Survey of Transfusion Practices in European Preterm Infants – supplementary materials.

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COMPARISON OF TRIAL THRESHOLDS AND ALLOCATION OF SURVEY CLINICAL SCENARIOS TO TOP AND ETTNO TREATMENT CATEGORIES AND OVERVIEW OF RESTRICTIVE AND LIBERAL TRANSFUSION THRESHOLDS IN THE LARGEST RBC TRIALS.

Table S1. Comparison of ETTNO and TOP trial thresholds and selection of restrictive and liberal ETTNO/TOP threshold for each of 15 clinical scenarios.

Clinical scenario	Critical or non- critical in	Critical or non-critical	Selected ETTNO/TOP		Selected ETTNO/TOP		Selected ETTNO/TOP	
	ETTNO trial[1]	in TOP trial[2]	threshold in for < 1 week	O .	threshold in for 1-2 week	0.	threshold in for >2 weeks	0.
Mechanically ventilated	Critical	Critical	Restrictive: Liberal:	11.0 13.7	Restrictive: Liberal:	10.0 12.5	Restrictive: Liberal:	8.5 12.3
CPAP with FiO2 >0.30	Critical or non- critical Trial cut off 12 hrs	Critical or non-critical Trial cut off 0.35	Restrictive: Liberal:	9.3 13.7	Restrictive: Liberal:	8.0 12.5	Restrictive: Liberal:	7.0 12.3
CPAP with FiO2 < 0.30	Critical or non- critical Trial cut off 0.25 for 12 hrs	Non-critical	Restrictive: Liberal:	9.3 13.7	Restrictive: Liberal:	8.0 12.3	Restrictive: Liberal:	7.0 12.3
Low flow (<2 L/min)	Non-critical	Critical or non-critical Trial cut off 1 L/min	Restrictive: Liberal:	9.3 13.0	Restrictive: Liberal:	8.0 12.5	Restrictive: Liberal:	7.0 11.0
No respiratory support	Non-critical	Non-critical	Restrictive: Liberal:	9.3 12.0	Restrictive: Liberal:	8.0 11.0	Restrictive: Liberal:	7.0 10.3

Critical = critical health state (ETTNO definition) or respiratory support (TOP definition). Non-critical = non-critical health state (ETTNO definition) or no respiratory support (TOP definition). Hb = hemoglobin. After categorization as critical or non-critical for in both trials, the highest threshold tested in either one of the trials was selected as liberal threshold and the lowest in either one as restrictive threshold.

Example of comparison in more detail

Infants on CPAP with FiO2 >0.30 would meet the 'critical' criteria for ETTNO only if the respiratory requirements persisted for at least 12 hours, but we did not specify a timeframe in our survey. For TOP, these infants would meet the criteria for 'critical' only if FIO2>0.35. This clinical scenario could therefore be classified as both 'critical' and 'non-critical' in both trials, leading to a relatively wide *ETTNO/TOP threshold* range of, for example for children more than two weeks old, 7.0 (restrictive) to 12.3 g/dL (liberal)

Table S2. Overview of restrictive and liberal transfusion thresholds in the four largest RBC RCTs. Restrictive study arms in RBC trials.

	TOP[2]	ETTNO [#]	[1]	PINT ^{##}	[3]		IOWA[4]	
	Respiratory support*	No support	Critical**	Non- critical	Respiratory support***	No support	Phase 1 ^{\$}	Phase 2 ^{\$\$}	Phase 3 ^{\$\$\$}
Randomization to 7 days after birth	11.0	10.0	11.3	9.3	11.5	10.0	11.3	9.3	7.3
Day of life 8-14	10.0	8.5	10.0	8.0	10.0	8.5	11.3	9.3	7.3
Day of life 15-21	8.5	7.0	10.0	8.0	8.5	7.5	11.3	9.3	7.3
Older than 21 days	8.5	7.0	9.0	7.0	8.5	7.5	11.3	9.3	7.3

Liberal study arms in RBC trials.

