Haemovigilance and Blood Regulations in Europe

Dafydd Thomas

Consultant in ICM

Welsh Blood Service

Chair NATA

Chair SHOT Steering Group

Immediate Past President BBTS

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Declaration of Interests

- No conflicts
- No conflict of interest with ICS manufacturers
- Immediate Past President BBTS
- Chair of NATA
- Chair of SHOT Steering Committee
- Seconded to Welsh Blood Service/National Wales Informatics Service

Declaration of Interests

- No conflicts – apart from coffee and curries
- I am happy to drink/eat without obligation
- No conflict of interest with ICS manufacturers
- Immediate Past President BBTS
- Chair of NATA
- Chair of SHOT Steering Committee
- Seconded to Welsh Blood Service/National Wales Informatics Service

Six Nations 2013: Wales 30-3 England

Biggest Wales wins v England

- **2013** - Wales 30-3 England
- **1905** - Wales 25-0 England
- **1979** - Wales 27-3 England
- **1899** - Wales 26-3 England
- **1907** - Wales 22-0 England
- **1922** - Wales 28-6 England
- **1968** - Wales 30-9 England

Taffy was a Welshman

- Taffy was a Welshman
- Taffy was a thief
- Taffy came to my house and stole a leg of lamb
- Taffy came to B’ham and stole Tony Davies Slides

Incident Reporting

- getting the balance right

Tony Davies

Transfusion Liaison Practitioner

SHOT / NHSBT BBT Team

Joan Jones

Head of Quality & Regulatory Compliance

Welsh Blood Service

HEMOVIGILANCE

AN EFFECTIVE TOOL FOR IMPROVING TRANSFUSION SAFETY

EDITED BY RENÉ R.P. DE VRIES AND JEAN-CLAUDE FABER

WILEY-BLACKWELL

Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

We protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness in use, and are used safely.

Spotlight on...

MHRA e-mail alerting service

We are pleased to introduce the MHRA e-mail alerting service.

› UK's Presidency of the EU

What's new

08 Sep 2005

Press release: Prescription only medicines seized near Birmingham

Investigators from the MHRA and local police today seized 26 tubs (300ml) of steroid cream.

07 Sep 2005

MDA/2005/051 - All biochemical test kits for the identification of Neisseria gonorrhoeae (N. gonorrhoeae)

Increased risk of false negative or ambiguous results.

02 Sep 2005

Updated patient information leaflets and labelling for painkillers

The Medicines and Healthcare products Regulatory Agency (MHRA) has asked manufacturers of over-the-counter (OTC) medicines to voluntarily update their Patient Information Leaflets (PILs) and labelling of painkillers that contain codeine and dihydrocodeine.

02 Sep 2005

Seroxat statement

In 2004, the Committee on Safety of Medicines Expert Working Group on the Safety of SSRIs completed its review of the large body of safety evidence from a wide range of sources – spontaneous suspected adverse drug reactions (from health professionals and patients), clinical trials (including the available clinical trial data for paroxetine), published literature and epidemiological databases.

Report a suspected safety problem

Quick Links Go

Hot topics

No content available. You must specify a list of content ids to documents to appear in this list.

Reporting safety problems

This section provides access to information on how to report suspected safety problems with medicines, medical devices, blood and blood components.

Medicines

Report a suspected adverse reaction or defect

The MHRA collects information on suspected adverse drug reactions and suspected defects in medicinal products.

Devices

Report an adverse incident

Any adverse incident involving a medical device or its instructions for use should be reported to the MHRA, especially if it lead to, or could have lead to, death, life-threatening illness or injury.

Blood

Report an adverse event or reaction

From 8 November 2005 the EU Blood Safety Directive will require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.

Serious Adverse Blood Reactions & Events (SABRE)

From 8 November 2005 the EU Blood Safety Directive will require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.

By November, this web page will contain an active link to a new, secure and confidential online reporting system that will enable Blood Establishments, Blood Banks and Hospital Transfusion Teams electronically to submit reports of serious adverse event or serious adverse reaction directly to the MHRA. This new reporting system is to be known as **SABRE – Serious Adverse Blood Reactions & Events.**

Healthcare and blood service staff will be able to register, log on to SABRE and then draft and submit initial Notifications and Confirmations of adverse events and adverse reactions.

The new system has been designed to be very simple to use, and will incorporate comprehensive online helptext at all stages. If at any time reporters require advice or assistance, staff in the MHRA Adverse Incident Centre will be available to provide assistance. Enquiries may be made either by e-mail or by telephone:
sabre@mhra.gsi.gov.uk
020 7084 3336

Related information:

Other sites:

- SHOT - Serious Hazards of Transfusion

SHOT

The MHRA, recognising the considerable experience and expertise held by SHOT (Serious Hazards Of Transfusion) and the value of the data that they collect and analyse, has included SHOT's questionnaires within the new reporting system. The questionnaires are an integral part of the online report form and, for the first time, enable SHOT to receive, store and analyse their questionnaire data electronically.

Enquiries for SHOT may be made either by e-mail or by telephone:
shot@nbs.nhs.uk
0161 251 4208

SABRE: Serious Adverse Blood Reactions & Events

SAVE SAVE & CLOSE SUBMIT DISCARD WORKSPACE FOOTNOTE HELP

MANAGE FOLDERS

Your folders:

- Workspace
  - Drafts
  - Reactions
  - Events
  - SHOT
  - All Documents

Report Source | Serious Adverse Reaction | Serious Adverse Event | Report to SHOT

Reporting Organisation

Reporting Organisation Address

Reporter's Name
(if different to Registered User)

Reporter's Email

Telephone No.

Fax No.

Job Title

Local Reference No.

MHRA Reference

Hospital Consultant

Serious Adverse Event

Serious Adverse Event ☐

Do you wish SHOT to have access to this * Yes ☐ No ☐

Report to SHOT only ☐

Incident Location *

Email address for

Reported locally? * Yes ☐ No ☐

Reported to Blood Estab? * Yes ☐ No ☐

If so, which Blood Establishment?

Blood Establishment Consultant

SABRE: Serious Adverse Blood Reactions & Events

TERMS & CONDITIONS REGISTER FORGOTTEN PASSWORD HELP

Log In

Not yet Registered? If you have not yet registered as a SABRE User, click the link above and submit the requested details for verification. Please note that the provision of certain information is compulsory for registration. On-line Help is available if required. For security reasons, new registrations will not be activated until registration details have been checked and verified by the MHRA.

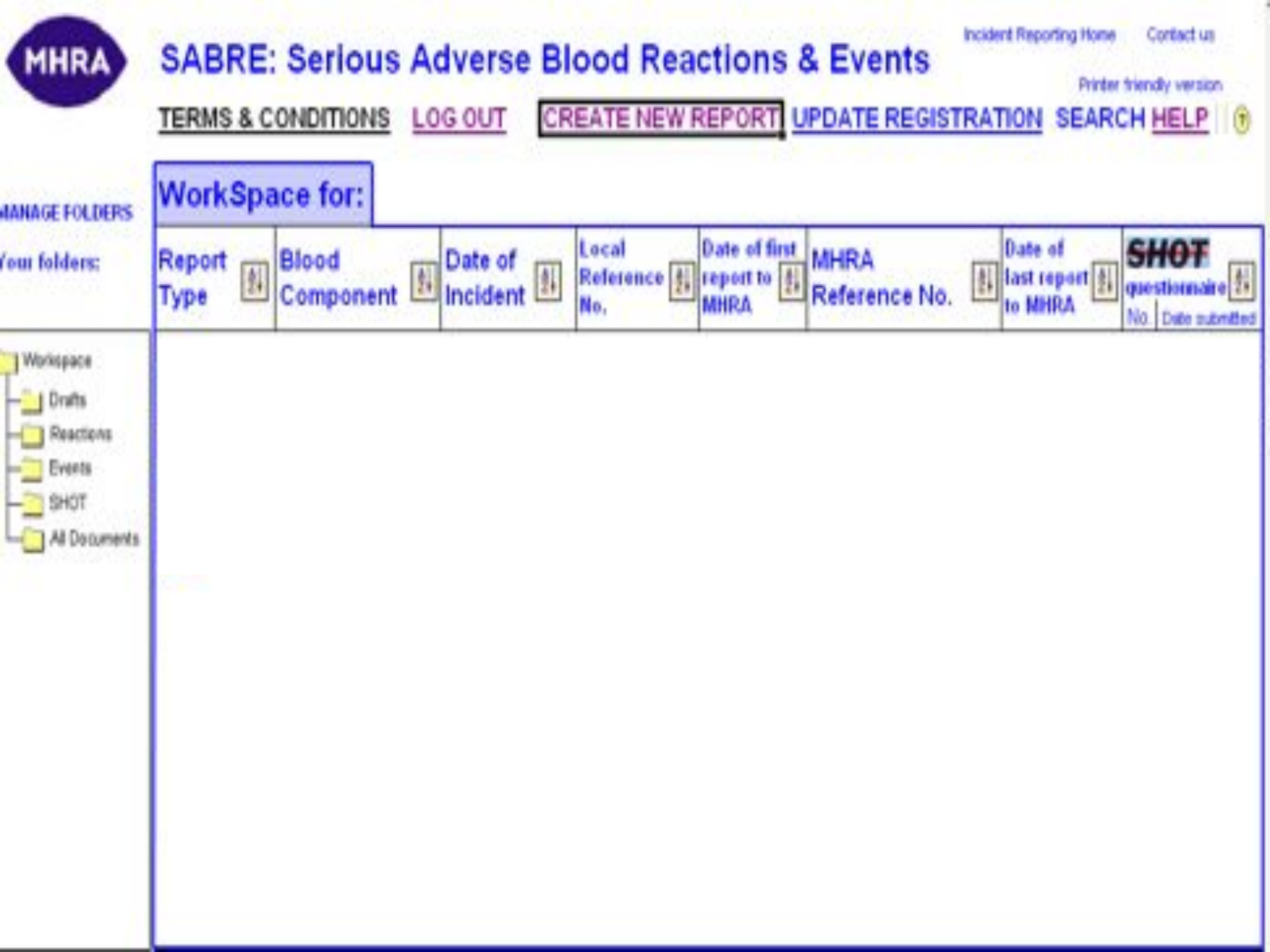
Email address

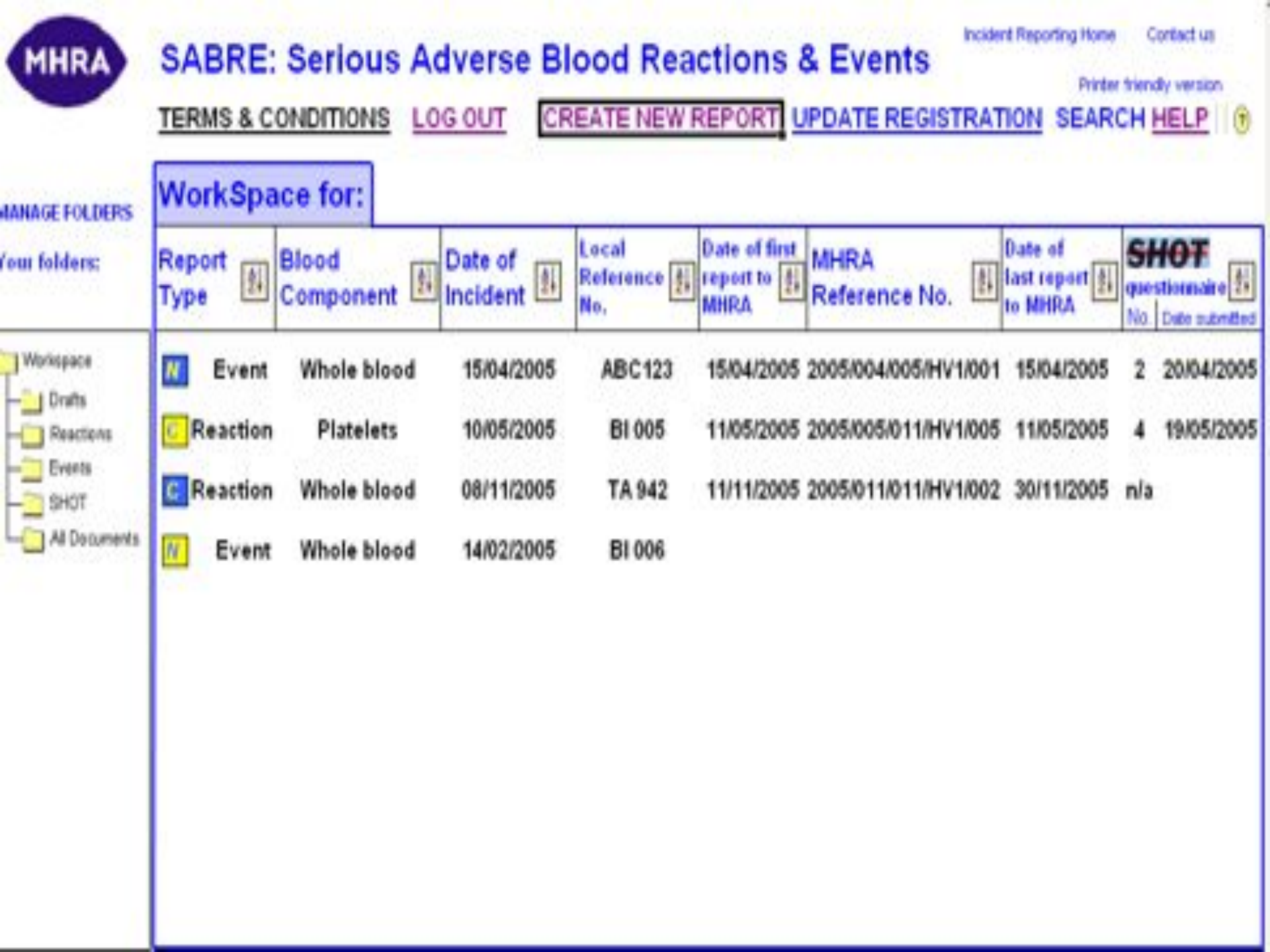
Registration No.

Password

SUBMIT

Forgotten Password? Please contact the Adverse Incident Centre on 020 7084 3080 or by email to sabre@mhra.gsi.gov.uk and be prepared to provide your registration number and to answer other questions in order to confirm your identity. Once we have verified your identity, we will set a new password and email it to you as soon as possible.


MHRA
SABRE: Serious Adverse Blood Reactions & Events
Incident Reporting Home
Contact us
Printer friendly version
TERMS & CONDITIONS
LOG OUT
CREATE NEW REPORT
UPDATE REGISTRATION
SEARCH
HELP
MANAGE FOLDERS
Your folders:
WorkSpace for:
Report Type
Blood Component
Date of Incident
Local Reference No.
Date of first report to MHRA
MHRA Reference No.
Date of last report to MHRA
SHOT questionnaire
No
Date submitted
Workspace
Drafts
Reactions
Events
SHOT
All Documents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Date of last report to MHRA
SHOT questionnaire
No
Date submitted
Workspace
Drafts
Reactions
Events
SHOT
All Documents
N Event Whole blood 15/04/2005 ABC123 15/04/2005 2005/004/005/HV1/001 15/04/2005 2 20/04/2005
C Reaction Platelets 10/05/2005 BI 005 11/05/2005 2005/005/011/HV1/005 11/05/2005 4 19/05/2005
C Reaction Whole blood 08/11/2005 TA 942 11/11/2005 2005/011/011/HV1/002 30/11/2005 n/a
N Event Whole blood 14/02/2005 BI 006

SABRE: Serious Adverse Blood Reactions & Events

SAVE SAVE & CLOSE SUBMIT DISCARD WORKSPACE FOOTNOTE HELP

MANAGE FOLDERS

Your folders:

- Workspace
  - Drafts
  - Reactions
  - Events
  - SHOT
  - All Documents

Report Source | Serious Adverse Reaction | Serious Adverse Event | Report to SHOT

Reporting Organisation

Reporting Organisation Address

Reporter's Name (if different to Registered User)

Reporter's Email

Telephone No.

Fax No.

Job Title

Local Reference No.

MHRA Reference

Hospital Consultant

Serious Adverse Event

Serious Adverse Event

Do you wish SHOT to have access to this * Yes No

Report to SHOT only

Incident Location *

Email address for

Reported locally? * Yes No

Reported to Blood Estab? * Yes No

If so, which Blood Establishment?

