

NHR adverse Events

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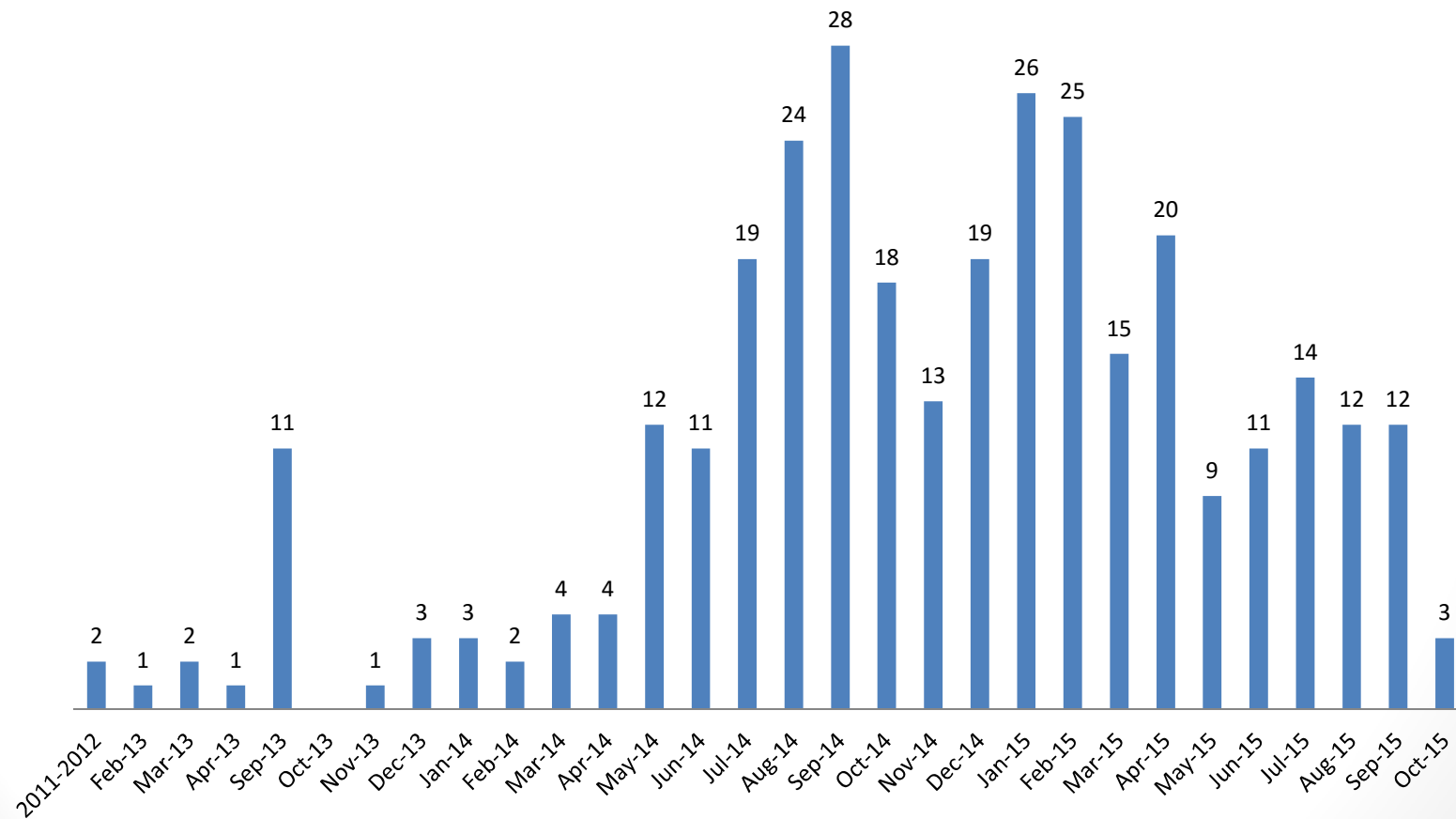
Birmingham Children's Hospital