	ТОР		ETTNC)#	PINT	##		IOWA	
	Respiratory support*	No support	Critical**	Non- critical	Respiratory support***	No support	Phase 1 ^{\$}	Phase 2 ^{\$\$}	Phase 3 ^{\$\$\$}
Randomization to 7 days after birth	13.0	12.0	13.7	11.7	13.5	12.0	15.3	12.7	10.0
Day of life 8-14	12.5	11.0	12.3	10.3	12.0	10.0	15.3	12.7	10.0
Day of life 15-21	11.0	10.0	12.3	10.3	10.0	8.5	15.3	12.7	10.0
Older than 21 days	11.0	10.0	11.3	9.3	10.0	8.5	15.3	12.7	10.0

^{*}mechanical ventilation, continuous positive airway pressure, FiO2 >0.35, or nasal cannula ≥1 liter per min (room air nasal cannula ≥1 liter per min was considered respiratory support).

^{**} at least 1 of the following criteria: invasive mechanical ventilation, continuous positive airway pressure with fraction of inspired oxygen >0.25 for >12 hours per 24 hours, treatment for patent ductus arteriosus, acute sepsis or necrotizing enterocolitis with circulatory failure requiring inotropic/vasopressor support, >6 nurse-documented apneas requiring intervention per 24 hours, or >4 intermittent hypoxemic episodes with pulse oximetry oxygen saturation <60%.

^{***} assisted ventilation, continuous positive airway pressure, or supplemental oxygen.

^{*}a conversation factor of 3.0 was used to convert IOWA and ETTNO thresholds.

^{##} different thresholds were specified for capillary and central blood sampling strategies, capillary thresholds are reported here.

 $[\]ensuremath{^{\$}}$ tracheally intubated for assisted ventilation

^{\$\$} nasal continuous positive airway pressure or supplemental oxygen

sss neither positive pressure nor oxygen

The Cochrane systematic review by Whyte et al [5] summarized the restrictive thresholds evaluated in their review as reported below. These thresholds are identical to the PINT thresholds.

Postnatal Age	Respiratory Support	No Respiratory Support
	Haemoglobin g/l (Hae	matocrit %)
Week 1	115 (35%)	100 (30%)
Week 2	100 (30%)	85 (25%)
Week 3	85 (25%)	75 (23%)

References

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RESULTS OF WEIGHTED ANALYSIS

Tables S3 and S4 show the median and interquartile ranges for hemoglobin and platelet count threshold for transfusion in a weighted analysis, where each center was assigned a weight equal to the number of NICU's included in their country divided by the total number of eligible NICUs in their country. This is a way to correct for biased outcomes as a result of variable response rates. Table S5 shows the weighted analysis of transfusion duration, volume and rate. Table S6 shows the weighted FFP indications. As can be seen, few changes occur as a result of weighting (highlighted), suggesting limited impact of variable response rates on our findings.

Table S3. Weighted and unweighted median and interquartile ranges for hemoglobin transfusion thresholds

	Unweig	Unweighted median (IQR)		ed median (IQR)	
<1 week					
Air	95	(84-100)	90	(84-100)	
Low flow	100	(90-110)	100	(90-105)	
High flow <30%	102	(96-113)	102	(99-110)	
High flow >30%	105	(100-120)	105	(100-120)	
Intubated	115	(105-120)	115	(105-120)	
1-2 weeks					
Air	80	(72-89)	80	(72-85)	
Low flow	90	(80-100)	90	(80-95)	
High flow <30%	90	(90-100)	90	(90-100)	
High flow >30%	100	(90-105)	100	(90-105)	
Intubated	100	(90-110)	100	(90-110)	
<2 weeks					
Air	75	(69-80)	75	(69-80)	
Low flow	80	(75-90)	80	(75-85)	
High flow <30%	85	(77-90)	85	(77-90)	
High flow >30%	90	(81-100)	90	(81-100)	
Intubated	96	(85-105)	100	(85-105)	

Table S4. Weighted and unweighted median and interquartile ranges for platelet count transfusion thresholds

	Unweig	ghted median (IQR)	Weight	ed median (IQR)	
<28 weeks GA					
No bleeding	30	(20-45)	30	(20-40)	
Ibuprofen	50	(39-60)	50	(40-60)	
Lumbar puncture	50	(50-50)	50	(50-50)	
Surgery	99	(50-100)	100	(50-100)	
Active bleeding	50	(50-99)	50	(50-100)	
28-32 weeks GA					
No bleeding	25	(20-30)	25	(20-30)	
Ibuprofen	50	(30-50)	50	(35-60)	
Lumbar puncture	50	(50-50)	50	(50-50)	
Surgery	80	(50-100)	100	(50-100)	
Active bleeding	50	(50-80)	50	(50-80)	

Table S5. Weighted and unweighted median and interquartile ranges for transfusion volume, duration and rate.