Blood Establishment Consultant

Root Cause and CAPA

- Defining the Root Cause
  - Important to get to the bottom of errors
- Corrective Actions (CA)
  - What do you need to do now
- Preventive Actions (PA)
  - What to do to prevent it happening again

Significant effort to harmonise reporting

- Frequent meetings with MHRA
- Focus of serious events/reactions
- Ease of reporting
- One report
- Better and clearer instructions
- Joint report
- HVUK ?
- Stalled due to departure of Judy langham

Thanks to

Tony and Joan

www.shotuk.org

We are a team after all!

Significant effort to harmonise reporting

- Frequent meetings with MHRA
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- Ease of reporting
- One report
- Better and clearer instructions
- Joint report
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- Stalled due to departure of Judy langham

Home
SHOT
Contact the IHN
▶ IHN Remit
▶ IHS Members Area
▶ International Haemovigilance Seminars
▶ EU
Resource Library
▶ Haemovigilance Databases

Netherlands

IHN Official Contact Person (OCP) and contact details

These may be found on the membership list in the Members Area of this website.

Haemovigilance System

You may follow the link below to the TRIP website:

TRIP website

TRIP Newsletter 2008

Latest News

IHN Award

IHN Award 2013 goes to Constantina Politis

View more...

IHS XVI Barcelona 5-7 March 2014

Registration details and travel fellowships

View more...

afssaps

Agence française
de sécurité sanitaire
des produits de santé

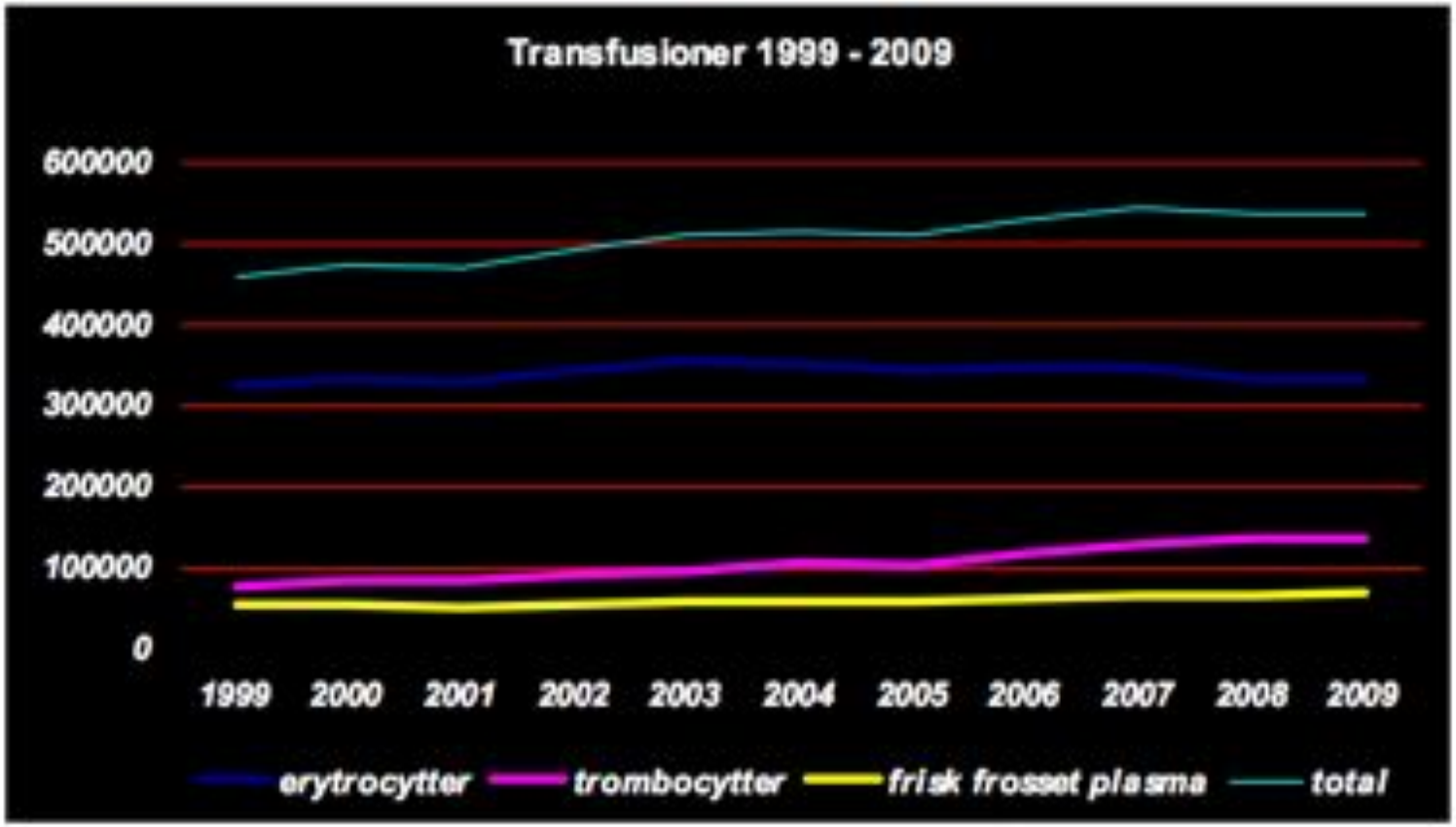
France
Annual Haemovigilance report 2009


TRANSFUSIE REACTIES IN PATIËNTEN
TRIP

DART

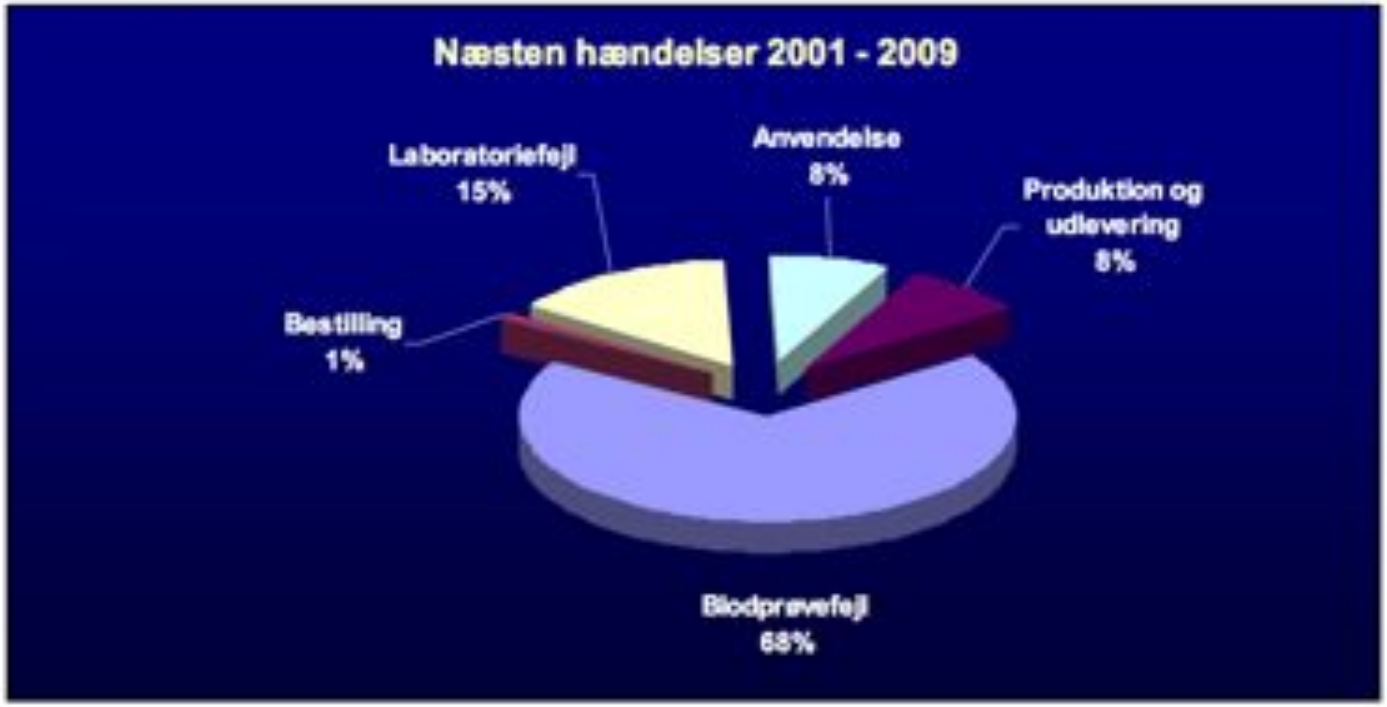
Haemovigilancerapport for 2009

Oversigt over transfunderede blodkomponenter 1999 – 2009



Næsten hændelser

Rapporten fra 2009 viser en meget kraftig stigning i indberetningen af near miss. Det drejer sig især om blodprøvetagning og mærkning af prøver. Stigningen skyldes, at 2 mindre transfusionscentre systematisk har opgjort alle prøver, hvor prøven blev kasseret pga. fejl eller mangler.



Igennem mange år, har der været arbejdet meget på at forbedre patientidentifikation og korrekt mærkning af prøver, da det er en potentiel kilde til alvorlige fejl. Trods dette er antal fejl meget stor, der bør derfor fokuseres på netop denne type fejl. De forkert mærkede prøver kommer ofte fra

SAMLET OVERSIGT 1999-2009

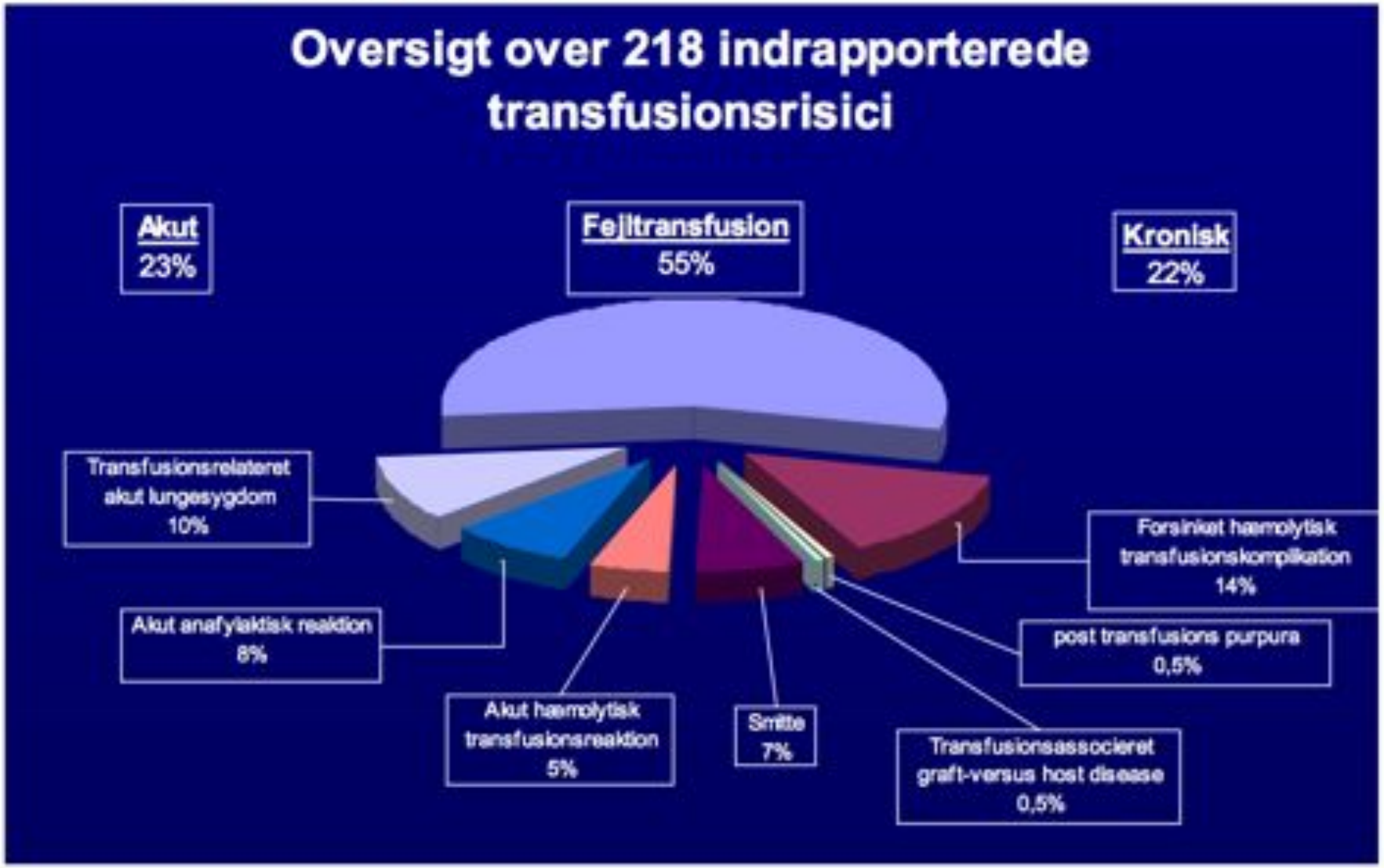
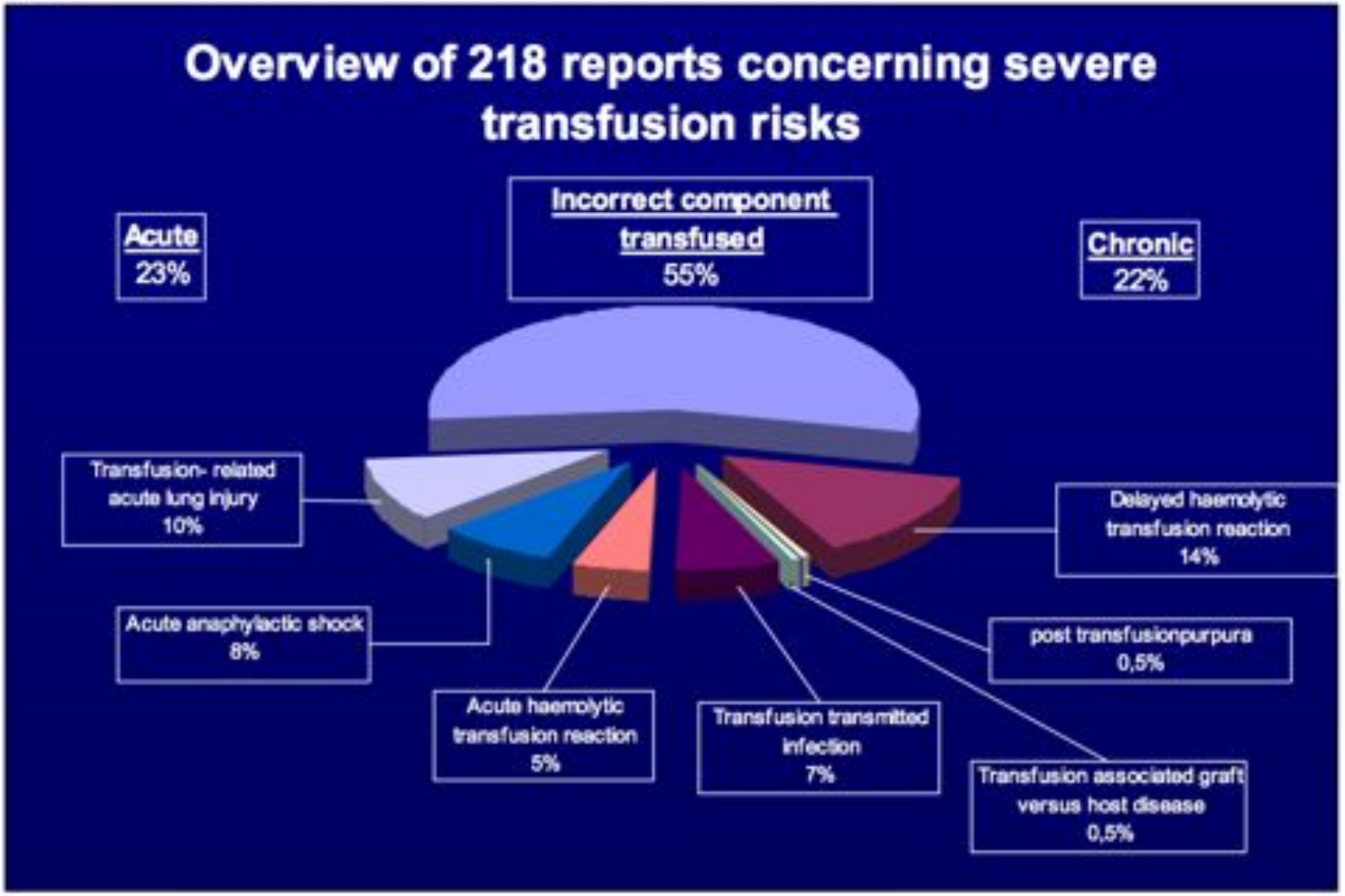


Fig.1


Overview of 218 reports concerning severe transfusion risks
Acute
23%
Incorrect component transfused
55%
Chronic
22%
Transfusion- related acute lung injury
10%
Delayed haemolytic transfusion reaction
14%
Acute anaphylactic shock
8%
post transfusionpurpura
0,5%
Acute haemolytic transfusion reaction
5%
Transfusion transmitted infection
7%
Transfusion associated graft versus host disease
0,5%

Objectives of the Global HV Consultation (1 of 3)

1. Highlight the importance of national haemovigilance systems and international networking for global blood safety and availability
2. Assess the nature and magnitude of current challenges and barriers to the implementation of haemovigilance systems, particularly in developing countries
3. Provide a platform for countries to share experiences and learn lessons for developing national haemovigilance systems in a stepwise manner

Objectives of the Global HV Consultation (2 of 3)

4. Define strategies for developing haemovigilance systems, including
   - harmonized reporting of transfusion-related adverse reactions and events
   - collection, analysis and use of national data for continuous learning
   - improvement in the safety of blood donors, blood products and patients

Objectives of the Global HV Consultation (3 of 3)

5. Building on existing international networks, discuss expansion of global mechanisms for networking countries and organizations to share data, information and experiences on haemovigilance, to

   - advocate and support the establishment of national haemovigilance systems
   - harmonize global data collection
   - organize joint activities
   - function as a forum for dialogue, advice and information gathering for all key stakeholders

Participating Countries

- AFR: Burkina Faso, Ethiopia, Ghana, Kenya, Mauritius, Namibia, Niger, Senegal, South Africa, Uganda
- AMR: Argentina, Canada, Brazil, Honduras, United States of America
- EMR: Afghanistan, Egypt, Iraq, Jordan, Kuwait, Oman, Pakistan, Qatar, Saudi Arabia, South Sudan, Tunisia, United Arab Emirates
- EUR: France, Netherlands, Slovenia, United Kingdom
- SEAR: Bangladesh, Bhutan, India, Nepal, Sri Lanka, Thailand
- WPR: Australia, Cambodia, China, Japan, Korea Lao PDR, Mongolia, Viet Nam **New Zealand**

What can SHOT teach Kiwis about blood risks?

