Network of Transfusion laboratories - by hospital level

**Transfusion laboratories structure.** There are 47 Hospital transfusion laboratories across the country. In addition these act as the transfusion laboratory support for a further 22 Hospitals and 6 Hospices. As expected, transfusion support differs significantly by the complexity of service delivered from each hospital-see Fig 1.

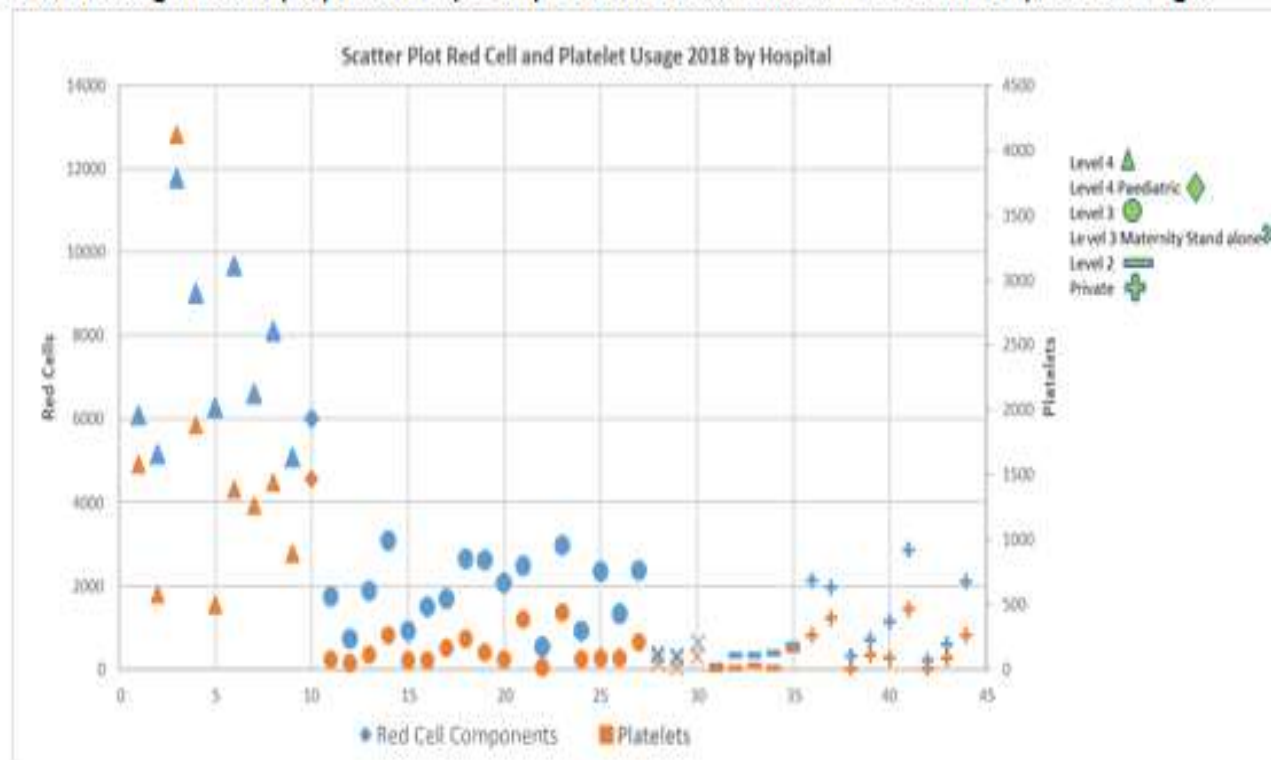


Figure 1 –  
Red cell  
and  
platelet  
usage  
2018 by  
hospital  
Level/type



# SHIFTING THE PARADIGM

Turn data into intelligence ? ROI 'single unit transfusion'