	Unweig	hted median (IQR)	Weighte	ed median (IQR)	
RBC					
Volume	15.0	(15.0-20.0)	15.0	(15.0-20.0)	
Duration	4.0	(3.0-4.0)	4.0	(3.0-4.0)	
Rate	4.0	(3.8-5.0)	5.0	(3.8-5.0)	
Platelet transfusion					
Volume	15.0	(15.0-15.0)	15.0	(15.0-15.0)	
Duration	1.0	(0.5-2.0)	1.0	(0.5-2.0)	
Rate	15.0	(7.5-20.0)	15.0	(10.0-30.0)	
FFP					
Volume	15.0	(15.0-20.0)	15.0	(15.0-18.0)	
Duration	2.0	(1.0-3.0)	2.0	(1.0-2.0)	
Rate	10.0	(5.0-15.0)	10.0	(5.0-15.0)	

Table S6. Weighted and unweighted proportions for FFP indications

	Unweigh	ted proportion (95% CI)	Weighte	d proportion (95% CI)	
Coagulopathy with active	93.3	(90.3-95.6)	93.8	(91.7-95.5)	
bleeding					
Active bleeding without	46.1	(40.8-51.4)	45.0	(40.9-48.9)	
coagulopathy					
Coagulopathy without	38.8	(33.7-44.0)	39.8	(36.0-43.8)	
active bleeding					
Sepsis	26.5	(22.1-31.4)	25.8	(22.4-29.4)	
Hypotension	24.8	(20.4-29.5)	23.8	(20.5-27.3)	

RESULTS OF NON-RESPONDER ANALYSIS

The table below shows the comparison of responses by early responders (first 20%) and late responders (last 20%), where late responders are considered a proxy for non-responders, with differences highlighted.

Table S7. Results of non-responder analysis.

Table 57. Results of non-responder analysis.	Early resp	onders	Late responders		
	Median	Count	Median	Count	
Threshold_Hb_no_oxygen_first_day	100	Count	100	Count	
Threshold_Hb_no_oxygen_first_week	100		100		
Threshold_Hb_no_oxygen_2weeks	80		80		
Threshold_Hb_no_oxygen_3weeks	75		75		
Threshold_Hb_low_flow_first_day	111		110		
Threshold_Hb_low_flow_first_week	100		100		
Threshold Hb low flow 2weeks	90		90		
Threshold_Hb_low_flow_3weeks	80		80		
Threshold_Hb_high_flow_oxygen_until_30_first_day	115		115		
Threshold_Hb_high_flow_oxygen_until_30_first_week	105		105		
Threshold_Hb_high_flow_oxygen_until_30_2weeks	100		100		
			85		
Threshold_Hb_high_flow_oxygen_until_30_3weeks	85		120		
Threshold_Hb_high_flow_oxygen_over_30_first_day	120				
Threshold_Hb_high_flow_oxygen_over_30_first_week	115		110		
Threshold_Hb_high_flow_oxygen_over_30_2weeks	100		100 89		
Threshold_Hb_high_flow_oxygen_over_30_3weeks	90				
Threshold_Hb_intubated_ventilated_first_day	120 116		120 120		
Threshold_Hb_intubated_ventilated_first_week					
Threshold_Hb_intubated_ventilated_2weeks	100		100		
Threshold_Hb_intubated_ventilated_3weeks	94		95		
Threshold_Hct_no_oxygen_first_day	34		30		
Threshold_Hct_no_oxygen_first_week	28		30		
Threshold_Hct_no_oxygen_2weeks	24		25		
Threshold_Hct_no_oxygen_3weeks	21		23		
Threshold_Hct_low_flow_first_day	32		30		
Threshold_Hct_low_flow_first_week	28		30		
Threshold_Hct_low_flow_2weeks	25		28		
Threshold_Hct_low_flow_oxygen_3weeks	25		25		
Threshold_Hct_high_flow_oxygen_until_30_first_day	35		35		
Threshold_Hct_high_flow_oxygen_until_30_first_week	30		32		
Threshold_Hct_high_flow_oxygen_until_30_2weeks	30		30		
Threshold_Hct_high_flow_oxygen_until_30_3weeks	25		30		
Threshold_Hct_high_flow_oxygen_over_30_first_day	38		35		
Threshold_Hct_high_flow_oxygen_over_30_first_week	34		35		
Threshold_Hct_high_flow_oxygen_over_30_2weeks	30		30		
Threshold_Hct_high_flow_oxygen_over_30_3weeks	30		30		
Threshold_Hct_intubated_ventilated_first_day	38		36		
Threshold_Hct_intubated_ventilated_first_week	35		35		
Threshold_Hct_intubated_ventilated_2weeks	30		30		
Threshold_Hct_intubated_ventilated_3weeks	30		30		
Volume_RBC_per_kilo	15,0		15,0		
Duration_RBC_transfusion _ 1 hour		2		1	
2 hours		10		5	
3 hours		11		17	