Dafydd Thomas

Consultant in ICM

Welsh Blood Service

Chair NATA

Chair SHOT Steering Group

Immediate Past President BBTS

What can anyone teach Kiwis about anything ?

Dafydd Thomas

Consultant in ICM

Welsh Blood Service

Chair NATA

Chair SHOT Steering Group

Immediate Past President BBTS

NZBLOOD

National Haemovigilance Programme

Annual Report 2011

ANNUAL SHOT REPORT 2011

Affiliated to the Royal College of Pathologists

The Steering Group includes members representing the following professional bodies:

British Blood Transfusion Society
British Society for Haematology
British Society of Gastroenterology
British Committee for Standards in Haematology
Faculty of Public Health
Institute of Biomedical Science
Health Protection Agency
(Health Protection Services Division)
NHS Confederation
Royal College of Anaesthetists
Royal College of Nursing
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Physicians
Royal College of Surgeons
Royal College of Paediatrics and Child Health
Intensive Care Society
Faculty of Intensive Care Medicine
The College of Emergency Medicine
Defence Medical Services
UK Forum

Serious Hazards of Transfusion (SHOT)

Steering Group Chair	Dr Hannah Cohen
SHOT Medical Director	Dr Paula Bolton-Maggs
Operations Manager	Ms Alison Watt
Research Analyst	Ms Debbi Poles
Transfusion Liaison Practitioner	Mr Tony Davies
Clinical Incidents Specialist	Mrs Julie Ball
Laboratory Incidents Specialists	Mrs Hema Mistry Mrs Christine Gallagher
National Coordinator for Transfusion Transmitted Infections (Health Protection Agency)	Ms Claire Reynolds Dr Su Brailsford

Steering Group (SG)

Chair: Dr Hannah Cohen

Dr Shubha Allard	British Committee for Standards in Haematology CMO's National Blood Transfusion Committee
Dr John Barbara	Founder Member
Prof Mark Bellamy	The Intensive Care Society, Faculty of Intensive Care Medicine
Dr Su Brailsford	Health Protection Agency & Faculty of Public Health
Mr William Chaffe	UK Transfusion Laboratory Collaborative
Dr Paul Clarke	Royal College of Paediatrics and Child Health
Mrs Sarah Corcoran	Clinical Risk Manager
Dr Heidi Doughty	Defence Medical Services
Prof Adrian Evans	The College of Emergency Medicine
Dr Patricia Hewitt	Consultant Specialist in Transfusion Microbiology, NHSBT
Ms Joanne Hoyle	Royal College of Nursing
Ms Mervi Jokinen	Royal College of Midwives
Mrs Joan Jones	Institute of Biomedical Science: Clinical Advisory Group, Wales
Mrs Judy Langham	Medicines and Healthcare products Regulatory Agency
Dr Sue Knowles	Former Interim Medical Director of SHOT
Dr Elizabeth Love	Former National Medical Coordinator of SHOT
Prof John S P Lumley	Founder Member
Dr Sheila MacLennan	UK Forum
Dr Brian McClelland	Founder Member
Joanne McIntyre	Lay Member
Dr Kieran Morris	Royal College of Pathologists; Northern Ireland Regional Transfusion Committee
Dr Andrew Mortimer	Royal College of Anaesthetists
Dr Tim Nokes	British Society for Haematology
Dr Derek Norfolk	Founder Member
Dr Sam Rawlinson	Scottish Clinical Transfusion Advisory Committee
Mr John Saxby	NHS Confederation
Ms Bhavna Sharma	Royal College of Obstetricians and Gynaecologists
Dr Dorothy Stainsby	Former National Medical Coordinator of SHOT
Dr Kevin Stewart	Royal College of Physicians
Dr Clare Taylor	Former SHOT Medical Director
Dr Andrew Thillainayagam	British Society of Gastroenterology
Dr Dafydd Thomas	British Blood Transfusion Society; Steering Group Chair elect
Mr John Thompson	Royal College of Surgeons
Dr Lorna Williamson	Founder Member

NB. All members of the WEG are members of the Steering Group in their own right.

WRITTEN BY

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- Dr Dorothy Dinesh, Transfusion Medicine Specialist*

OTHER CONTRIBUTORS

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- Dr Krishna Badami, Transfusion Medicine Specialist*
- Dr Deepak Badami, Transfusion Medicine Specialist*

*NZBS National Haemovigilance Group

ACKNOWLEDGEMENTS

- Jillian Sinden, Executive Assistant
- Carolyn Jeffrey, Business Analyst, Information Services

CONTACT DETAILS

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Private Bag 7934
Wellington 6242
Telephone: 64 4 380 2243
Facsimile: 64 4 389 5606
Email: haemovigilance@nzblood.co.nz
NZBS website: www.nzblood.co.nz

Table 2.3
Total number of reports per 10,000 components by UK country 2007-2011

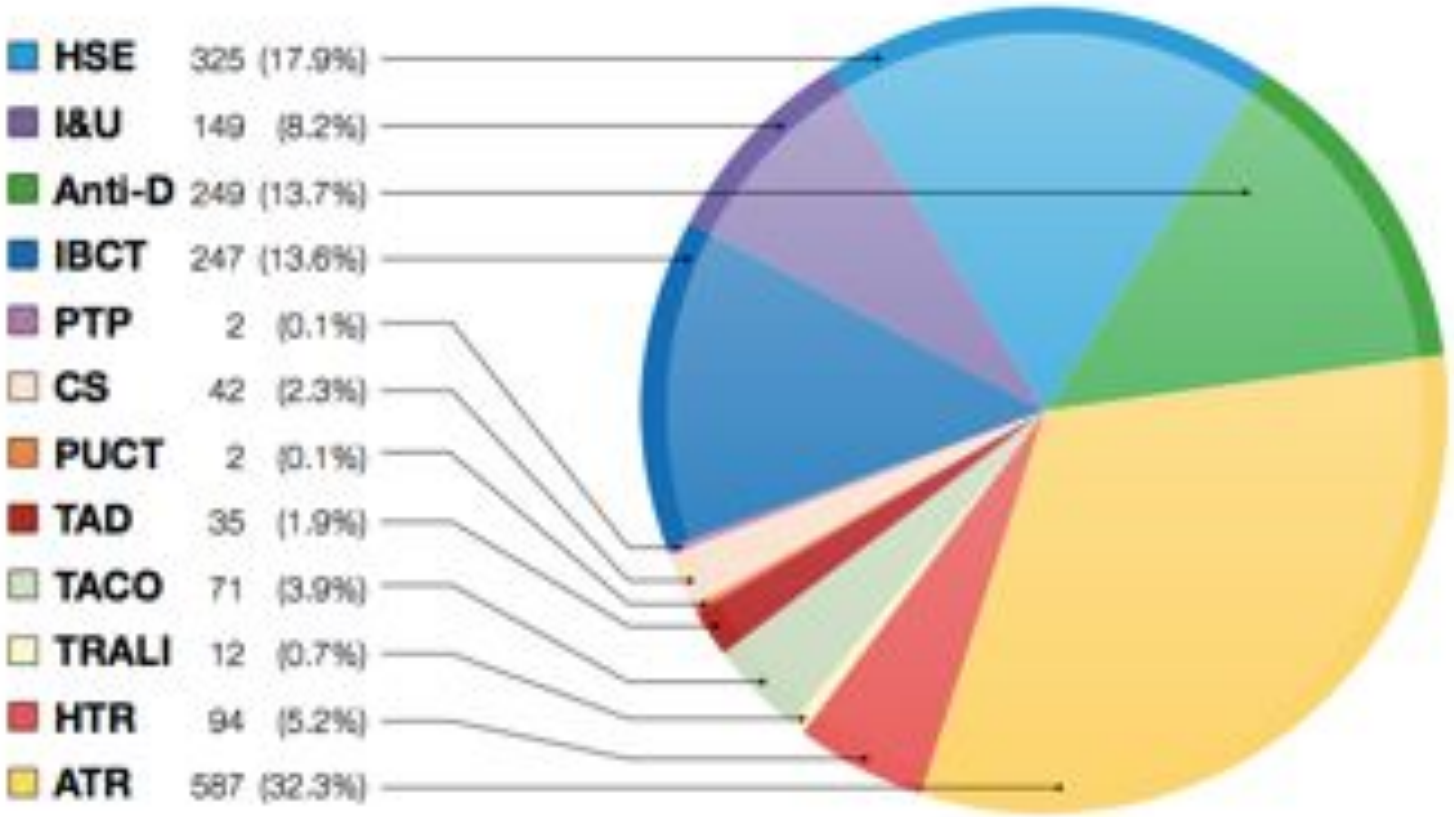
	2007	2008	2009	*2010	**2010	2011
England	4.6	7.7	8.1	8.9	10.1	10.9
Northern Ireland	6.6	10.0	10.5	16.0	20.8	21.1
Scotland	3.1	5.4	6.8	10.6	12.2	14.3
Wales	8.4	12.3	19.6	15.2	18.1	16.4
United Kingdom	**4.8**	**7.8**	**8.5**	**9.5**	**10.9**	**11.6**

** Column 1 for 2010 reports is calculated using the total number of completed reports in 2010, which is directly comparable to the historical data.*

*** Column 2 for 2010 is calculated using the total number of reports that have been started in 2010 (3200), including those which are not completed and were therefore not analysed in the rest of the 2010 report. These figures are not directly comparable to historical data, but are more indicative of the actual participation in 2010 and correlate to the figure used to monitor participation 2011 and forthcoming years.*

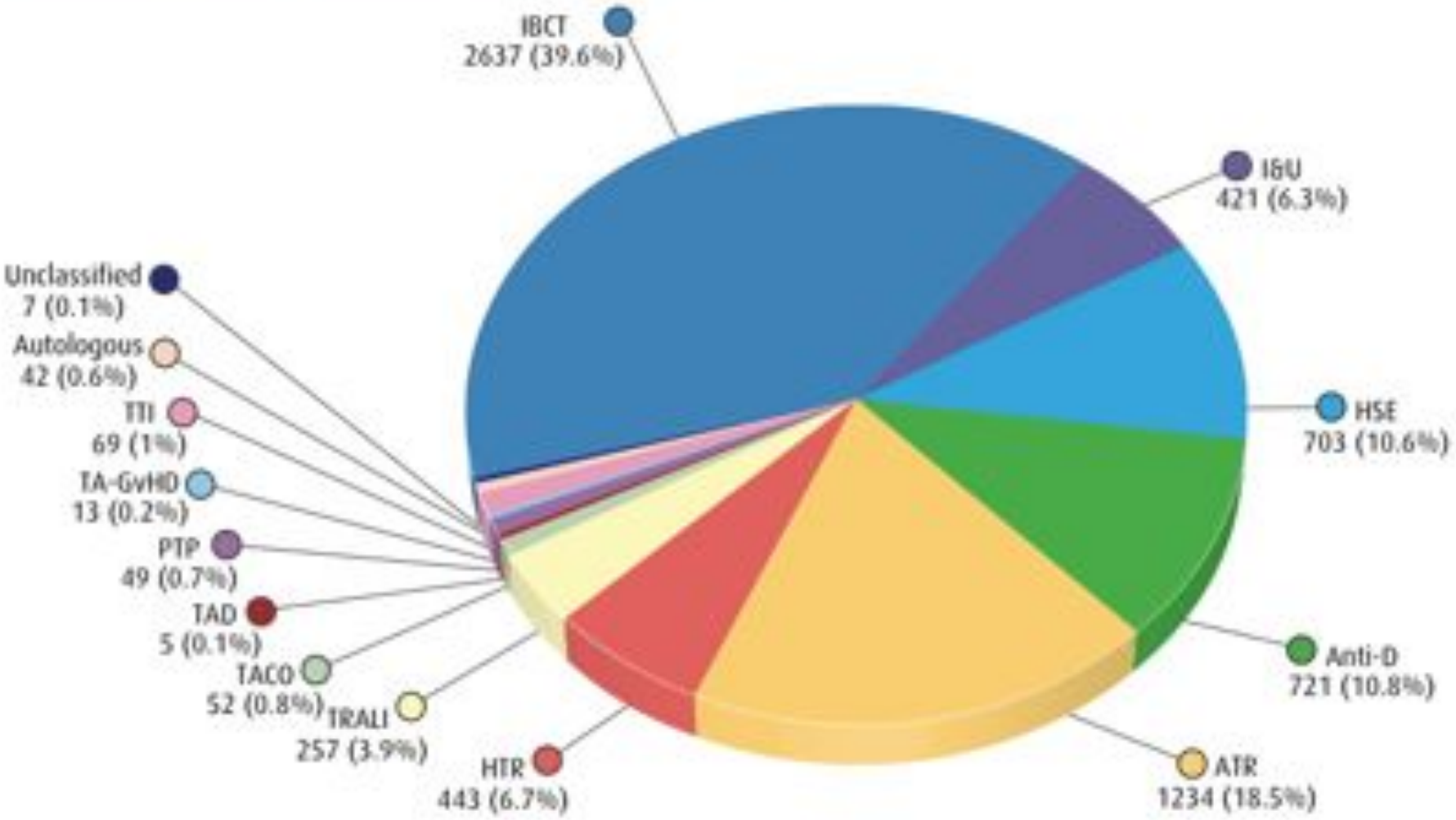
Authors: Paula Bolton-Maggs and Hannah Cohen

Figure 4.1
Cases reviewed in 2011 (excluding near miss and instances where the patient received a correct component despite errors having occurred – RBRP) n=1815



An increased number of reports were submitted for 2011 compared to previous years. The age range of patients who were the subject of SHOT reports in 2011 was wide, from birth to aged 103 years. The median age was 61 years. Younger patients featured in the anti-D Ig errors (median age 29 years, range 15 to 58) and in the haemoglobinopathy group (median 28 years, range 1-50). As in previous years the patients with transfusion-associated circulatory overload were older with a median age of 72 years.

Figure 5
Cumulative numbers of cases reviewed 1996–2009 *n* = 6653



Hemovigilance and Blood Regulations in Europe

How are we doing? How are they doing?

Dafydd Thomas

Consultant in ICM

Welsh Blood Service

Chair NATA

Chair SHOT Steering Group

Immediate Past President BBTS

‘If you can stay calm
while all around you
is in total chaos...

‘If you can stay calm while all around you is in total chaos...

then you probably haven’t fully understood the seriousness of your situation...!’