Hospital/Ref	Date	Denominator	Single Unit Transfusion Rate
Hospital			
<b>National Blood Strategy Implementation Group</b> 24/64 acute hospitals reported transfusions on the day (67 RC Trx episodes with 201 units trx'd to 51 pts)	National Study Day Wednesday 19/02/2002	Peri-op (within 48 hrs)  RC transfusion 19 <sup>th</sup> June (Vs NBUG Guideline, Jan '01)	12% of RC transfused
<b>Hospital A Dublin</b> 4,500 RBC	Jul-Dec 2016	Trx within 24 hrs	40% of RC transfused
		Haematology pts (45% of all use) within 24 hrs	32% of RC transfused (88% double unit no inter-unit Hb check)
<b>Hospital B Cork</b> 1,148 RBC	Jan-Feb 19 <sup>th</sup> 2018	Bleeding & non-bleeding pts in a single transfusion episode - within 48 hrs	13% of transfusion episodes
		- within 72 hrs	9.1% of transfusion episodes
<b>Hospital C Cork</b> 133 crossmatches	Jan-June 2018	Per crossmatch	18% of crossmatches
<b>Hospital D Limerick</b> 71 pts./119 RCC 182 pts./330 RCC	May - August 2010	Per transfusion episode	46%, 51%
<b>UK National comparative Audit-TACO audit</b>	<b>Mar-April 2017</b>	<b>157 hospitals 1,788 non-bleeding in-pts, all&gt;60 yrs</b>	<b>37% of pts</b>
- Haematology	July 2017	1091 out-pts 153 hospitals/3,830 RCC	21% of pts. 43% in pts. (2016 - 27%) 24% OPD (2016 - 13%)

# SHIFTING THE PARADIGM

ESTABLISHING THE NATIONAL TRANSFUSION ADVISORY GROUP

**NTAG**-INAUGURAL MEETING RCPI JAN 2020 ( TOR INC)

Engage in Guideline development in relation to Transfusion practice

Recommend Transfusion Policies and Practices and associated implementation and accessibility pathways

Engage in National documentation development

Review national output data, including Patient Safety data from the NHO and other sources, and prioritise risk reduction measures.





# SHIFTING THE PARADIGM

*NTAG 'PILLARS'*

*PROVIDE SUSTAINABILITY*

*ENSURE STAKEHOLDER REPRESENTATION*



Irish Haematology Society Transfusion SIG  
ACSLM NTAG Scientific Committee  
National Haemovigilance SIG

# SHIFTING THE PARADIGM

## ‘BURNING PLATFORMS’ - VIEW FROM JAN 2020

- ◉ O Rh D negative red cell components
- ◉ Patient safety WBIT, TACO, clinical application
- ◉ Patient Blood Management (PBM)
- ◉ National comparative Audit
- ◉ Life threatening Demand, Massive Haemorrhage, Mass Casualty event planning, Contingency