	4 hours		29		31
	5 hours		2		3
	6 hours		10		9
	Other		1		1
Withhold_enteral_feeding	no		37		46
	yes		24		16
	other		6		5
Threshold_platelets_below_		30		30	
Threshold_platelets_below_		50		50	
Threshold_platelets_below_		50		50	
Threshold_platelets_below_		50		50	
Threshold_platelets_below_		90		100	
Threshold_platelets_28_to_3		30		25	
Threshold_platelets_28_to_3		50		50	
Threshold_platelets_28_to_3		50		50	
Threshold_platelets_28_to_3		50		50	
Threshold_platelets_28_to_3	32_weeks_major_surgery	80		100	
Volume_platelets_per_kilo		15		15	
Duration_platelet_transfusion			0		2
	30 minutes		21		14
	1 hour		22		26
	2 hours		13		17
	3 hours		5		4
	4 hours		3		3
	other		2		2
Indication_FFP_volume_repl			9		23
Indication_FFP_active_bleed			26		32
Indication_FFP_coagulopath			20		28
Indication_FFP_coagulopath	y_active_bleeding		67		62
Indication_FFP_sepsis			17		21
Volume_FFP_per_kilo		15		15	
Duration_FFP_transfusion	15 minutes		0		0
	30 minutes		8		10
	1 hour		25		19
	2 hours		19		19
	3 hours		7		5
	4 hours		7		13
	other		1		2
Routine_diuretics_RBC	never		35		38
	always		1		4
	sometimes		30		24
Routine_diuretics_platelets	never		58		51
	always		1		2
	sometimes		7		12
Routine_diuretics_FFP	never		54		45
	always		1		3
	sometimes		9		18
Consent_non_emergency	No consent		4		4
transfusion	Verbal consent only		2		10
	Verbal consent documenten by clini		10		2
	Verbal and written consent from pa	rents	46		50
	Other		4		1

QUESTIONNAIRE

This document contains all the survey questions that were analyzed in this manuscript. Two questions were not analyzed, see specifications below.

How many babies are born at <32 weeks gestation at your unit each year? Due to a Limesurvey error, data entry for this question was inaccurate and could therefore not be analyzed.

Which form of platelets does your unit use for neonatal transfusions? One of the answer options was 'Platelet hyperconcentrate', which is a product that is used very sparsely, but would be given at a dose of only 3-5 ml/kg, depending on exact product specifications. On further analyses we observed that many entries that selected 'platelet hyperconcentrate' subsequently reported giving this at a dose of 15 ml/kg. It is likely that these centers use regular platelet transfusion products, not hyperconcentrate, but we were not able to obtain this information. Therefore we have not analyzed these data.