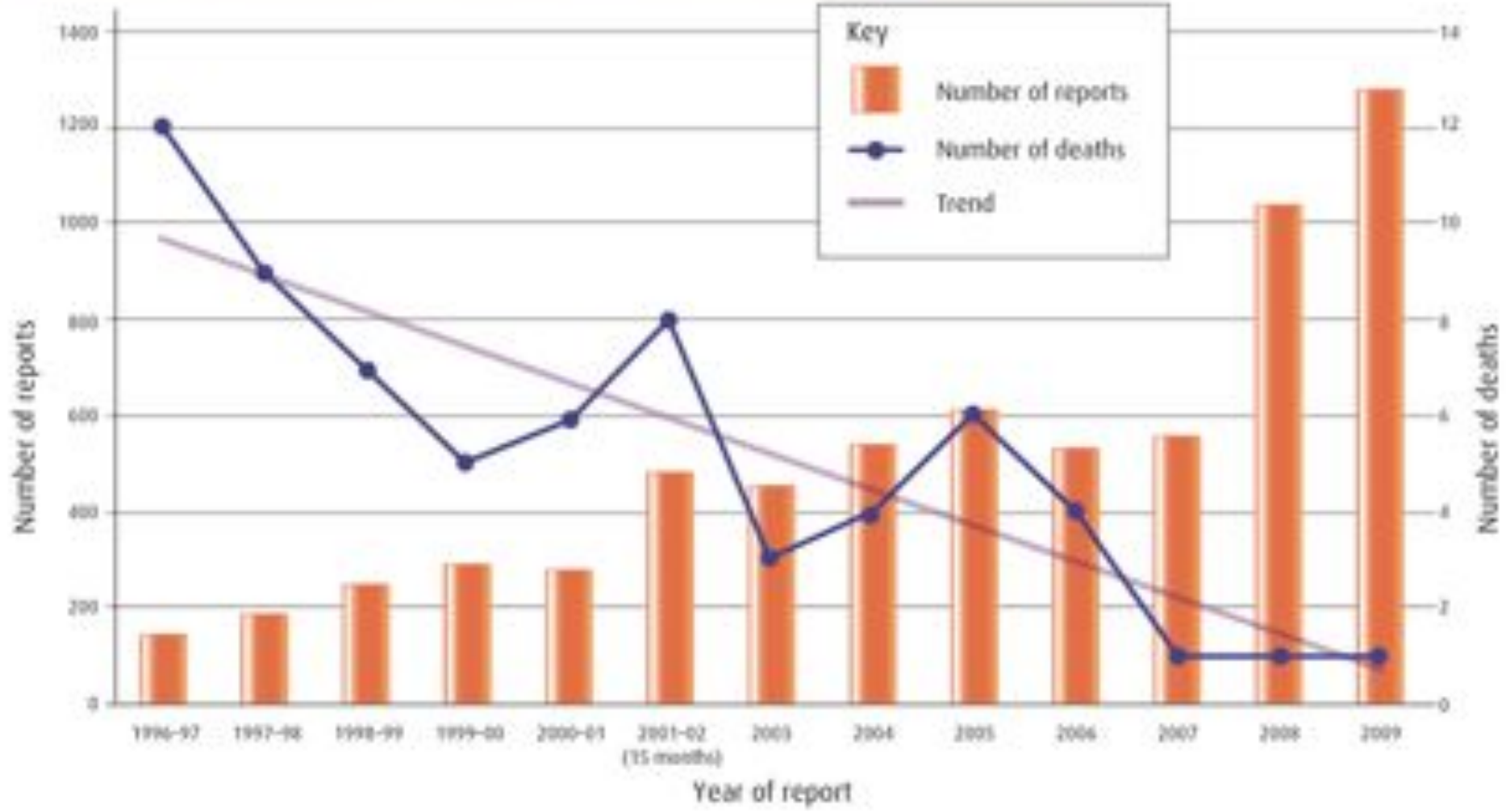
SHOT 2011

- the risk of death is 0.0027 per 1000 components issued
- the risk of major morbidity 0.0399 per 1000 components issued.

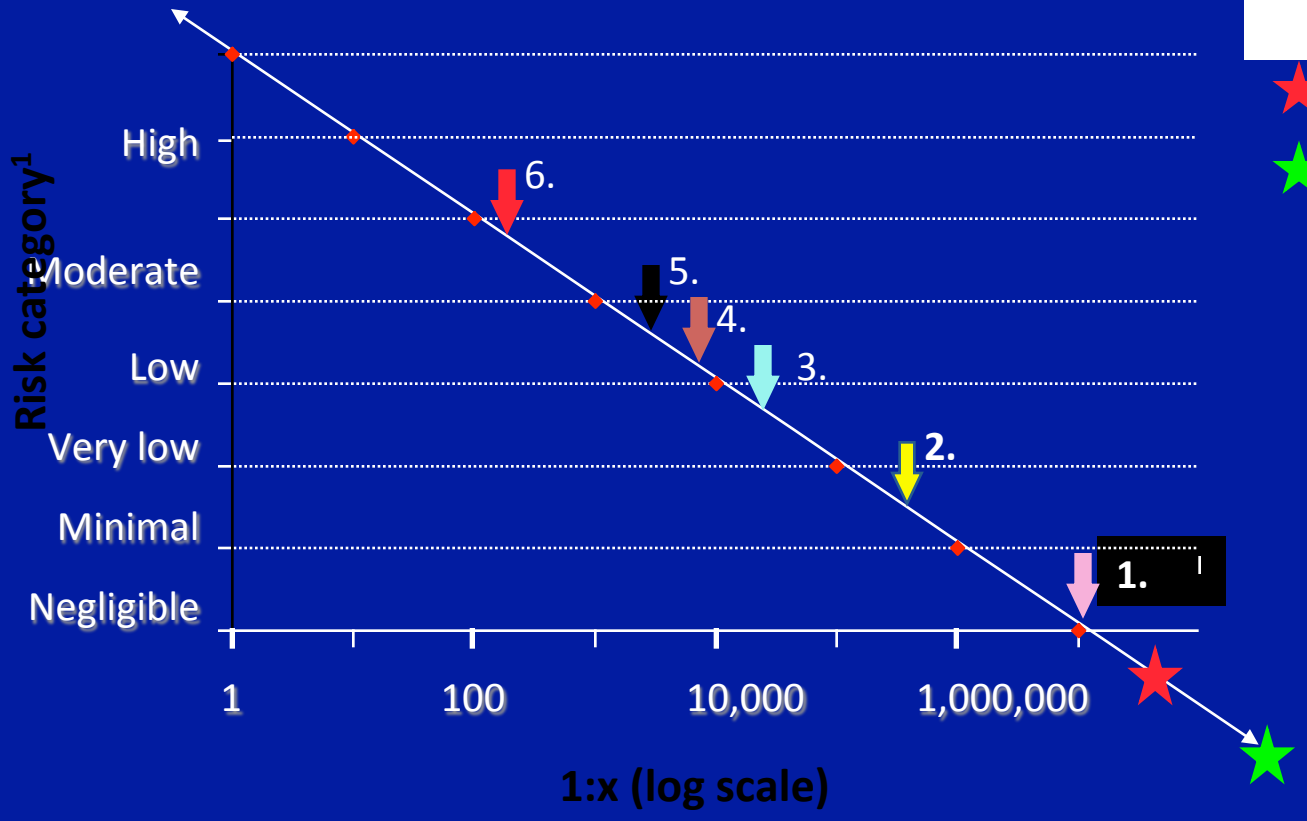
SHOT 2011

- the risk of death is 2.7 per 1,000,000 components issued
- the risk of major morbidity 3.99 per 100,000 components issued.

Figure 1
Total reports and total deaths definitely due to transfusion between 1996 and 2009



Are we at risk from blood that is donated?



Provisional estimates (08/03) of infection in 1 donation:-

- HIV (1 in 8 m)
- HCV (1 in 30 m)

Death in 1yr due to:-

1. Hit by lightning
2. Accident on railway
3. Playing soccer
4. Accident on road
5. Influenza
6. Smoking 10 cigarettes/day

[1] Adapted from Health of the Nation, Dr K Calman, 1996.

- Reports are not dis-similar as we are dealing with the same species.
- Similar practices on the same species and by the same species with similar clinical practices

- We are all individuals

afssaps

Agence française
de sécurité sanitaire
des produits de santé

France
Annual Haemovigilance report 2009

Table 2 Cumulative mortality/morbidity 1999-2009

	Death	Major morbidity	Minor or no morbidity	Total	%
ICBT	2	13	104	119	55
AHTR	0	2	9	11	5
AAS	0	14	4	18	8
TRALI	1	14	6	21	10
DHTR	1	0	30	31	14
PTP	0	1	0	1	0,5
TA-GVHD	1	0	0	1	0,5
TTI	0	6	10	16	7
Total	**5**	**50**	**163**	**218**	**100**
Ratio/100.000 BC	**0,1**	**0,9**	**2,9**	**3,9**	

1. Introduction

1.1. News in 2009

2009 was principally marked by:

• The occurrence of a donor serious adverse effect (DSAR) during plasmaphaeresis that resulted in the death of a female donor. The measures immediately put in place and those envisaged in the short- and medium-term have been analysed; the enquiry is still in progress.
In any case, Afssaps decided to urgently put in place an electronic declaration system, including the declaration of SAEs and DSARs, which were previously only declared on paper: e-FIT V2 beta[2] (March 2010). This system shall offer the haemovigilance network the possibility of immediate responsiveness, via the simultaneous communication of information to all the participants. The introduction of a system similar to the configuration of the current declaration for recipient adverse reactions (RAR) was also scheduled for 2011 with e-FIT V3.

• The drawing up by the "Allergy" task force of a procedure for the examination of serious allergic reactions (grades 3 and 4) during transfusions involving VIP-MB (05/06/09) and warning on the issues regarding:
- The examination of patients according to a protocol drawn up by the task force
- Recommendations for transfusion-related care
- A proposal submitted to the RHCs for a common aetiological enquiry procedure
These documents are available on the Afssaps website: http://www.afssaps.fr

• As a result of the influenza A pandemic[3], EFS, with approval from DGS, decided, as a precautionary measure, to move forward to 30 April 2009 the date of the measures for the exclusion of the donation of blood by donors having returned from North America less than 28 days previously (as for the prevention of the transmission of the West Nile virus). This measure was repealed on 28/1/2010.


TRANSFUSIE REACTIES IN PATIËNTEN
TRIP

Figure 1 shows the level of participation over the years 2002 (baseline measurement) up to and including 2010.

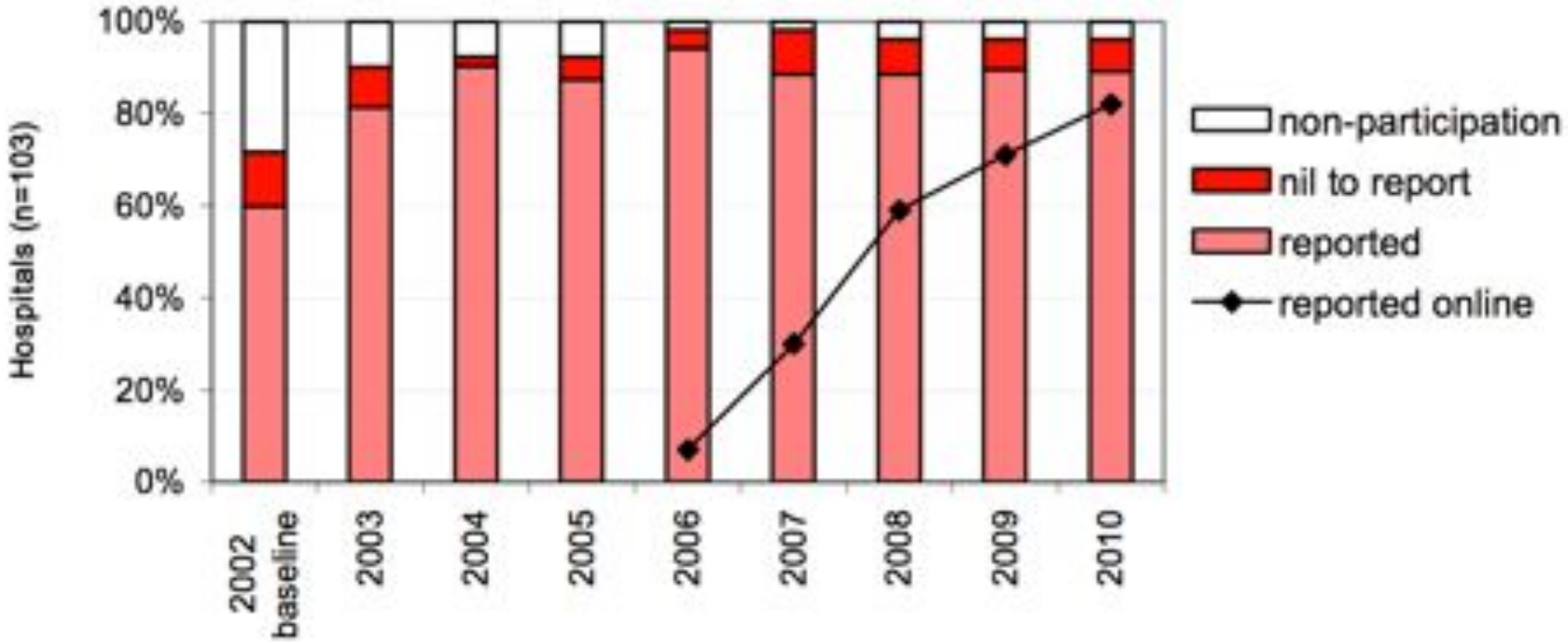


Figure 1 Participation per year

Table 2 Incidents reported to TRIP, 2003–2010

Incident	2003	2004	2005	2006	2007	2008	2009	2010	No. hospitals with reports in 2010
Incorrect bc transfused	34	36	60	64	64	59	61	58	30
Near miss	31	62	79	77	74	55	72	68	19
Other incident	5	12	51	86	100	83	110	117	30
Look-back (info reported by hospital to TRIP)		2	2	1	4	9	6	50	13
Viral contamination of bc				2	0	2	1	4	3
Positive bacterial screen[$]	61	10	13	27	29	2	4	3	3
Bacterial contamination of bc[$]					5	23	22	40	20
Total incidents	131	122	205	257	276	233	277	340	54

[$] see remarks about revised definitions in section 3.2
bc = blood component

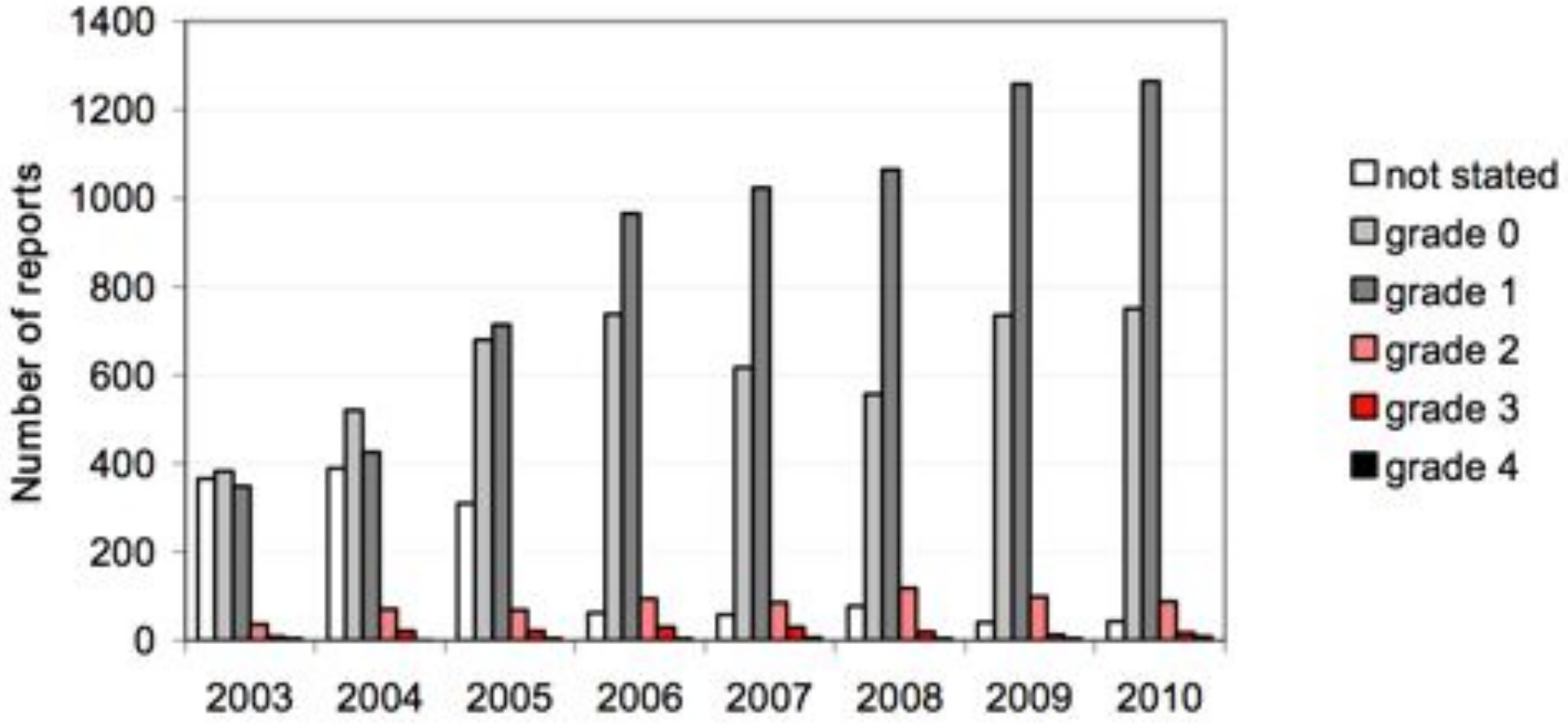


Figure 2 Severity of the transfusion reactions, 2003 – 2010

Relationship to the blood transfusion (imputability)