Summary of Events

- There have been 305 adverse events entered onto the NHR
- Many have been backdated
- 8 events 2011-2013
- 158 events in 2014
- 139 events in 2015
- X number of centres have reported events
- X number of cases were discussed at local M&M meeting

Number of Events Reported

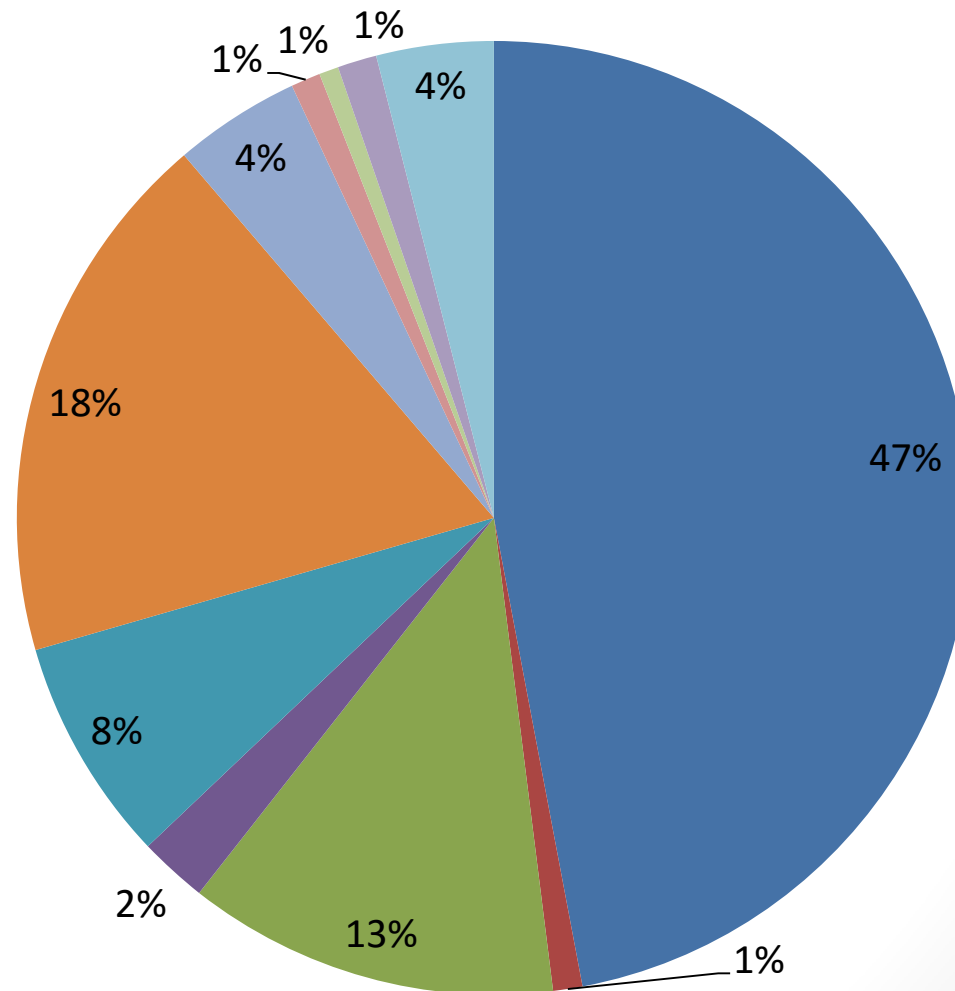
Adverse events by month



Total Events

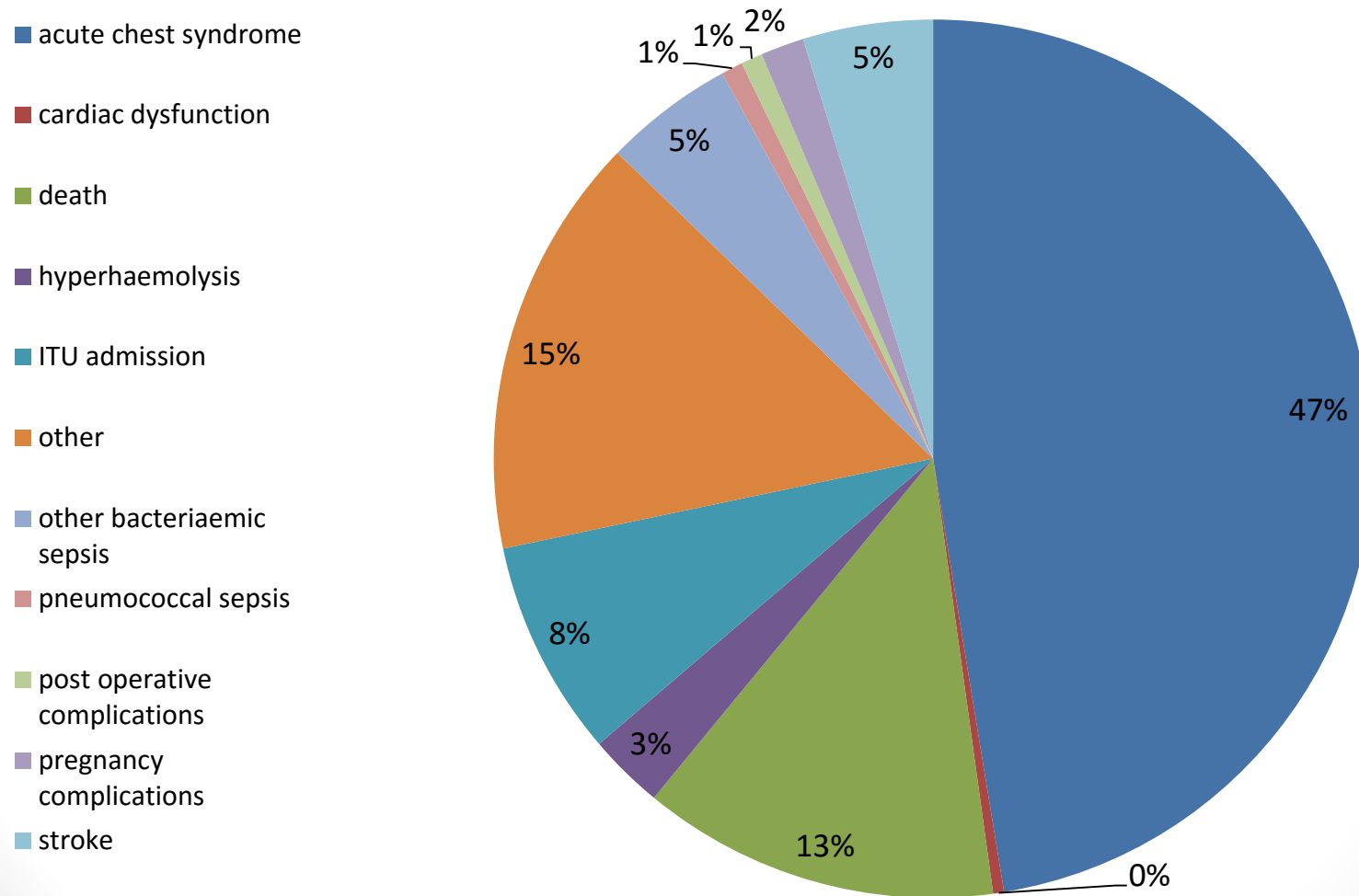
- acute chest syndrome
- cardiac dysfunction
- death
- hyperhaemolysis
- ITU admission
- other
- other bacteriaemic sepsis
- pneumococcal sepsis
- post operative complications
- pregnancy complications
- stroke