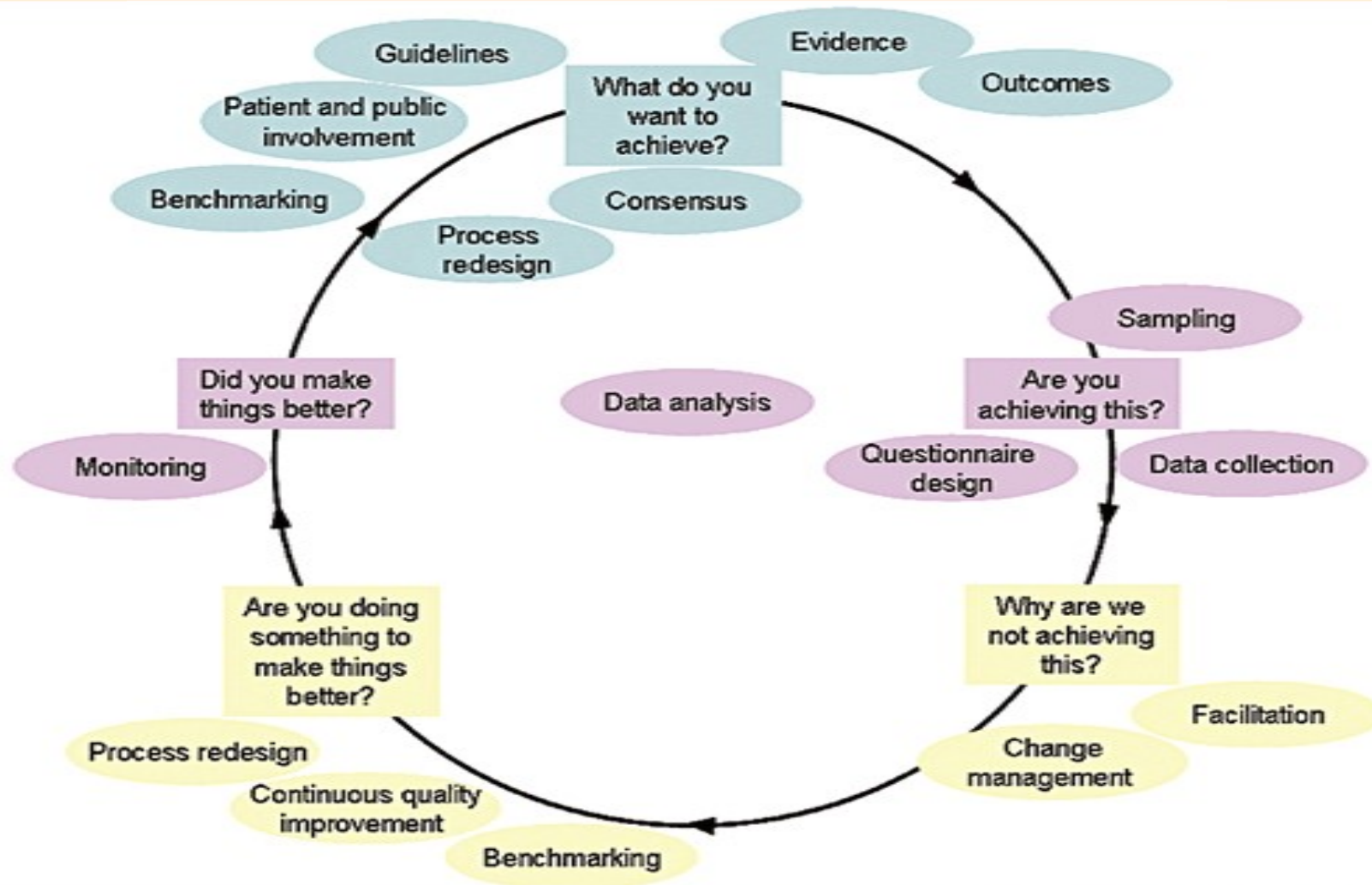
Structured approach to Test, Implement and Spread improvement across system



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Medscape®

www.medscape.com



Source: Transfusion AIT Transfusion Med © 2008 Blackwell Publishing Ltd.