Imputability	*Definition* *(Imputability is applicable to transfusion reactions)*
Certain	*clinical symptoms present, and* *- clear course of events, temporally related to the transfusion, and* *- confirmed by laboratory findings, and* *- other causes excluded*
Probable	*clinical symptoms present, but* *- no clear course of events or not temporally related to the transfusion, or* *- not confirmed by laboratory findings, or* *- other possible cause present*
Possible	*clinical symptoms present, but* *- not temporally related to the transfusion, and* *- not confirmed by laboratory findings, and* *- other possible cause present*
Unlikely	*clinical symptoms present, but* *- not temporally related to the transfusion, and* *- not confirmed by laboratory findings, and* *- another more probable explanation present*
Excluded	*clearly demonstrable other cause*

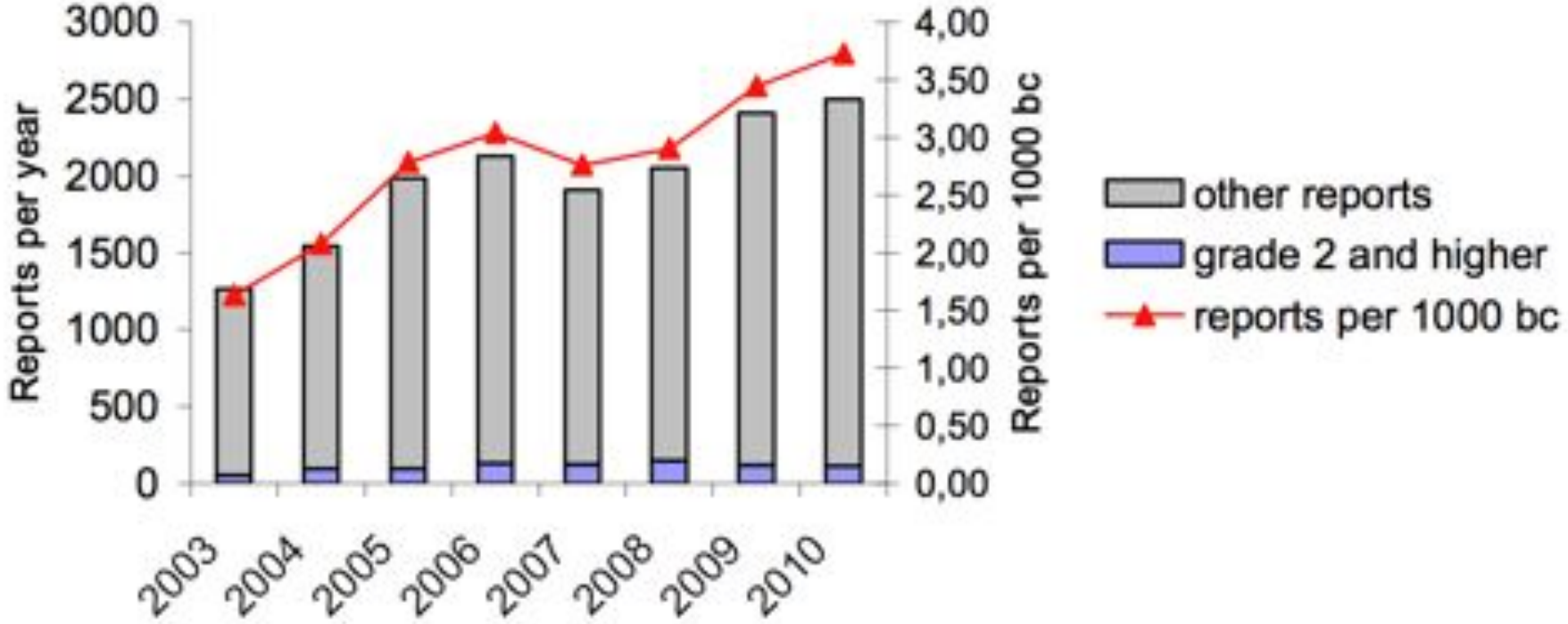


Figure 4 Number of reports per year, 2003 – 2010

A. Recommendations based on the 2010 TRIP Report

	Recommendation	Who?
1.	TRIP should revise and refine the definitions for the current categories of transfusion reactions. New categories should be defined for hypotensive transfusion reactions and transfusion associated dyspnea (as recommended in 2009).	TRIP
2.	A classification is needed (similar to that in use by SHOT) for the link between a transfusion reaction, the patient's clinical condition and a fatal outcome in the patient.	TRIP
3.	A standard protocol should be developed for the further investigation of serious anaphylactic transfusion reactions.	TRIP and Sanquin clinical advisory service

4.	In order to monitor optimal use of blood components, TRIP wishes to encourage reporting of incidents which lead to unnecessary transfusion or avoidable product loss.	Hospital transfusion committees and hemovigilance staff
5.	TRIP will collect figures concerning transfusions to infants and children in order to gain insight into the incidence of transfusion reactions in this patient group..	TRIP and hemovigilance staff
6.	Hospitals should have a defined procedure for investigation of recipients of blood components which retrospectively might have been infectious.	Hospital transfusion committees and hemovigilance staff

B. General recommendations

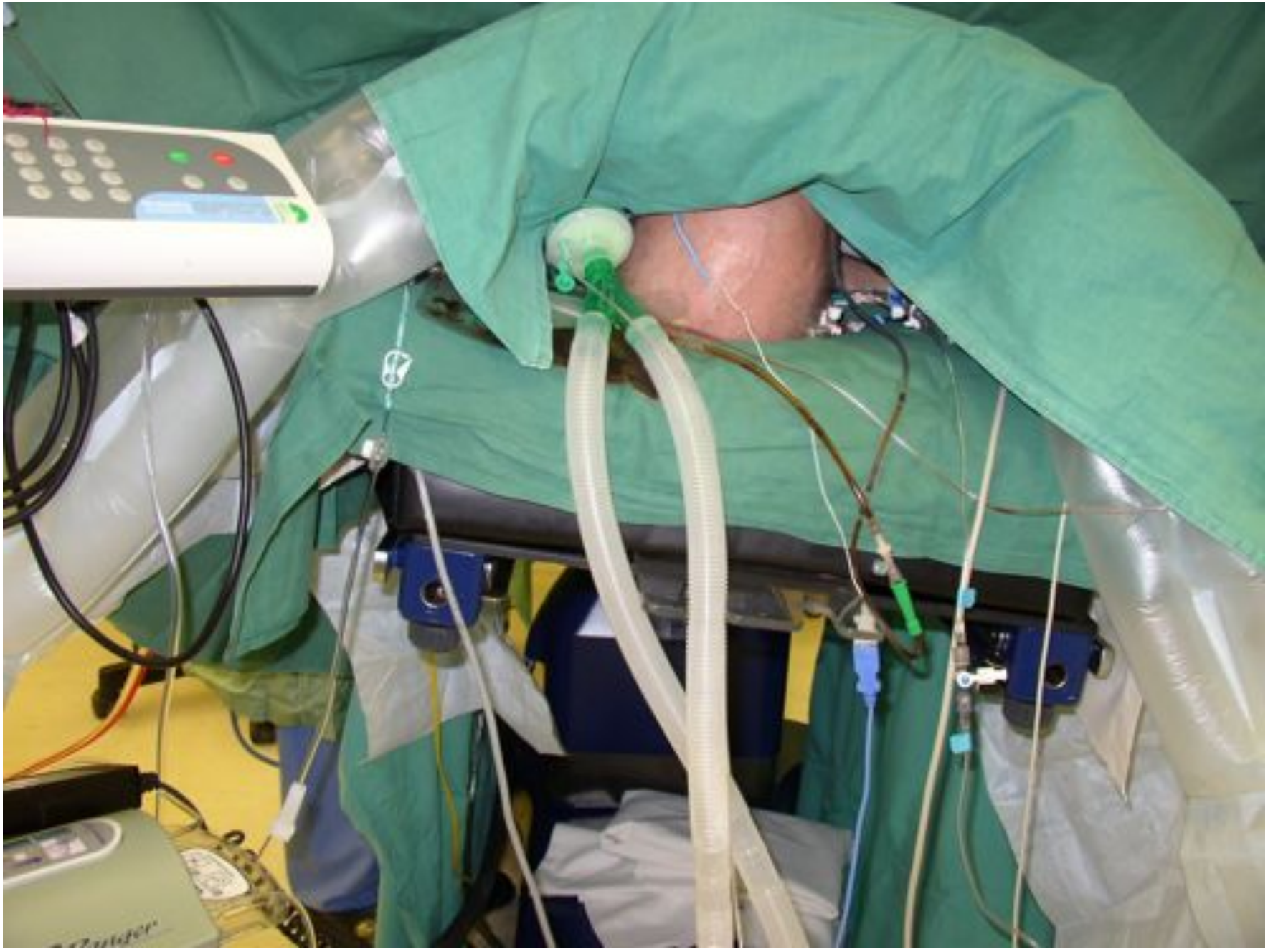
7.	Action is required on the implementation of hemovigilance for Blood Management Techniques as recommended in 2009: the blood transfusion committees should ensure that a protocol is created for the use of blood management techniques, with correct transfusion triggers and a procedure for reporting side effects and incidents.	Hospital transfusion committees and hemovigilance staff

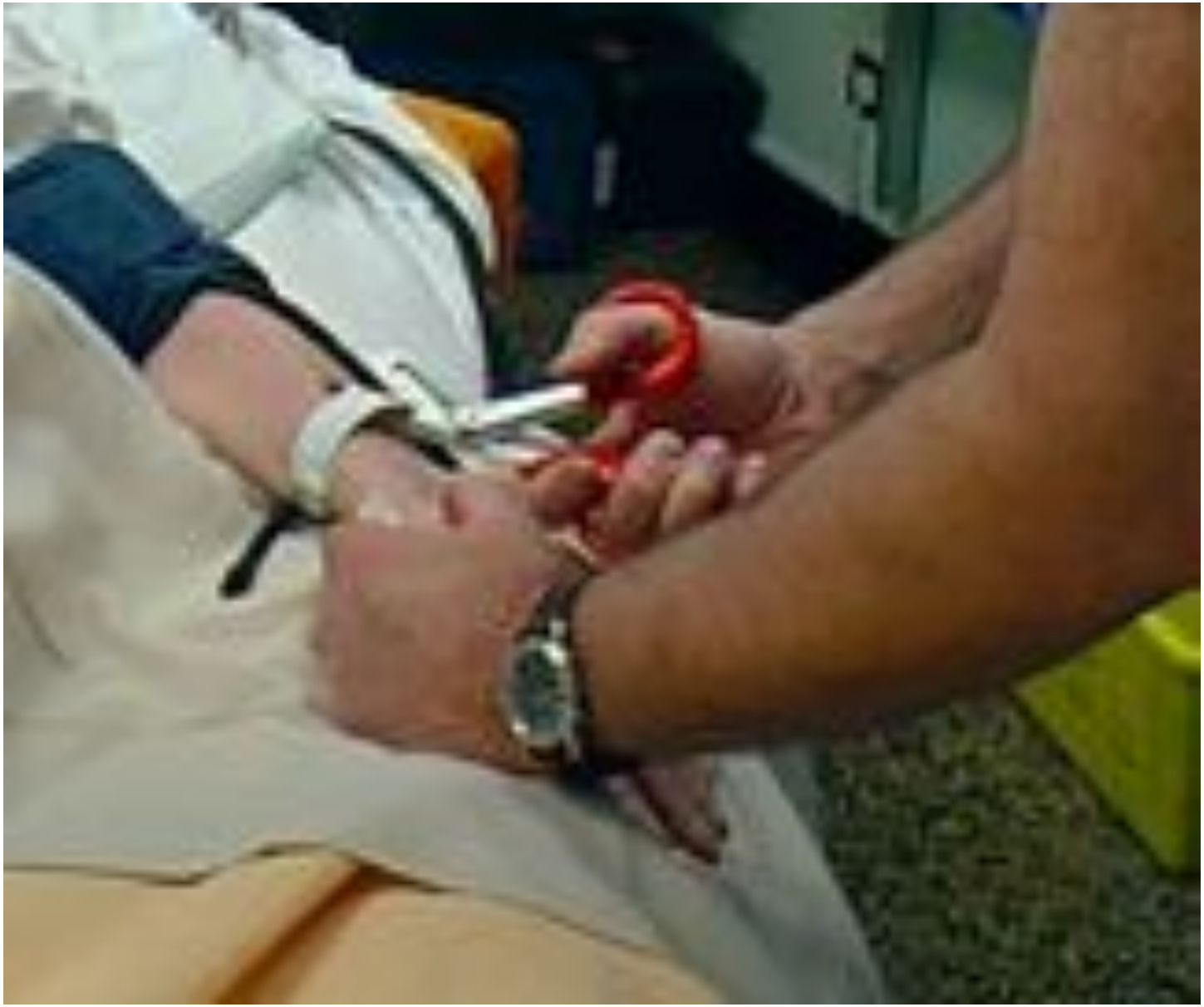
Back to Basics

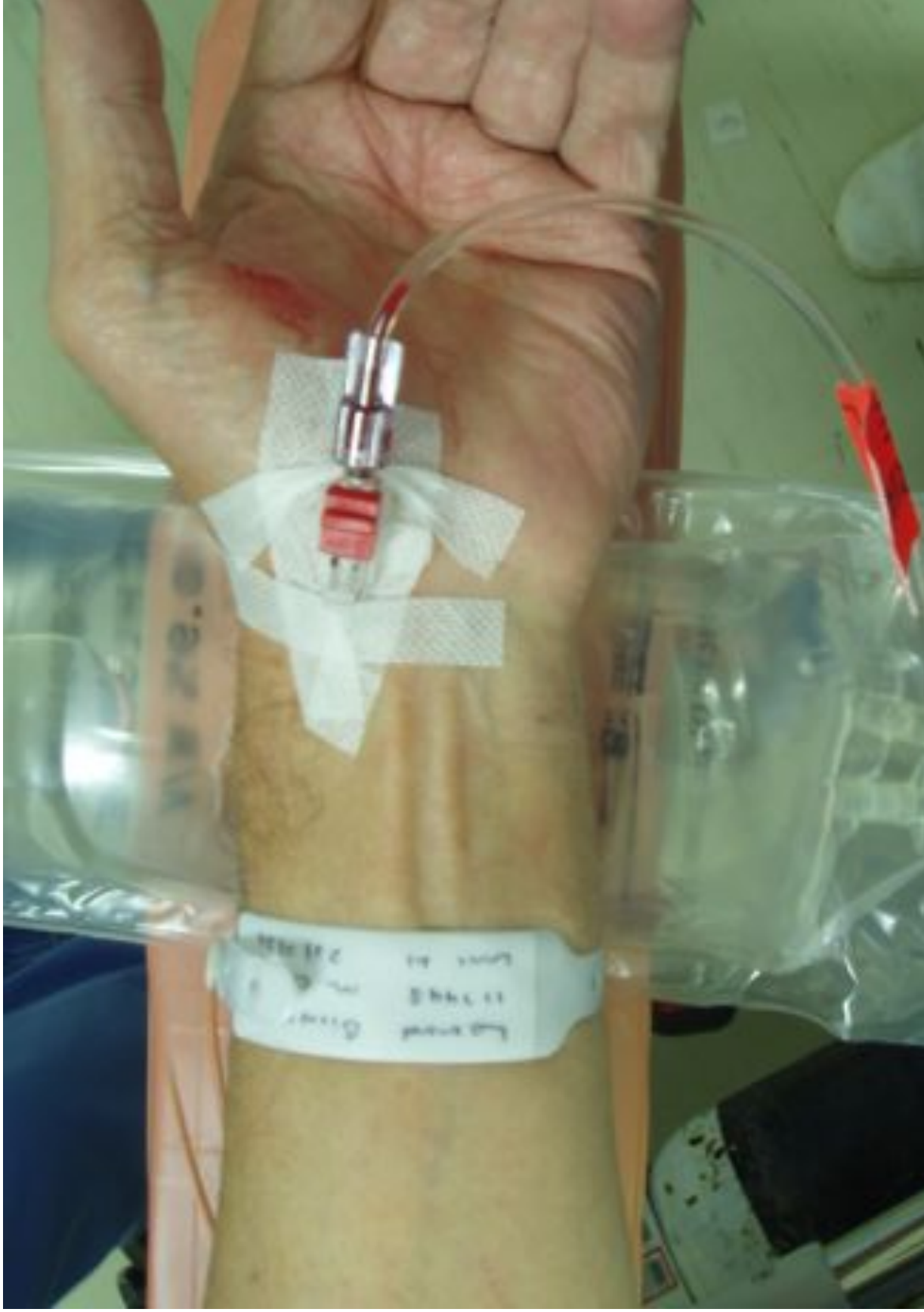
- Similar problems with drug prescribing have also been examined. The level of errors in prescription of medications has been reported by the General Medical Council recently101, with the highest error rate in foundation year 1 (8.4%) and year 2 (10.3%).