Adverse events



Adverse Events in Adults

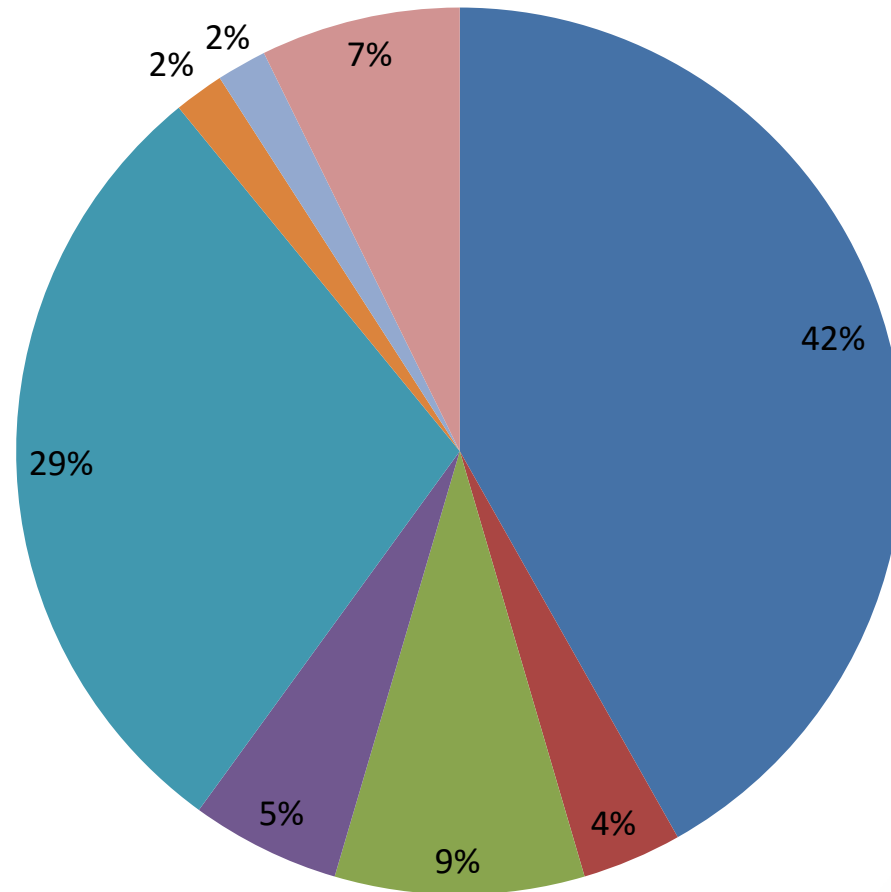
Adverse events in Adults



Adverse Events in Children

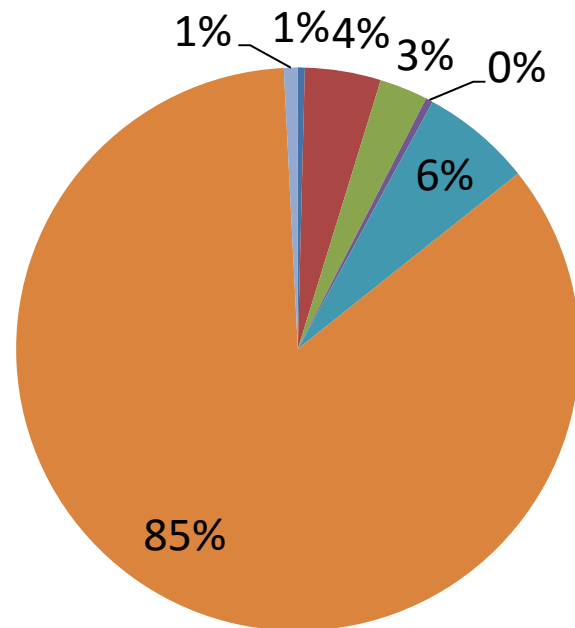
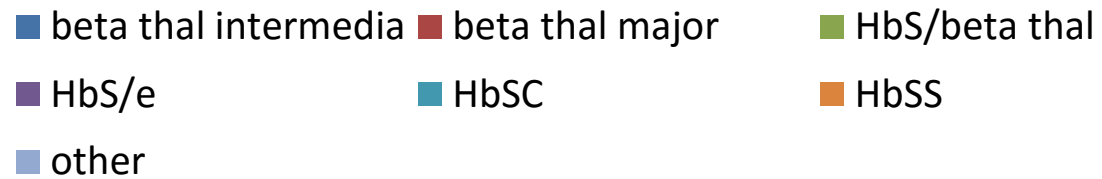
- acute chest syndrome
- cardiac dysfunction
- death
- ITU admission
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- other bacteriaemic sepsis
- pneumococcal sepsis
- stroke