Do you use any of the following on your neonatal unit? (if yes, please indicate when you would use them): Antithrombin III, Tranexamic acid, Another agent which promotes clotting/coagulation, Another agent which prevents clotting/coagulation. The specifications that were given for 'another agent' often contained indications that were unlikely to be correct. For example, .. Therefore, these data were considered unreliable and not analyzed or presented.

We did not report RBC thresholds for babies <24 hours of age, because...

The survey also contained questions about treatment with recombinant human erythropoietin and supplementation of iron, which will be analyzed separately and have not been presented here.

Neonatal blood components survey

Hello,

You have been contacted as a representative clinician for your neonatal unit. As part of an international survey on blood products, we are contacting representatives from neontal units who regularly care for infants born at <32 weeks' gestation.

We would be very grateful if you could spare a few minutes to help us to better understand the variations in neonatal blood product transfusion practices, which exist across Europe, by answering the following questions on behalf of your neonatal unit.

If practice varies between attending clinicians at your unit, please indicate the response you feel best represents the general consensus amongst senior clinicians in your hospital: we only want one response for each neonatal unit. Please also note that there are no right or wrong answers!

We are looking to develop a network of interested neonatologists, health care professionals, and transfusion specialists aimed at advancing the practice of neonatal transfusion medicine and designing new clinical studies. Please let us know at the end of the survey if you are interested in taking part.

Participation in this survey is voluntary.

No individual, hospital or neonatal unit will be identifiable from any reports or publications from this survey. Location information is collected to allow us to track who has responded and ensure that we have a good representative sample from each country.

If you have any questions or concerns about this survey, please contact the representative for your country (the person who sent you the survey invitation) or alexandra.scrivens@ouh.nhs.uk

There are 30 questions in this survey.

General Questions

Does your neonatal unit/hospital routinely look after babies born at less than 32 weeks of completed gestation?

Please choose only one of the following:

- Yes
- No

How many babies are born at <32 weeks gestation at your unit each year?

Choose one of the following answers Please choose **only one** of the following:

- <50
- 50-100
- 100-200
- >200

Please indicate on the map the location of your hospital.

Your responses and your hospital will not be identifiable from any report or publication from this survey. Tracking location in this way allows us to track which hospitals have responded to our survey. This information will be used for this purpose only.

Please write your answer here:

Red Blood Cells

Please answer the following questions relating to how your unit routinely cares for infants born under 32 weeks of gestational age.

The next questions will ask about the threshhold(s) which you use for red cell/blood transfusion in preterm babies. Please select which units your hospital uses to decide whether a blood transfusion is necessary.

Choose one of the following answers. Please choose **only one** of the following: Haemoglobin level in g/L or g/dL / Haematocrit

What haemoglobin level would use you as a threshold to transfuse the following babies born at <32 weeks' GA?

Please give answers in g/L where 1.0 g/dL = 10 g/L

Only answer this question if the following conditions are met:

Answer was 'Haemoglobin level in g/L or g/dL' at question '5 [RBC3]' (The next questions will ask about the threshhold(s) which you use for red cell/blood transfusion in preterm babies. Please select which units your hospital uses to decide whether a blood transfusion is necessary)

	less than 24 hours of age	24 hours to 7 days of age	2 weeks of age	3 weeks of age
Infant on no added oxygen or respiratory support (g/L)				
Infant on <2L/min added oxygen by low flow nasal cannula (g/L)				
Infant on 21-30% oxygen by non-invasive respiratory support (Including continuous positive airway pressure (CPAP), Biphasic intermittent positive airway pressure (BiPAP; synchronised or unsynchronised), nasal high flow) (g/L)				
Infant on >30% oxygen by non-invasive respiratory support (g/L)				
Infant who is intubated and ventilated (g/L)				

What haematocrit would use you as a threshold to transfuse the following babies born at <32 weeks' GA?