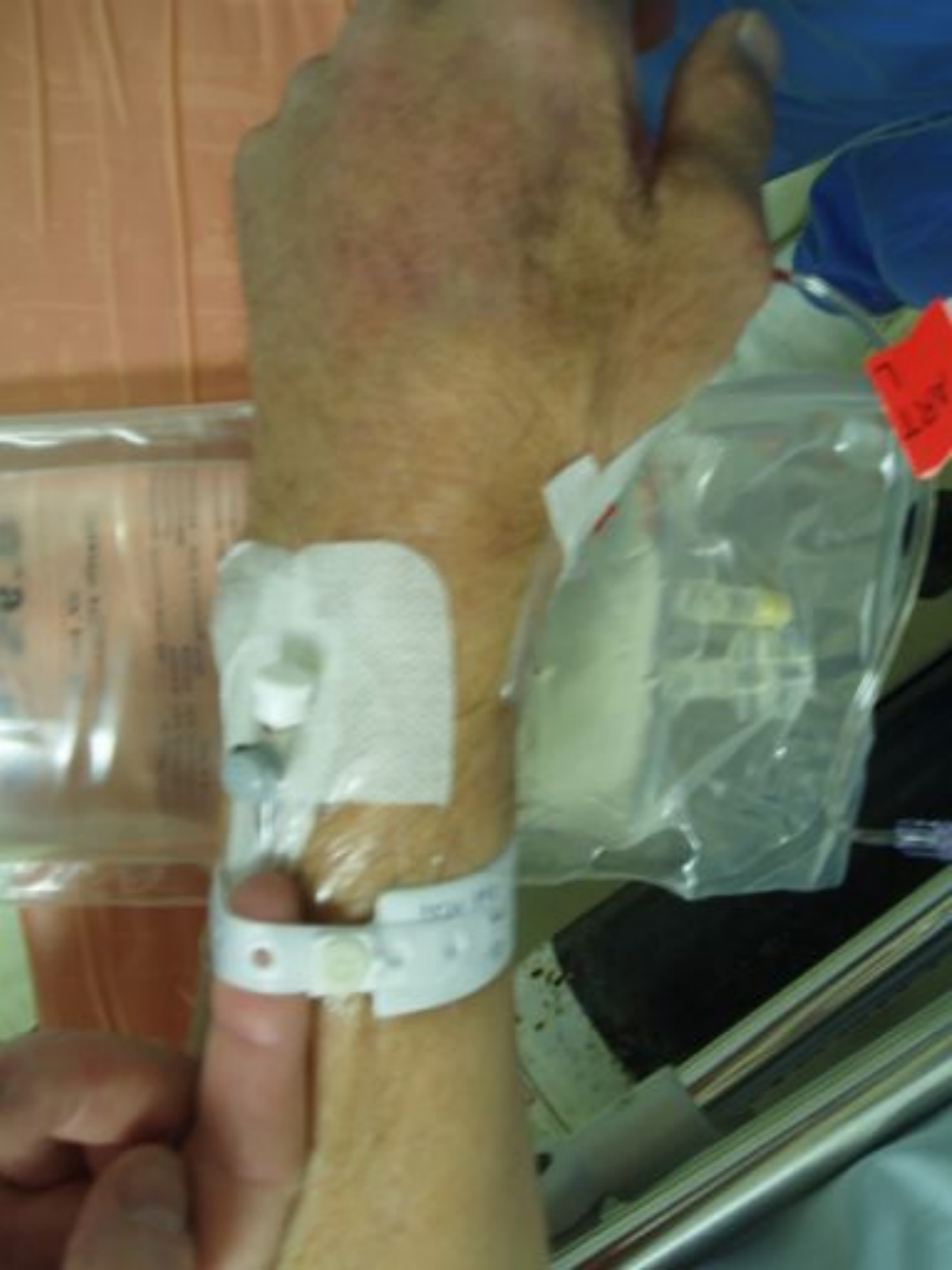
- Anaesthesia -simulation

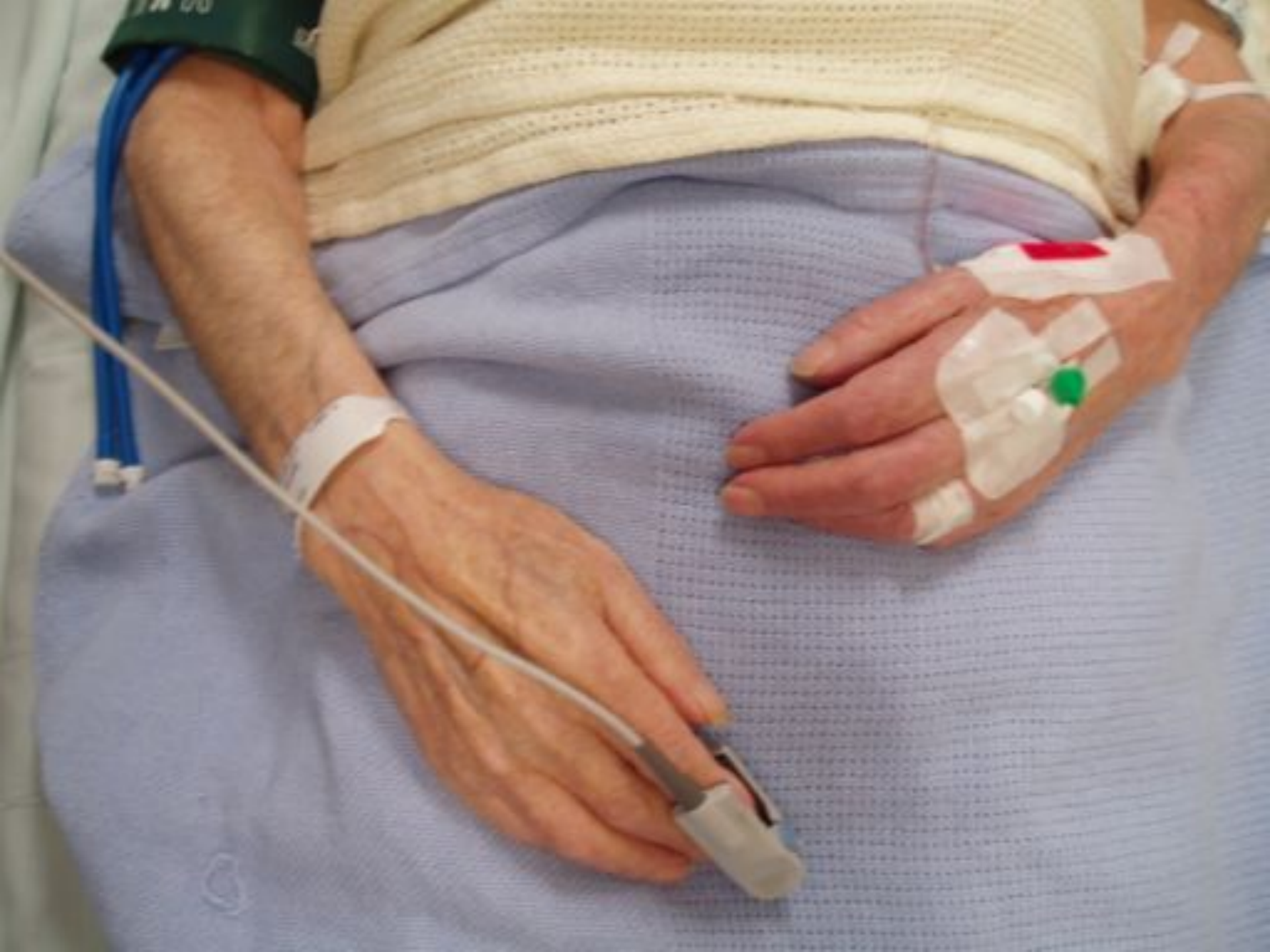

AMERICAN
AVIATION
LEARN TO
FLY HERE!