Adverse events in Children



Patient Demographics

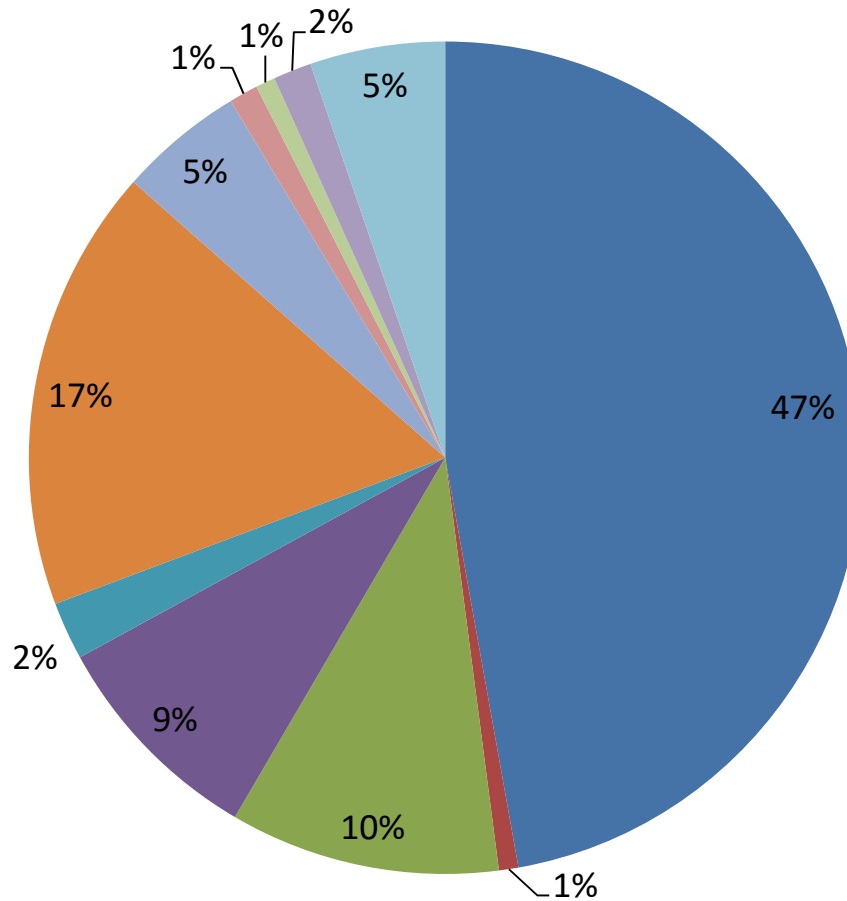
Adverse Events by Diagnosis



Adverse Events by diagnosis

Adverse Events in HbSS

- acute chest syndrome
- cardiac dysfunction
- death
- ITU
- hyperhaemolysis
- other
- bacteriaemic sepsis
- pneumococcal sepsis
- post operative complications
- pregnancy complications
- stroke



