

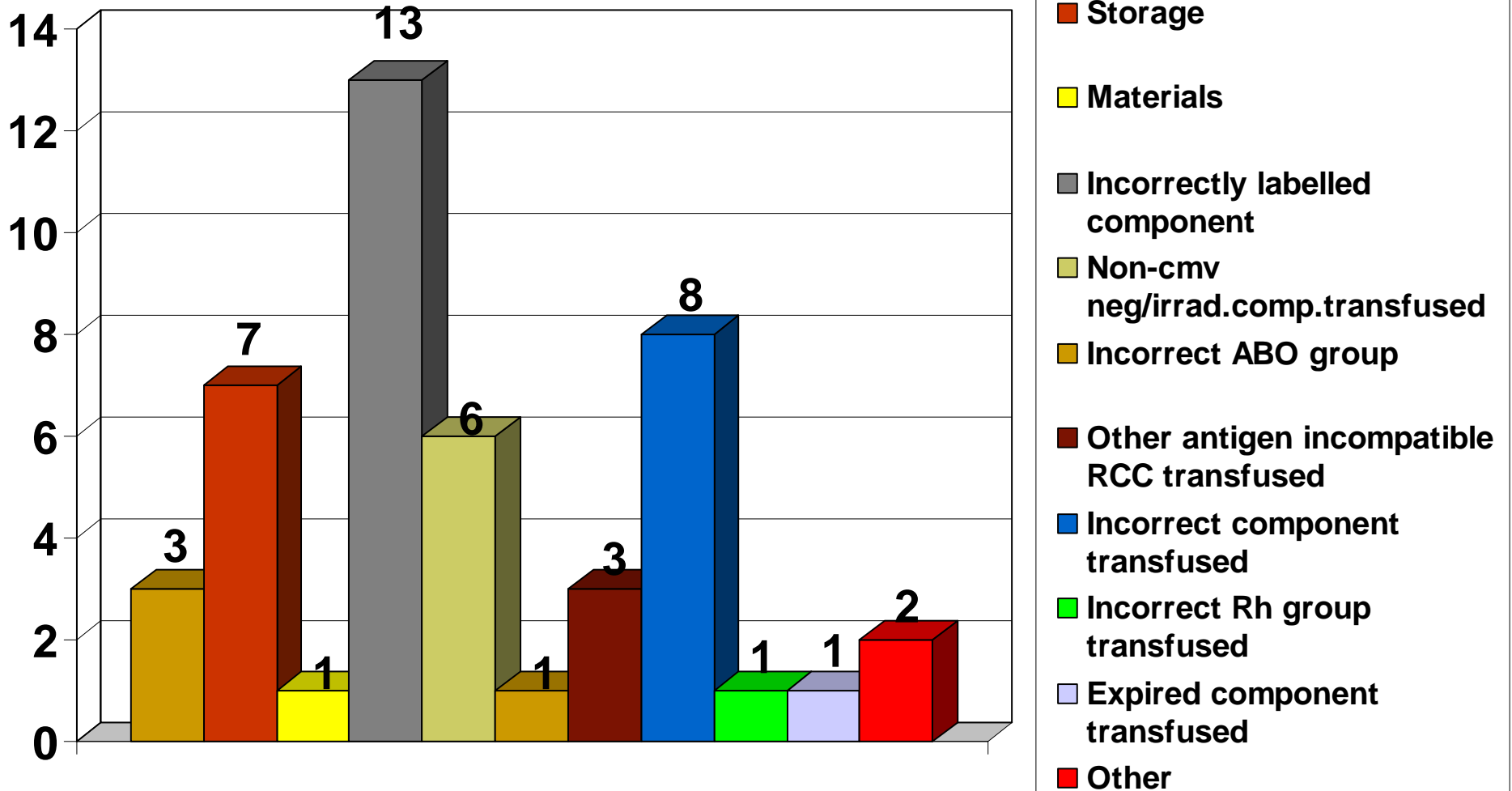


NHO Annual Conference 2010

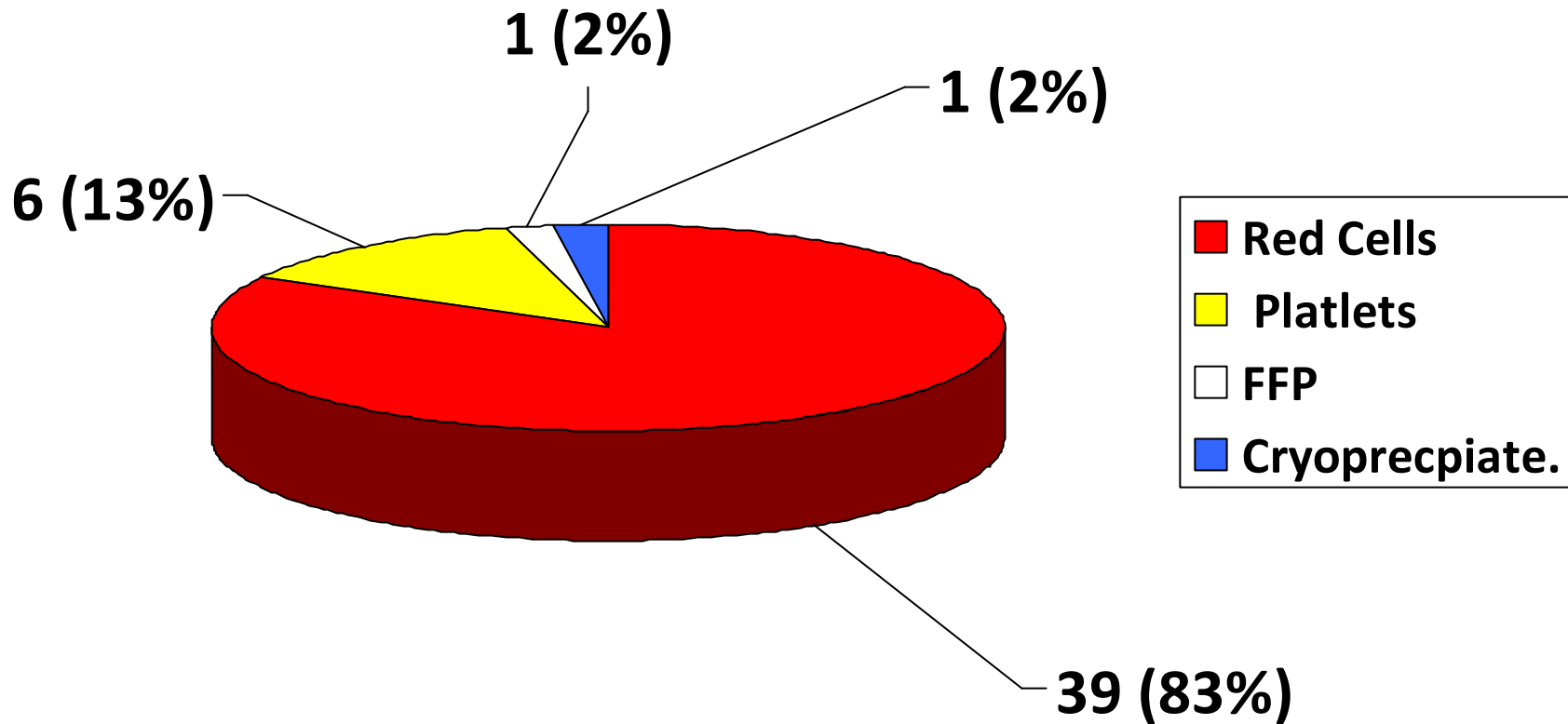
Mandatory Serious Adverse Events (SAE) 2009.

Jackie Sweeney

Mandatory SAE by category ($n=46$)



Mandatory SAE: Components Implicated (n=46*)

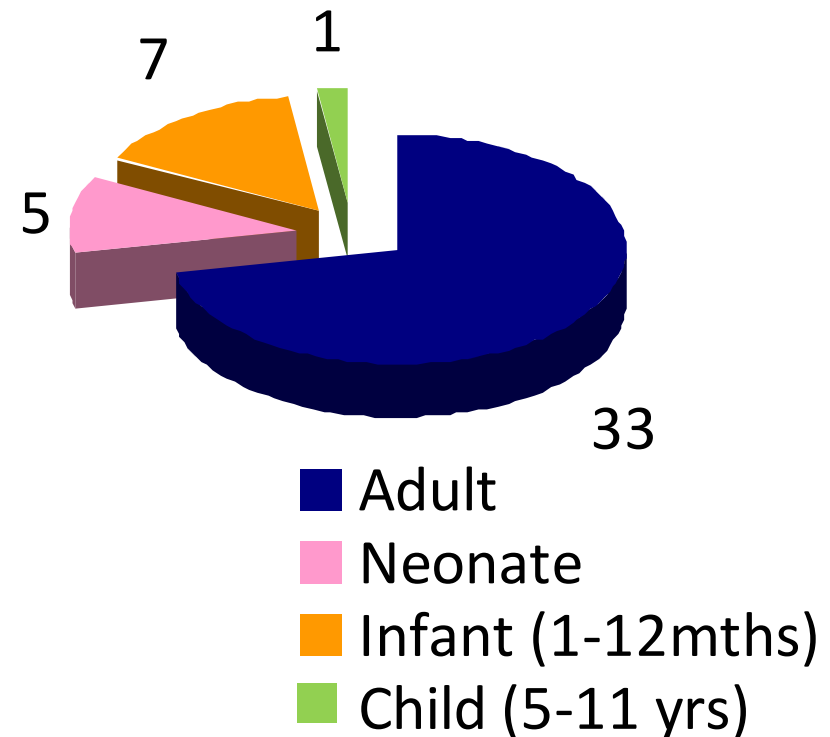


*one case involved multiple components



Mandatory SAE ($n=46$)

- 46 mandatory SAEs were reported in 2009 compared to 53 in 2008.
- Only 25 (20%) out of 122 SAE/IBCT involved paediatric cases, but 13 (52%), that is just over half of all paediatric cases were mandatory compared to 33 (34 %) of all adult cases.
- Focus of this presentation: Mandatory Paediatric SAE.
- Note: clinical staff also implicated in some mandatory SAEs.