# SHIFTING THE PARADIGM

Effecting clinical change

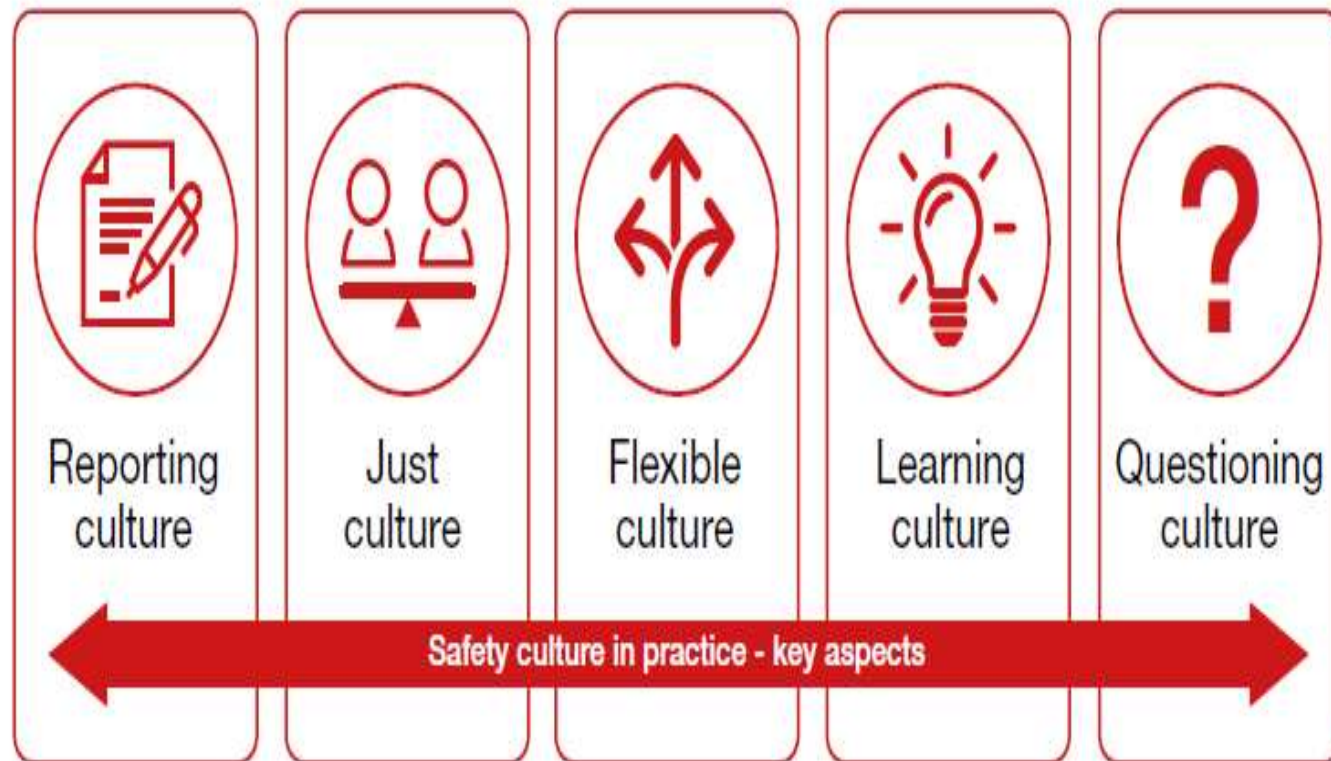


Figure 5.1:  
Critical elements  
of a safety culture

# SHIFTING THE PARADIGM

COVID view  
March 2020

Approach-  
*NTAG* Multi  
disciplinary  
Working  
Groups  
for priority  
interventions/  
enhancements

Shortage  
preparedness

Use of CMV  
negative  
components

Audit of transfusion  
support for COVID-19  
infection

Patient  
information  
leaflet

Over-arching  
transfusion  
committees

Transfusion  
support for  
FNP

Patient blood  
management  
PBM

Life threatening  
haemorrhage

Procuring  
peripheral  
blood  
samples/WBIT

Education  
& training



# SHIFTING THE PARADIGM

## Hospital Emergency Blood Management (EBM) Plan for Managing Shortages of Blood Components

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### National Transfusion Advisory Group NTAG proposed Framework

#### Authorised by:

Dr Joan Power, Clinical lead for Transfusion  
Prof Stephen Field, Medical & Scientific Director, IBTS  
Dr Michael Dockery, Chair, National Transfusion Advisory Group

#### Contents

1. Introduction & Development
2. Scope and Purpose
3. Terms and Abbreviations
4. Roles and Responsibilities

#### Appendix 1: IBTS Communication and Hospital Action

#### Appendix 2: Indication for transfusion in red cell shortage

#### Appendix 3: Proposed generic actions for hospitals at each phase

#### NTAG members

Dr. Michael Dockery, Dr. David Menzies, Ms. Roisin Brady, Dr. Valerie Broderick, Ms. Marina Cronin, Dr. Maeve Doyle, Prof. Stephen Field, Mr. Tony Finch, Ms. Grainne Flynn, Mr. Fergus Guilfoyle, Dr. Mary Keogan, Dr. Siobhan Kennelly, Mr. Richard Lodge, Dr. Peter McKenna, Dr. Kieran Morris, Mr. Damien Nee, Ms. Maureen Nolan, Ms. Norma O'Brien, Dr. Hilary O'Leary, Prof. Colm O'Morain, Mr. Kevin Sheehan/ Mr Barry Doyle,, Ms. Angela Petraska, Dr. Joan Power, Prof. Paul Ridgway, Mr. Stephen Roe, Dr. Jeremy Smith, Mr. Keith Synnott

The NTAG Plan will be considered for update Quarter one 2022.