Adverse Events by diagnosis

- 18 adverse Events in HbSC

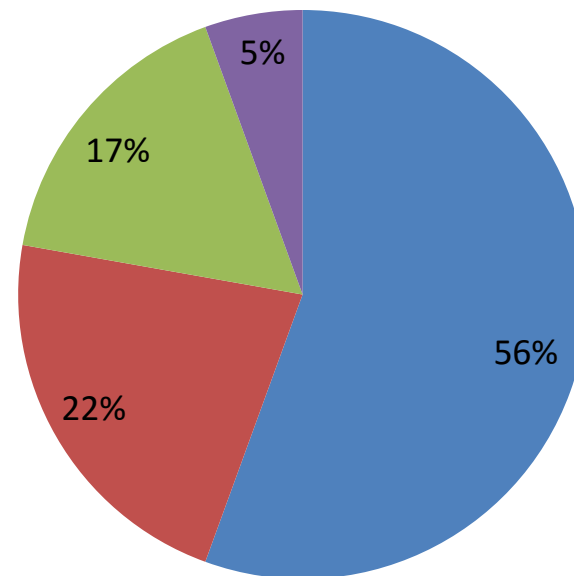
Adverse Events in HbSC

■ acute chest syndrome

■ death

■ other

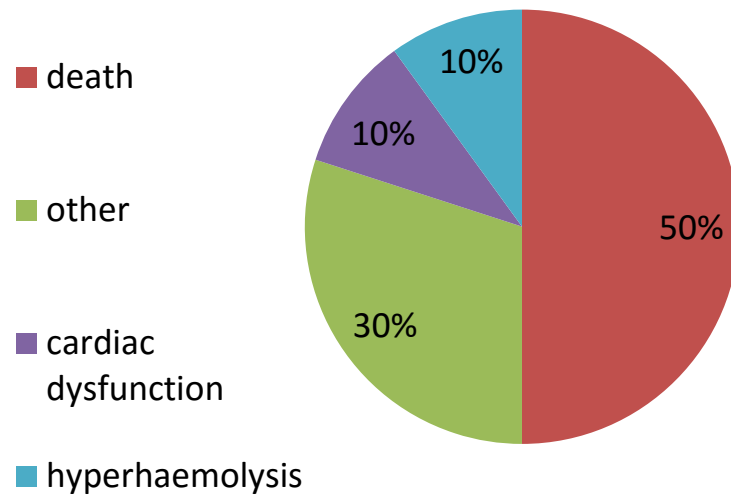
■ stroke



Adverse Events by diagnosis

9 adverse events reported in patients with beta thalassaemia major, and 1 patient with beta thalassaemia intermedia