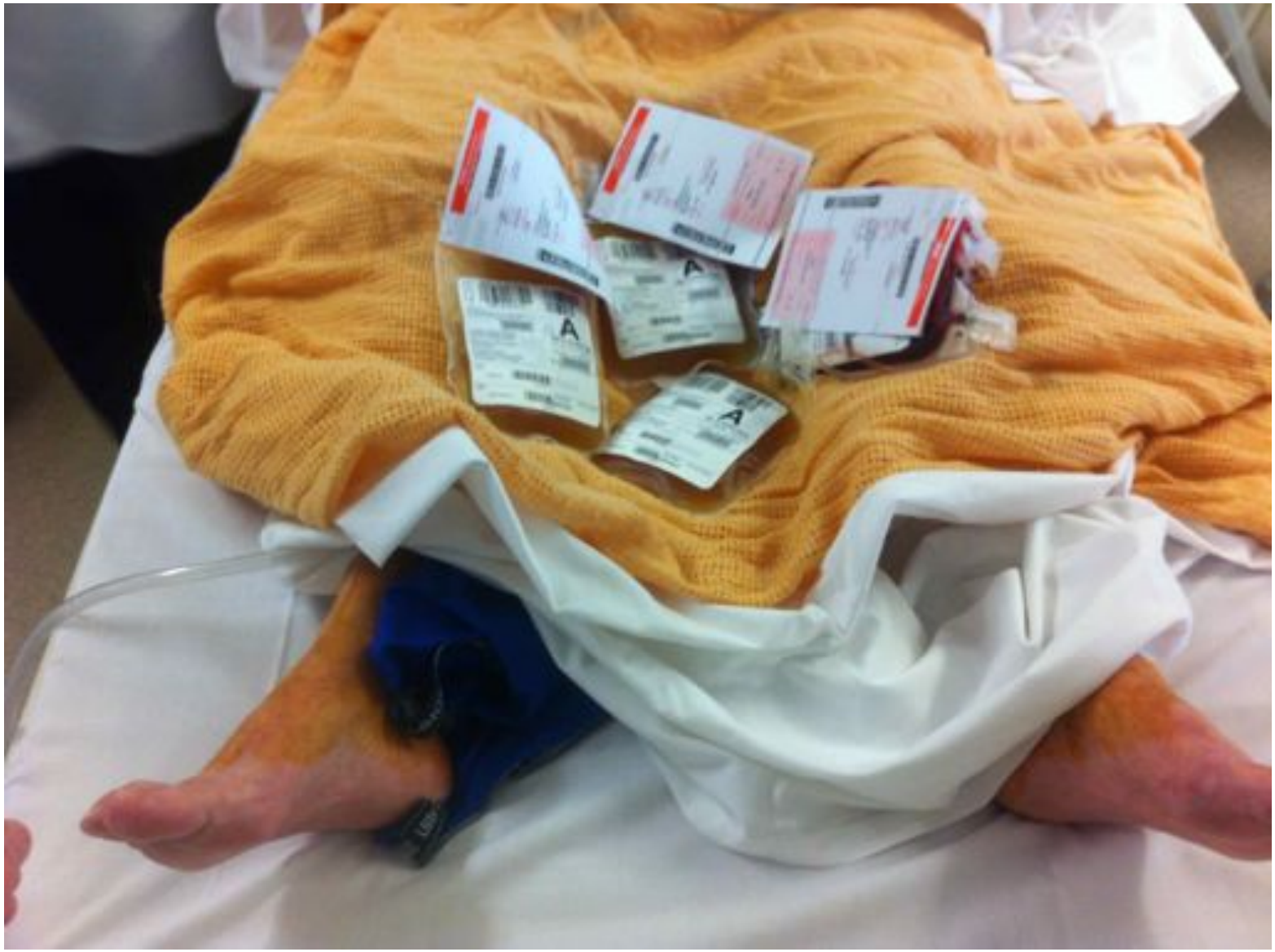






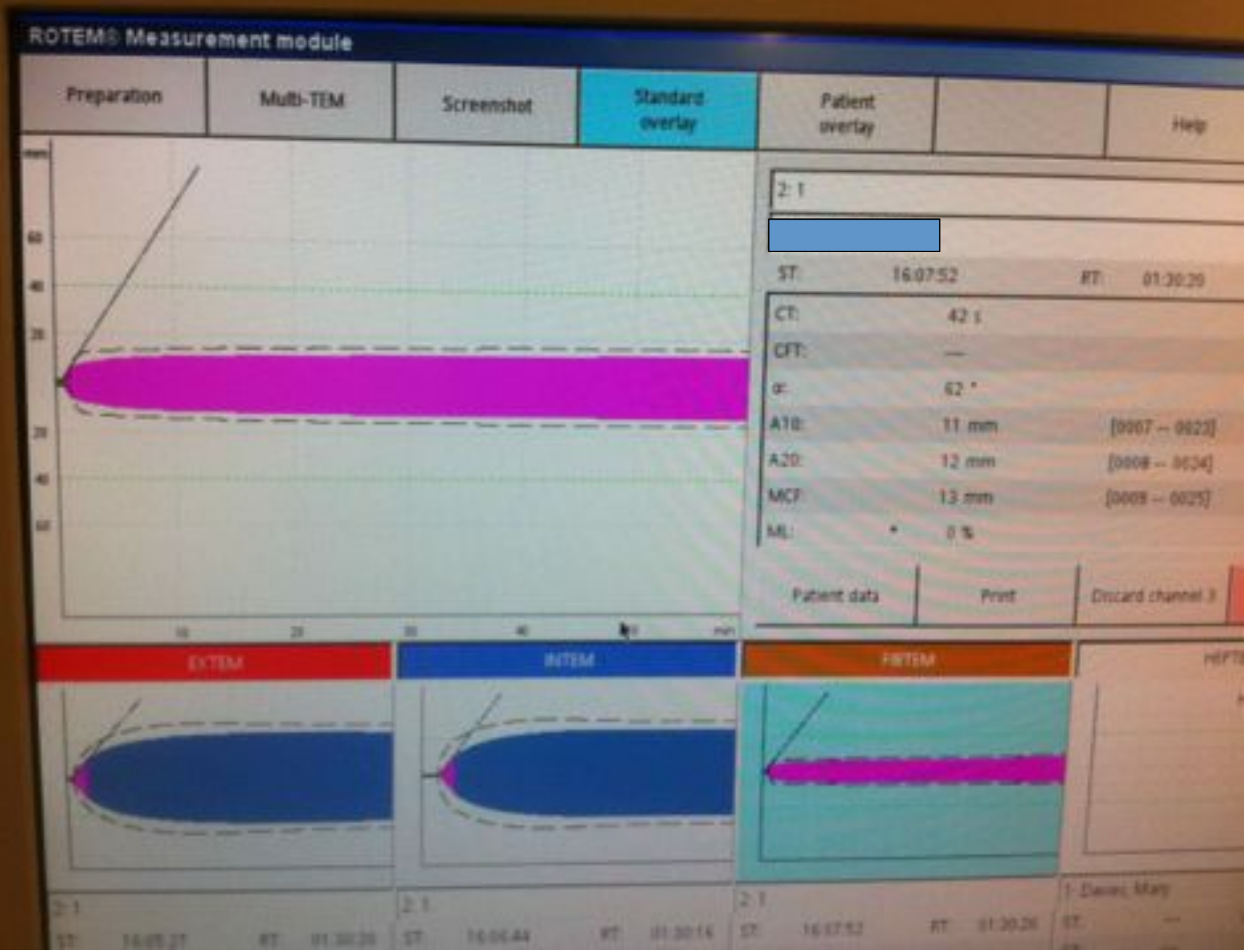






26 November 2012

12 November 2012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Preparation
Multi-TEM
Screenshot
Standard overlay
Patient overlay
Help
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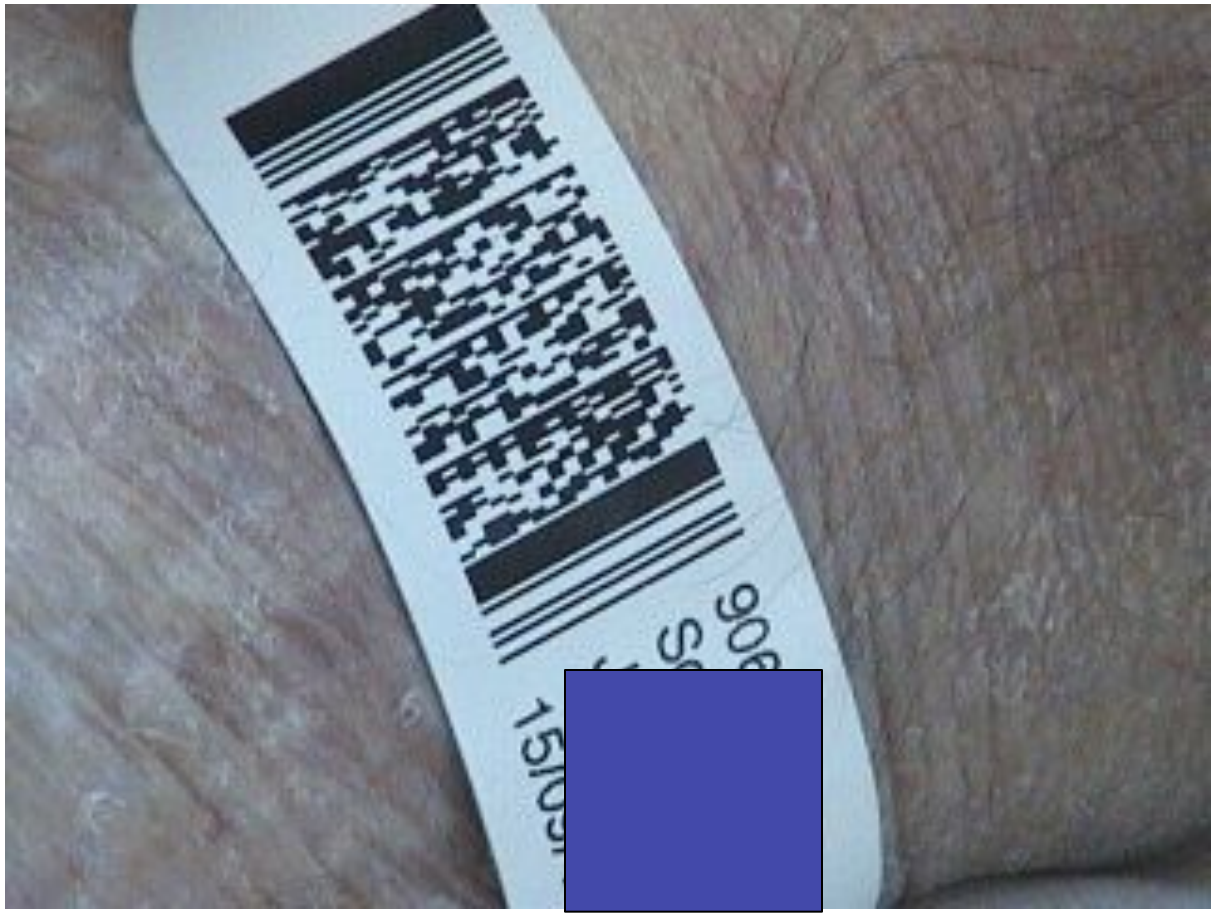
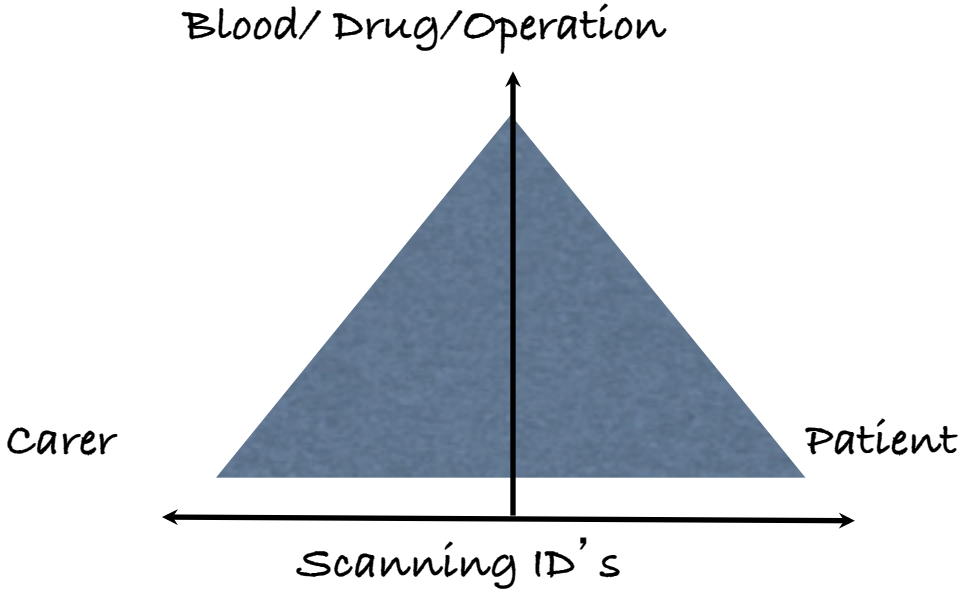
RT: 01:30:20
CT: 42 s
CFT: —
α: 62 °
A10: 11 mm
A20: 12 mm
MCF: 13 mm
ML: 0 %
Patient data
Print
Discard channel 3
EXTEM
INTEM
FIBTEM

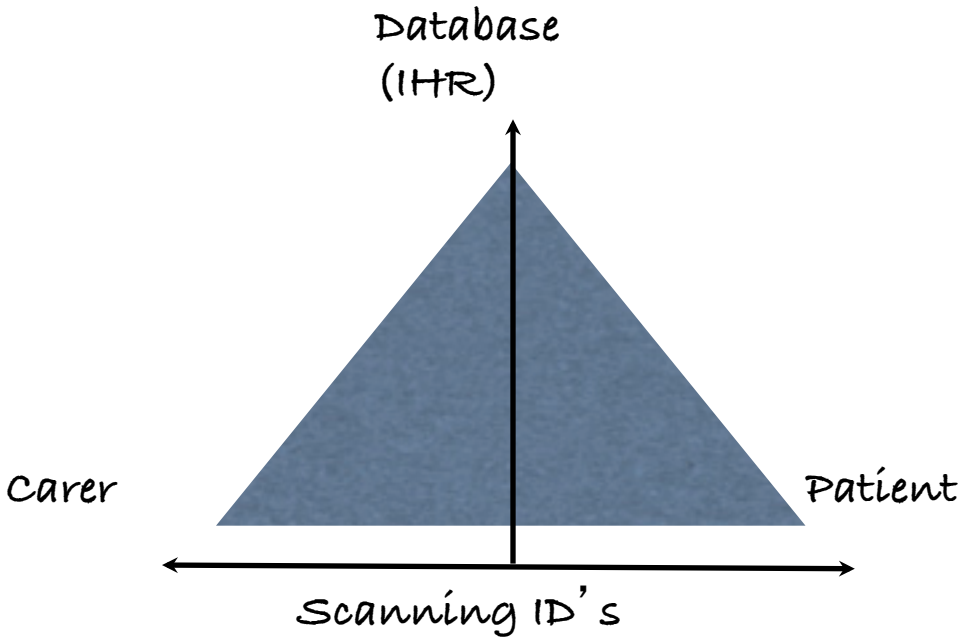
Eye readable and scanned information

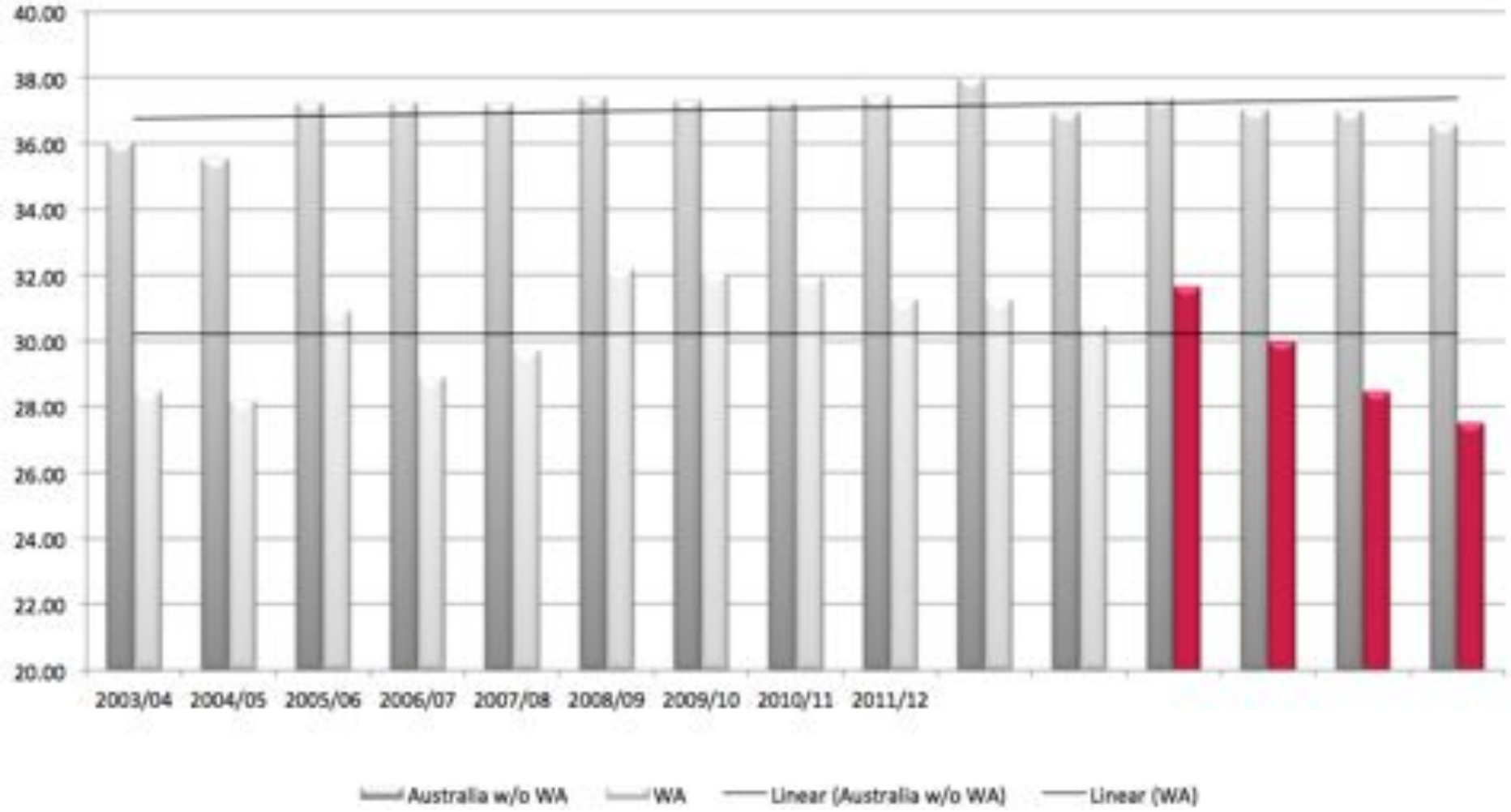


The Consent Triangle



The Consent Triangle

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WA
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Linear (WA)

Vigilance of Cell Salvage

Similar to haemovigilance

- Very similar errors
- Some are machine based
- Some are clinically based
- Some are human error
- Some are compounded by a number of these

All Wales Intra-Operative Cell Salvage Data Collection Form

This form should be completed for every surgical case where blood has been collected with the intention of intra-operative cell salvage EVEN if the blood collected is not processed.

1. Trust	Hospital	For BBT use only

2. Patient Details	3. Procedure Details		
Hospital number	Name of procedure		
Surname			
Forename	Date of operation	/ /	
D.O.B.	In hours	Emergency	
Address	Out of hours	Elective	
	Malignancy	Infected fields	
	Obstetrics	Trauma	
	Jehovah's Witness		
	Surgeon		
	Anaesthetist		
	Cell Salvage Operator		
Age	Male	Female	Patient died	No	Yes

4. Cell Saver Equipment Used

BRAT	Electa	Cell Saver 5	Orthopat	CATS	Other
Anti-coag used	Heparin		Citrate	Other	
Blood filter used	40µ filter		Leucodepletion filter	None	
Collection reservoir			Lot No.		
Harness set			Lot No.		

5. Salvaged Blood Volume Details Processed Yes No		6. Total No. allogeneic units transfused during hospital stay	
Intra-op processed (ml)			
Volume of anticoagulant intra-op (ml)		Red cells	
Volume of irrigation used (ml)		FFP	
Volume of swab wash (ml)		Platelets (adult dose)	
Volume salvaged RBC intra-op (ml)		Cryoprecipitate	
Post-op processed (ml)		Other	
Volume of anticoagulant post-op (ml)			
Volume salvaged RBC post-op (ml)			
Time collection started		Pre-Op Hb	
Time re-infusion started		Discharge Hb	

7. Reason if blood was not processed

Inadequate volume collection | Training purposes | Technical problem

8. Problems / Faults

Technical Machine | Bowl | Harness | Software

Other (Please state)

Procedural (Operator/Surgeon/Patient)

Operator error | Communication failure

Training issue | Unforeseen circumstance

Top copy – Patient notes **2nd copy** – Audit form – WBS

All Wales ICS Form Version 5 Revised: September 2005


HAEMONETICS
HAEMONETICS

Benefits of ICS

- Little risk
  - Serious Hazards of Transfusion (SHOT) Report 2011 (17 incidents)
    - 2 febrile reactions
    - 6 adverse events (all hypotensive on reinfusion via a leucodepletion filter)
    - 9 minor events relating to operator/equipment errors – training!
- Is that a lot?
  - Probably not
  - Wales ~ 3000 ICS procedures annually

Clinical scenario

- **Profound hypotension**
- **All when LDF being used**
- **Citrate used as anticoagulant**
- **Warm Blood**
- **? Blood being pressurised**
- **BP restored on stopping infusion**

Clinical scenario

- **Profound hypotension**
- **Bradykinin release, cytokine effect**
- **Seen in LDF at bedside**
- **Anaesthetists need to be made aware**
- **Stop infusion, vasoconstrictors, other fluid.**
- **Transient**
- **Remove filter in urgent situation**

Clinical scenario

- **Profound hypotension**

Theoretical explanation

- **Transient**
- **Remove filter in urgent situation**

Iwama H. Bradykinin-associated reactions in white cell-reduction filter. *Journal of Critical Care* 2001; 16(2): 74-81.

Bradykinin-Associated Reactions in White Cell-Reduction Filter

Hiroshi Iwama

Purpose: The purpose of this study was to examine the effect of temperature on bradykinin generation during blood transfusion using positively charged (positive filter), negatively charged (negative filter), and neutral (neutral filter) filters.

Materials and Methods: Whole blood collected from six volunteers at 4°C or 37°C was passed through the positive or negative filter. In six surgical patients during surgery, autologous blood transfusion at 37°C was initiated through the positive filter, and the same transfusion was reintroduced through the negative filter. Whole blood from another six volunteers at 4° or 37°C was passed through the neutral filter.

Results: The positive filter did not generate bradykinin at any temperature, whereas the negative filter generated bradykinin by approximately 4,000-fold when warm blood was used but did not at cool blood. Blood pressure decreased and heart rate increased during warm blood transfusion using the negative filter but did not change using the positive filter. Plasma bradykinin levels increased in patients with use of the negative filter. The neutral filter generated bradykinin when warm blood was used but at levels lower than for the negative filter.

Conclusions: Use of negative filter results in the temperature-dependent generation of bradykinin, which becomes a potential anaphylatoxin when warm blood is used.