# SHIFTING THE PARADIGM



**National Transfusion Advisory Group NTAG; Guidelines for use of CMV antibody screened negative (CMV negative) cellular blood components (red cells, platelets and granulocytes) in the Irish healthcare setting. Version 01/September 2020**

**I. Hann<sup>1</sup>, C. Cantwell<sup>2</sup>, B. Doyle<sup>3</sup>, A. Hodgson<sup>4</sup>, AM. McCann<sup>5</sup>, K. Morris<sup>3</sup>, S. Ni Loinsigh<sup>6</sup>, M. Williams<sup>7</sup> and J. Power<sup>1</sup>.**

*<sup>1</sup>Irish Blood Transfusion Service, Munster Regional Transfusion Centre <sup>2</sup>Midlands Regional Hospital Mullingar <sup>3</sup>Irish Blood Transfusion Service, National Blood Centre <sup>4</sup>University Hospital Sligo & Mayo <sup>5</sup>St. James's Hospital Dublin <sup>6</sup>University Hospital Galway <sup>7</sup>Children's Health Ireland -Crumlin*

**Authorised by:**

**NTAG Working Group Chair: Prof I. Hann**

**Clinical Lead Advisor for Transfusion: Dr J. Power**

**Medical & Scientific Director Irish Blood transfusion service IBTS: Prof S. Field**

**Chair National Transfusion Advisory Group NTAG: Dr M. Dockery.**

# SHIFTING THE PARADIGM

## CMV guidelines implementation planning - in progress

Guideline Recommendation by patient cohort	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Allogeneic HCST Autologous HCST	Barrier Allogeneic HCST patient false CMV pos Enabler <ul style="list-style-type: none"> <li>IHS</li> <li>ACSLM</li> </ul>	<ul style="list-style-type: none"> <li>Ensure pre-transfusion CMV serology at admission</li> <li>Cycle of education, error id and audit</li> </ul>	<ul style="list-style-type: none"> <li>CLA</li> </ul>	✓	○	○	Outcomes: -Capture of Haem/onc patients transfused pre dx as IR report to HTC - capture of HSCT pts presenting as possible false pos ( passive anti-CMV ab)
Neonatal population	No change - IT flags	<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	cLA		✓	○	
Pregnant women	No change -IT flags	<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>			✓		
foetuses	No change- It flags Requires issue from IBTS	<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>		○	○	
Patients with HIV infection	Enablers Med scientists IT when available	<ul style="list-style-type: none"> <li>Communication with ID colleagues Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li>CLA</li> </ul>	✓			
Solid organ transplant patients	Enabler <ul style="list-style-type: none"> <li>IHS</li> <li>ACSLM</li> </ul>	<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>				
Patients with immunodeficiency		<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>				
Patients undergoing mgt for oncological disorders		<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>				
Pts receiving granulocytes	Enabler - rarely transfused requires Cons Haem ok	<ul style="list-style-type: none"> <li>Education</li> <li>National Prescription</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>	✓			



# SHIFTING THE PARADIGM

## *National Transfusion Advisory Group Working Group: National Patient Information Leaflet*

Chair: Ms. Norma O'Brien & Dr. Kieran Morris

Members: Ms Grainne Flynn, Mr Stephen Roe, Ms Joanne Scanlon, Ms Maureen Nolan, Ms Angela Petraska, Ms Miriam Kennedy, Dr Joan Power

- To develop a Stakeholder proposed, National Patient Information Leaflet for patients who may require transfusion component support in all hospitals country wide
- To update transfusion associated risks from NHO output
- To form the first part in the development of a national patient consenting process for transfusion



# SHIFTING THE PARADIGM

## You may need a blood transfusion



This leaflet is designed to help you and your family understand what a blood transfusion is and how you can help make this a safer treatment for you.

Your doctor or nurse will explain if you are likely to need a blood transfusion and why. They will ask your permission to give you a blood transfusion. This means you share the decision to receive a blood transfusion. If you are unconscious, your doctor must treat you in your best interest. This includes giving you a transfusion without getting permission from you. (See Q9.)