Adverse Events in Beta thalassaemia

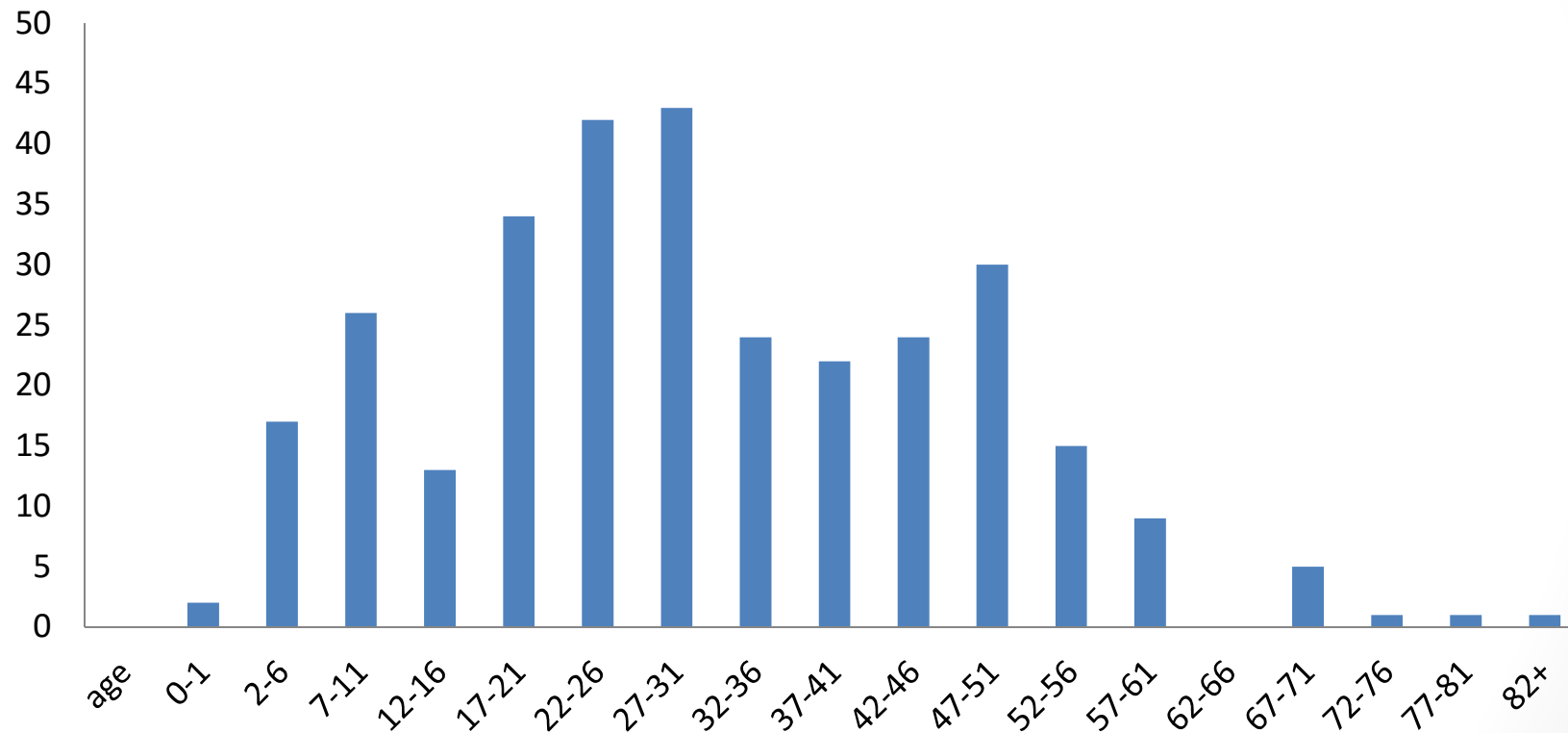


Adverse Events by diagnosis

- 7 patients with HbS/beta thalassaemia
- 5 patients had acute chest
- 1 had bacteraemic sepsis
- 1 death (P.E post removal of femoral line post RCX)

Patient Demographics

Age range of Patients



ITU admissions

- ITU admissions can be reported as an event which account for 8% of all adverse events
- An ITU admission can also be reported as a sub-group.
- Out of the 20 Adults categorised as “ITU admissions” 5 patients had acute chest and 3 had sepsis as a primary diagnosis, and 2 were pregnancy related
- Including the sub-group - 60 Adult patients have been reported as requiring ITU = 24% of the total adverse events recorded
- 17 out of 55 children required ITU = 31% of total adverse events recorded

Red Cell Exchanges

- 119 reported emergency red cell exchanges performed in adults = 47% of all adult adverse events reported
- 98 (82%) of these patients had reported chest involvement in the description
- Many reported rapid recovery post exchange
- No information about whether these are manual or automated

- 23 reported emergency red cell exchanges performed in children = 41% of paediatric adverse events reported
- 17 of these for chest syndrome
- 0 reported red cell exchanges for acute stroke, 1 reported for worsening moya moyo, 1 during resuscitation, and 4 for abdominal involvement, mainly including splenic and liver enlargement.

The 'others'

- 30 Adults & 16 children reported as having event 'Other'.
- In Adults cholestasis hepatic sequestration and priapism were the most common, others varied included pneumonia, post op complications to an acute psychotic episode.
- 5 of the children had joint effusions or infections, 3 severe pain requiring HDU, 1 endocarditis, 2 seizures, 1 pneumonia, 1 worsening moya moya despite regular exchanges. Other reports included splenic and hepatic sequestration, and abdominal crisis.