Testing of Donations ($n=3$)



1. Patient with Anti-c & Anti-E antibodies, & HLA antibodies became pyrexial, & developed a tachycardia & dyspnoea during a transfusion of RCC. Check of on-call work showed unit tested positive on crossmatch, but crossmatch card read incorrectly as negative. No evidence of haemolysis or additional RCC antibodies.
2. Failure of crossmatch controls during crossmatch of pre-transfusion sample. Root cause analysis (RCA): Human error. Investigations found unit compatible.
3. Post-menopausal female typed as group O Rh D positive & O Rh D positive unit transfused. Sample referred to reference centre: patient grouped as Rh D negative.

Labelling Errors (n=13)



- Labelling errors largest category of SAE (29%).
- All attributable to human error.
- Eleven involved red cells & 2 involved platelets.
- Most frequent ($n=7$) error was transposition of labels within the same crossmatch.
- One case involved neonate: Change in baby's name & second pre-transfusion sample not requested or sent to HBB. Second aliquot of paedipack issued using the original name on the request form.

Incorrect ABO group Transfused (no reaction) ($n=1$)



Case History (Paediatric)

- One month old group B Rh D positive baby required transfusion of red cells.
- No maternal sample available as baby referred from another hospital.
- A crossmatch between red cells and neonatal serum was required to exclude passive A or B antibodies, or group O cells should have been issued.
- In this case Group B Rh D positive unit selected without crossmatch.
- RCA: on call medical scientist not normally working in transfusion practice issued unit.

Incorrect Component transfused (no reaction) ($n=8$)



- Comprised 17% of all mandatory SAEs.
- Two of the cases involved adult patients.
- The remaining six cases involved paediatric patients:
 - 2 cases patients were exposed to other donors even though aliquots still available from an existing paedipack. RCA attributed the 1st SAE to a busy workload, and the 2nd case to a lack of communication.
 - In another case, an on-call medical scientist ordered the incorrect component from the supply centre instead of a paedipack.

Incorrect Component transfused Paediatric Cases ($n=6$)



- Further case a neonate was exposed to an additional donor when an aliquot of a paedipack was issued & the remaining aliquots were not returned to controlled storage.
- An additional case involved a neonate where remaining aliquots of a paedipack recalled by the supply centre for suspected bacterial contamination due to a false positive bacterial alert on an associated platelet component. The baby was not commenced on any antibiotic treatment, but was exposed to another donor

Incorrect Component transfused

Paediatric Cases



- Final case (not a mandatory SAE) but, is included with paediatric cases resulting in increased donor exposure.
- A unit of red cells suitable for neonatal use was issued to a satellite fridge for an infant undergoing a surgical procedure.
- The baby had been transfused with one split of a paedipack, and required a top-up transfusion prior to the procedure.
- Instead of requesting further splits of paedipack from the HBB the infant was transfused with the RCC & a further RCC had to be issued to the satellite fridge.

Transfusion of Other Antigen Incompatible RCC (no reaction)($n=3$)



Case History (Paediatric)

- Rh D positive neonate whose mother was Rh D negative with Anti D, Anti E, and Anti Jk^a antibodies, developed haemolytic disease of the newborn with associated jaundice & an elevated bilirubin.
- Baby was transferred to another hospital & required a transfusion for Hb 7.9 g/dl.
- Group O Rh D negative paedipack ordered from supply centre but no patient details given, nor was supply centre informed of requirement for Jk^a negative component.
- Baby transfused with Jk^a positive unit.
- Day prior to transfusion HBB received an antibody report on the maternal blood sample from supply centre indicating previous antibody history.
- No connection made between the maternal sample & the unit for transfusion.
- Baby suffered no sequelae and made a full recovery.

Mandatory SAE: Key Points



- High incidence of 'high risk' cases involving neonates and infants highlight the need for particular vigilance in this area.
- Several mandatory SAE associated with on-call medical scientists with a busy workload.

Conclusion & Recommendations.

- UK Transfusion Collaborative (2009) recommends HBB have systems in place to ensure adequate skill mixes and staffing levels to ensure a safe & effective service to patients during routine & 'out of hours.'
- HBB must be vigilant where patients have special requirements & adhere to hospital policy to ensure the correct components are issued.
- Paediatric patients have specialised blood requirements, and errors may have serious sequelae.
- Presentation today by Dr. J.O'Riordan & Ms. B.Quirke: paediatric RCC available from IBTS.