### This leaflet explains

1. What is a blood transfusion? ..... 2
2. Why would you need a blood transfusion?..... 3
3. What are the risks of blood transfusion?..... 3
4. Can you avoid a blood transfusion? ..... 5
5. How is a blood transfusion given?..... 5
6. What are the different blood components?..... 6
7. What should the patient do to ensure safe blood transfusion? ..... 6
8. Transfusion records – how long are they kept?..... 7
9. What happens if you refuse a blood transfusion?..... 7

## 7. What should the patient do to ensure safe blood transfusion?

**You have a vital role in making sure that you are identified correctly:**

**Make sure your identification information is correct:** When the staff member is taking your sample to match your transfusion, make sure they know who you are. They should ask you (**but not prompt**) your:

- full name
- date of birth.

They should then check this against your hospital identification band. If the name or date of birth on your hospital identification band is incorrect, please tell your **Healthcare staff**

**Please remind the clinical staff if you have:**

- had a reaction to a blood transfusion in the past
- been told you have special transfusion needs.

**And you must let your healthcare staff know if you have any unpleasant feelings or symptoms. These can include:**

- headache
- rash
- nausea
- vomiting
- fever
- chills
- shaking
- breathing difficulties.

These symptoms may occur during or after your transfusion and mostly within 24 hours. **Healthcare staff** are familiar with these and if needed, they will:

- stop the transfusion
- take blood tests and **give you treatment for your symptoms**.

**Other safety measures in place:** If you are transfused as an out-patient, your **healthcare staff** will give you a phone number to call the hospital in case you develop a reaction after you leave hospital.

If you have special transfusion needs (for example irradiated blood, which is needed for some patients with cancer or receiving particular medication), **it is recommended** that you receive an **'alert'** card from your hospital. Also, the computer system in the hospital blood bank will have a warning flag to ensure that only blood that suits your special needs may be issued from the laboratory for you.

# SHIFTING THE PARADIGM



NTAG Patient Blood Management

## National Transfusion Advisory Group NTAG

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### Governance

Dr Joan Fitzgerald, Consultant Haematologist Chair NTAG WG: PBM

Dr Joan Power, Clinical lead for Transfusion

Prof Stephen Field, MSD IBTS

Dr Michael Dockery Chair NTAG

### Working Group Scope – Draft 1

#### Objective

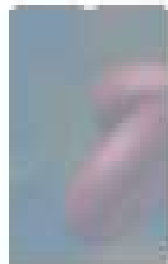
To develop a Stakeholder proposed NTAG Guideline for Patient Blood Management. Interim guidance may be issued. The NTAG PBM Guideline will be a controlled document(s) and the review process will be established. The Guideline will be authorised by the NTAG WG Chair, the Clinical Lead Advisor, M & SD IBTS and Chair NTAG.

Timely use of evidenced-based medical and surgical concepts designed to maintain Hb concentration, optimise haemostasis and minimise blood loss

*Society for the Advancement of Blood Management, Professional definition Patient Blood Management, Sept.2012.:<http://www.sabm.org/>*



# SHIFTING THE PARADIGM



NTAG Working Group: Acute Life Threatening Haemorrhage.

## National Transfusion Advisory Group NTAG

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### Governance

Chair WG: Mr Morgan McMonagle Consultant General, Vascular and Trauma Surgeon,  
University Hospital Waterford.

Dr Joan Power, Clinical Lead Advisor for Transfusion

Prof Stephen Field, Medical and Scientific Director IBTS

Dr Michael Dockery, Chair NTAG



# SHIFTING THE PARADIGM

## Pre-'Transfusion crisis' intervention

Quality Improvement

Further national structures to support NTAG Working groups with  
Pathway to develop national sustained cycle of Healthcare improvement

## Core elements;

- NHO renewal - governance, resourcing and data analysis
- Clinical data capture 'Turn data into intelligence'  
Well defined, consistent data item collection & recording  
(numerator, denominator, inclusions and exclusions) of high quality
- Multi-annual national audit programme

## ***PBM Message to patients***

*You should only receive a Blood Transfusion if it is necessary and  
you should have the opportunity to discuss the risks, benefits and  
alternatives with your doctor*