Hyperhaemolysis

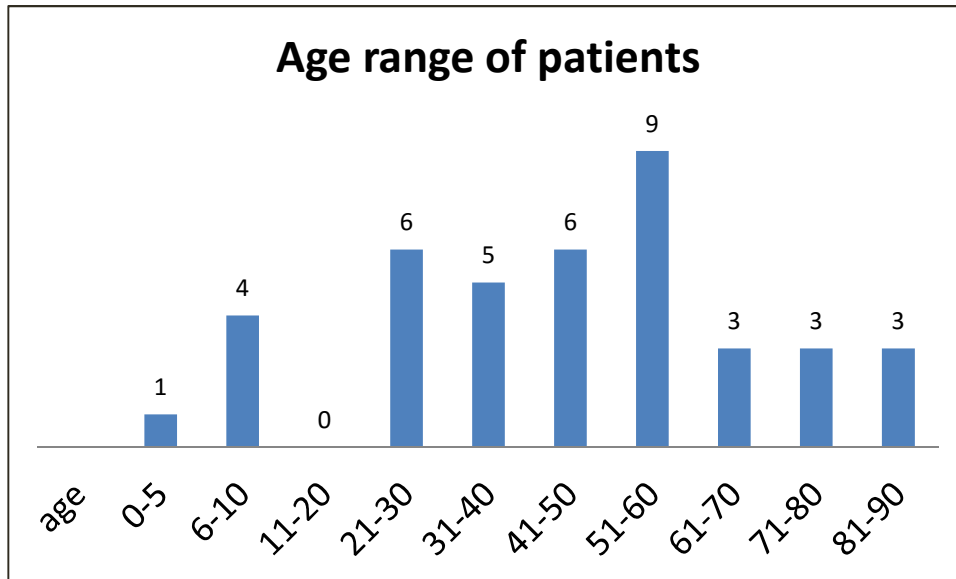
- There were 6 events recorded as hyperhaemolysis.
- Other episodes commented that hyperhaemolysis had occurred in the description.
- There were a further 6 episodes of hyperhaemolysis recorded (12 total).
- 5 were during chest crisis, and 4 patients required ITU during their hospital admission
- 1 patient was treated with IVIG alone, 3 patients reported to be treated with IVIG and EPO, 3 treated with IVIG and steroids, 1 patient treated with steroids and rituximab
- There was 1 death attributed to hyperhaemolysis
- All episodes should be reported to SHOT

Strokes

- 5 children were reported to have had strokes ages 5y, 8y, 8y, 10y, 11y.
- 2 of these patients were on active RCX or top ups, and one reported a pre stroke S% of <30%
- The other 3 had all had TCD scans
- 1 patient was reported to have had abnormal TCD's since age 2 (now 8) and was started on hydroxycarbamide. Unsure if abnormal meant conditional or high velocities. Severely affected by this event.
- 1 patient reported to have conditional velocities, but not high

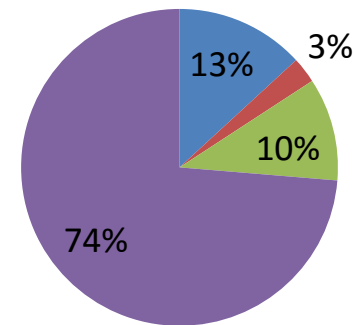
Deaths

- Total of 38 deaths recorded 33 adults and 5 children.



Deaths by diagnosis

■ beta thal major ■ HbS/beta thal ■ HbSC ■ HbSS



Deaths

- 4 patients died abroad/out of area
- 13 patients died of other co-morbidities, mainly including renal failure, liver failure/cirrhosis,
- 5 patients died of sepsis
- 3 died of anaemia (including splenic sequestration)
- 2 patients had malignant co-morbidities
- 1 patient died of cardiac failure, following poor chelation
- 1 elderly patient died of a P.E after prophylactic heparin omitted following femoral line removal
- 1 patient died of hyperhaemolysis, after being transfused at another centre, when history of previous hyperhaemolysis wasn't noted
- Others included drug toxicity (methadone), and a sub arachnoid haemorrhage

Common Themes/Learning Points

- Communication between different hospitals, and different specialities makes a real difference to patient outcomes.
- Lots of reports where patients had recovered quickly with good inter hospital, and inter disciplinary working
- Other reports about how outcomes could have improved with better communication between teams
- Many patients are very complex with multiple co-morbidities
- Many comments for the more elderly patients
- Reports about difficulty with managing patients with hepatic sequestration, despite maintaining low S%
- Lots of issues with adherence to medication for thalassemia patients

Recommendations

- There is under reporting of adverse events nationally
- There is limited information about patients with hyperhaemolysis, perhaps it may be useful for someone to collect some more data retrospectively ? BCH team happy to do – to lead to a standardised treatment protocol
- ? Remove ITU as primary event, as can lead to conflicting data
- Red cell exchange a mandatory category
- Looking at whether red cell exchanges are performed manually or automated - by tick box