Haemovigilance

- Let us learn from what we have put in place for allogeneic surveillance
- Let us use technology already in place to monitor alternatives

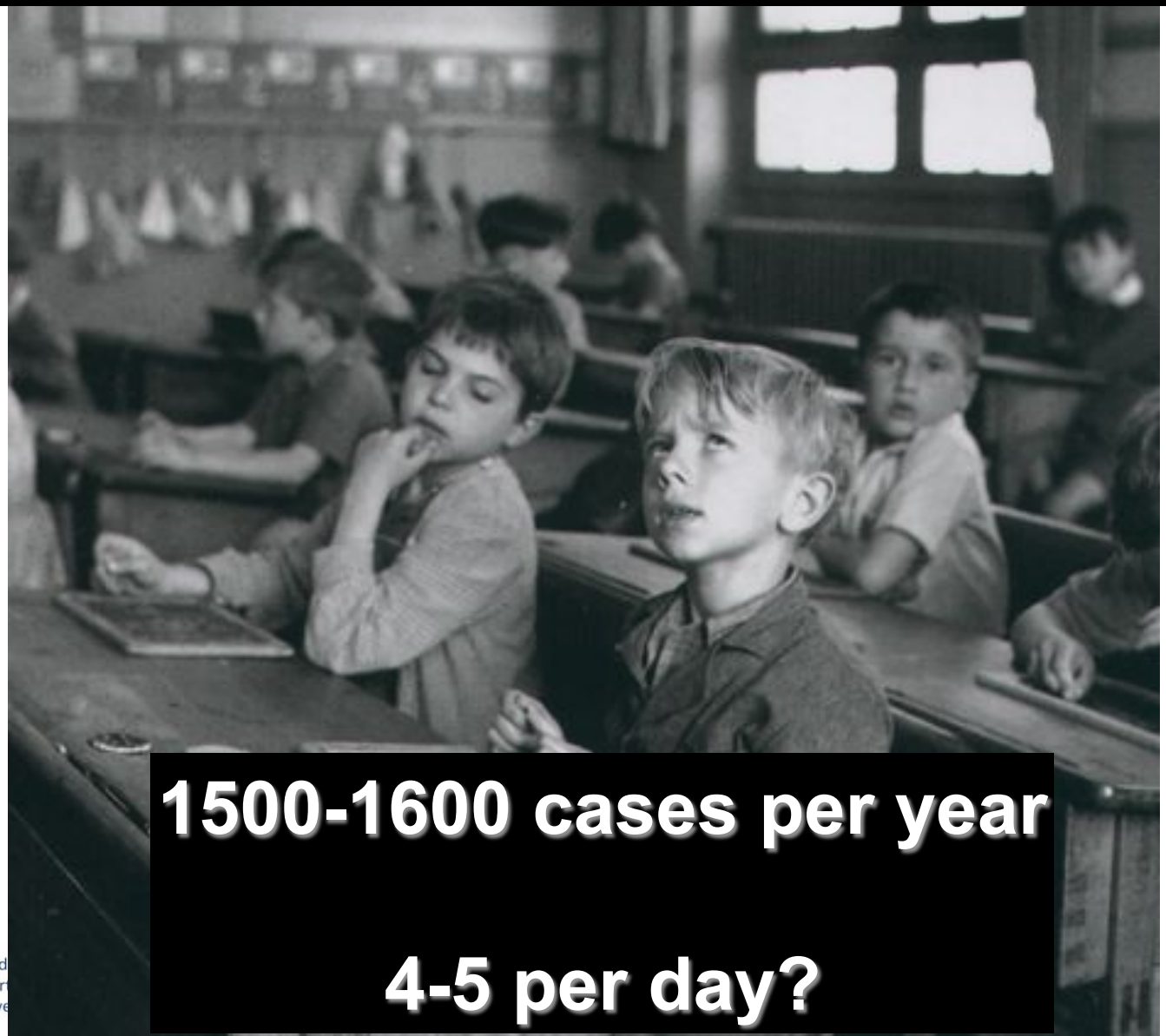
Standardise Streamline Consensus or just copy!

We are at such an early stage we could agree on a standardised collection of data

Rewrite if going towards electronic data collection

- More opportunity to report adverse events or reactions
- Prompt
- ?opportunity to follow up and complete outcome data at 24hrs
- List of patients to visit
- Lead clinician role? Delegated role

On line web based capture of data?




EE 3G
10:38
100%
SIGN
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Veg Garden
SQ Mobile
Spell Check
Convert It!
BT Wi-fi
Citrix
iResus
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Handy Level
AirPort Utility
Allrecipes
Quickoffice
Settings
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Calendar
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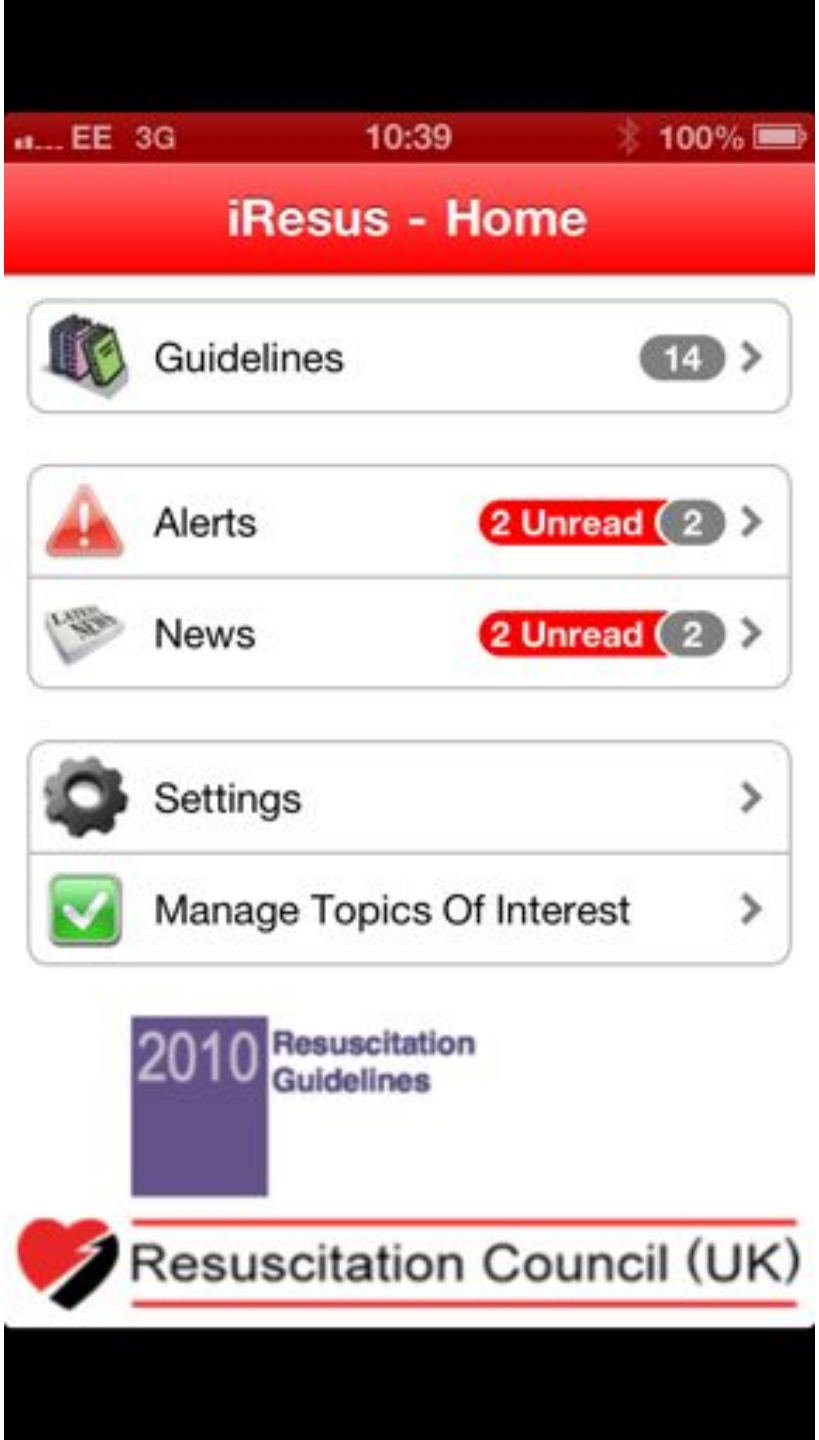
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Alerts
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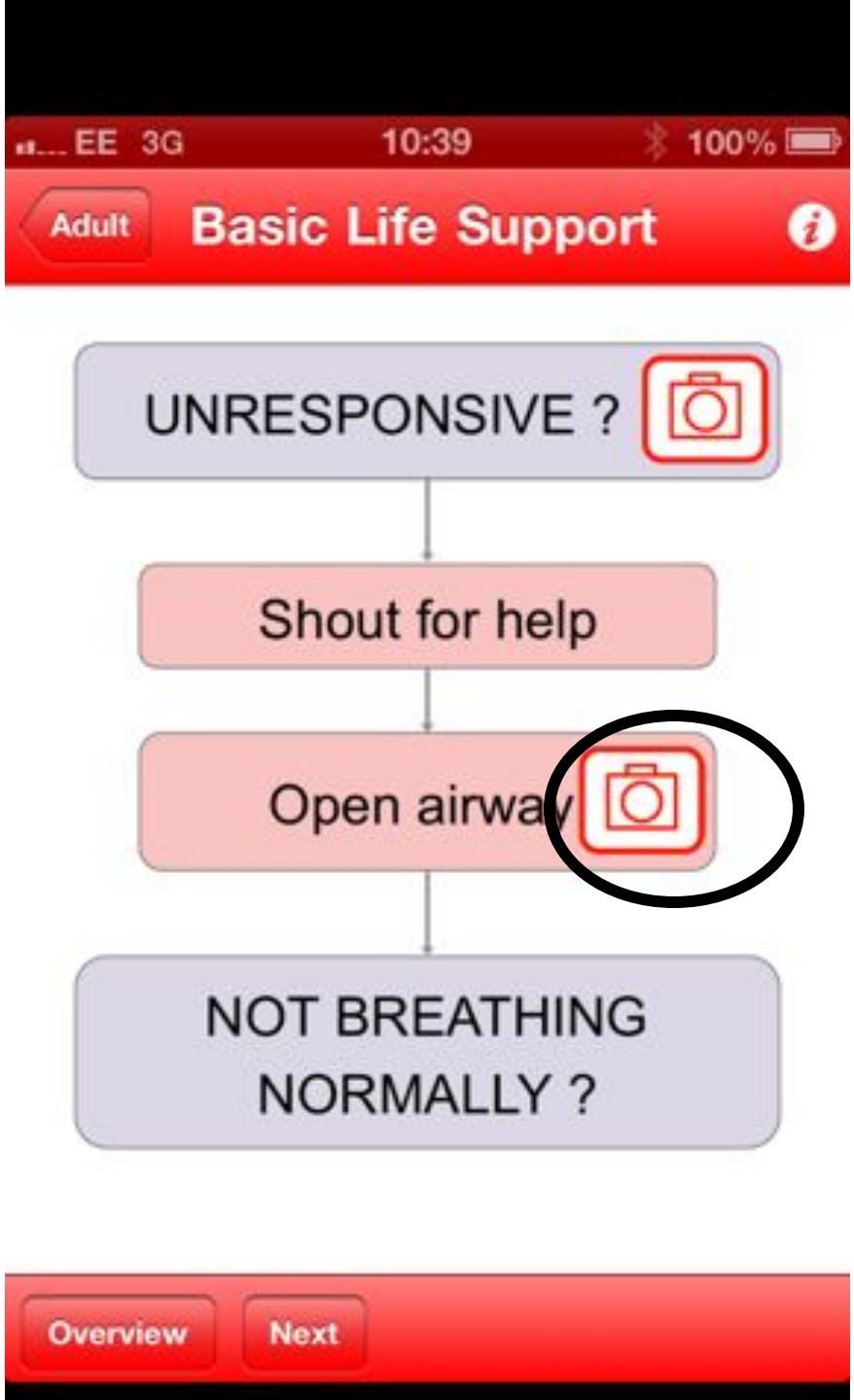
Manage Topics Of Interest
2010
Resuscitation
Guidelines
Resuscitation Council (UK)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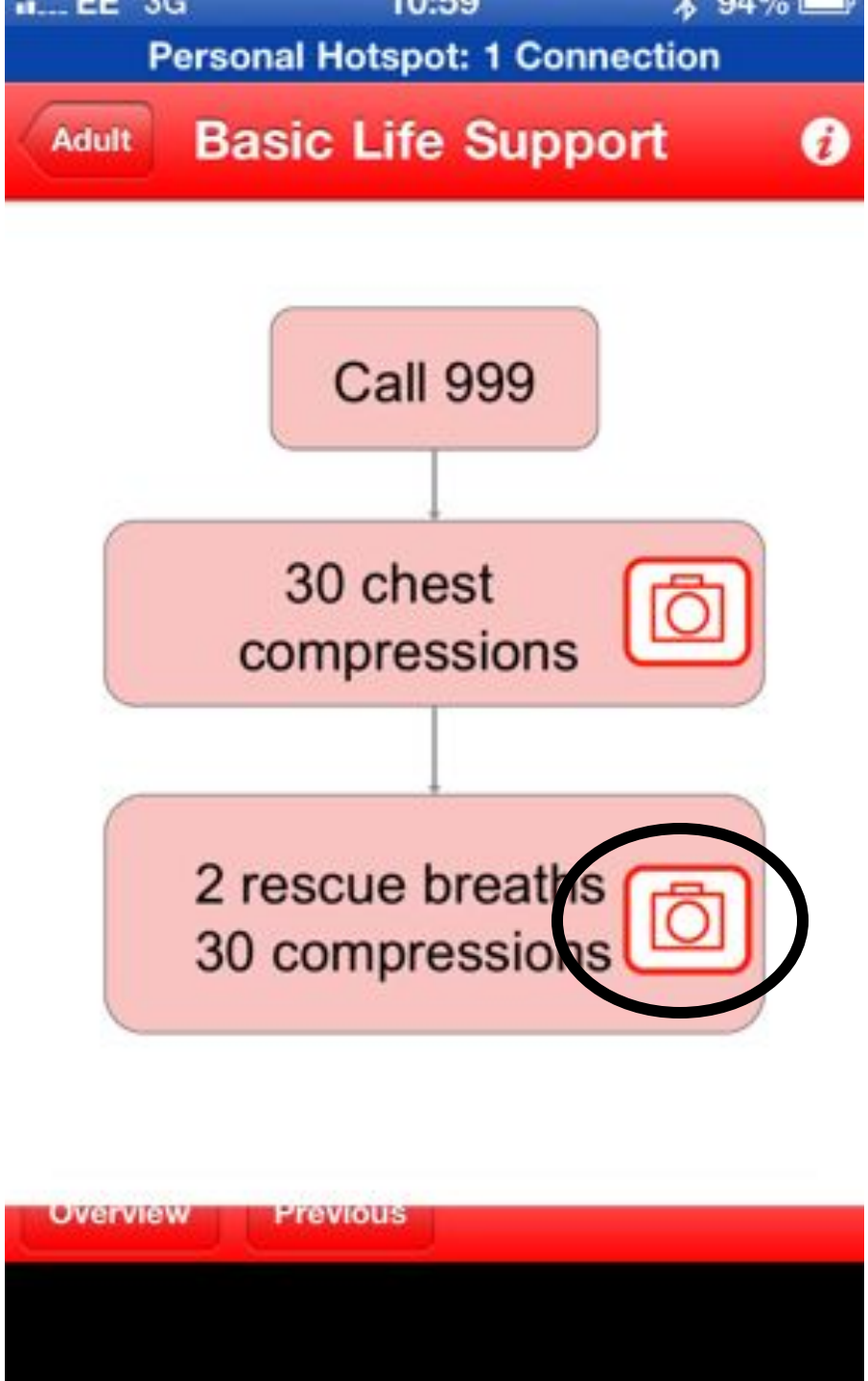
100%
Adult
Basic Life Support
UNRESPONSIVE ?
Shout for help
Open airway
NOT BREATHING NORMALLY ?
Overview
Next


EE 3G
10:39
100%
Adult
Basic Life Support
Open airway
UNRESPONSIVE ?
Open the airway and check for breathing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Adult
Basic Life Support
Call 999
30 chest compressions
2 rescue breaths
30 compressions
Overview
Previous


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94%
Personal Hotspot: 1 Connection
Adult
Basic Life Support
Rescue breaths
Blow steadily over 1 second to make chest rise
Call 999
Overview
Previous