Please give answers as haematocrit percentage. e.g. haematocrit 0.1 = 10% = answer 10

Only answer this question if the following conditions are met: Answer was 'Haematocrit' at question '5 [RBC3]' (The next questions will ask about the threshhold(s) which you use for red cell/blood transfusion in preterm babies. Please select which units your hospital uses to decide whether a blood transfusion is necessary)

	less than 24 hours of age	24 hours to 7 days of age	2 weeks of age	3 weeks of age
Infant on no added oxygen or respiratory				

	less than 24 hours of age	24 hours to 7 days of age	2 weeks of age	3 weeks of age
support				
Infant on <2L/min added oxygen by low flow nasal cannula				
Infant on 21-30% oxygen by non-invasive respiratory support (Including continuous positive airway pressure (CPAP), Biphasic intermittent positive airway pressure (BiPAP; synchronised or unsynchronised), nasal high flow)				
Infant on >30% oxygen by non-invasive respiratory support				
Infant who is intubated and ventilated				

What volume of red cells would you typically transfuse to a haemodynamically stable baby on your neonatal unit?

Please give your answer in $\mbox{ml/kg}$. Only numbers may be entered in this field.

Please write your answer here: ...

Over what duration would you normally give an RBC transfusion in a haemodynamically stable baby born at <32 weeks?

Choose one of the following answers. Please choose **only one** of the following: 6 hours / 5 hours / 4 hours / 3 hours / 2 hours / 1 hour / 30 minutes / 15 minutes / Other

Do you withhold enteral feeds during red blood cell transfusions for babies born <32 weeks gestational age? (if you choose 'sometimes', please specify when you would withhold feeds)

Choose one of the following answers. Please choose **only one** of the following: Yes / No / Sometimes

Platelets

please answer the following questions

At which platelet count threshold would you usually transfuse the following babies in the first week since birth? (answers given as x10^9/L or micromol/L)

	Stable, no bleeding	Active bleeding e.g. new intraventricular haemorrhage	Undergoing ibuprofen treatment for PDA	Before a lumbar puncture	Before major surgery (e.g. laparotomy)
An infant born at <28 weeks' gestation					
An infant born at 28-32 weeks' gestation					

Which form of platelets does your unit use for neonatal transfusions?

Choose one of the following answers. Please choose **only one** of the following:

- Standard/Normal concentration platelets
- Platelet hyperconcentrate
- I do not know
- Other

What volume of platelets would you typically transfuse to a haemodynamically stable baby on your NNU?

Please give your answer in ml/kg. e.g. '15' = 15ml/kg. Only numbers may be entered in this field. Please write your answer here: ...

Over what duration would you normally transfuse platelets in a haemodynamically stable baby on your NNU?

Choose one of the following answers. Please choose **only one** of the following:

4 hours / 3 hours / 2 hours / 1 hour / 30 mins / 15 mins / Other

Plasma/Fresh Frozen Plasma

For which main indication(s) would you prescribe fresh frozen plasma (FFP) to babies in your hospital?

Check all that apply. Please choose all that apply:

- · Volume replacement/hypotension
- · Active bleeding without coagulopathy
- · Coagulopathy with no active bleeding
- · Coagulopathy with active bleeding
- Sepsis
- · Other:

Do you routinely perform coagulation/clotting tests in babies born <32weeks who are not bleeding?

Choose one of the following answers. Please choose only one of the following:

Yes / No

What volume of plasma/FFP would you usually administer to a haemodynamically stable baby born at <32 weeks on your NNU?

Please give your answer in ml/kg. e.g. '15' = 15ml/kg. Only numbers may be entered in this field. Please write your answer here: ...

Over what duration would you usually give a plasma/FFP transfusion in a haemodynamically stable baby on your NNU?

Choose one of the following answers. Please choose **only one** of the following:

4 hours / 3 hours / 2 hours / 1 hour / 30 mins / 15 mins / Other

Do you use any of the following on your neonatal unit? (if yes, please indicate when you would use them)

Comment only when you choose an answer. Please choose all that apply and provide a comment:

- Antithrombin III
- Tranexamic acid
- Another agent which promotes clotting/coagulation
- Another agent which prevents clotting/coagulation
- No

Transfusion management

Do you routinely prescribe diuretics alongside blood component transfusions?

Please choose the appropriate response for each item:

	No, never	Yes, always	Yes, sometimes
Red blood cells			
Platelets			
Plasma/FFP			

In common practice on your unit, what consent do you obtain from parents for a nonemergency blood component transfusion?

Choose one of the following answers. Please choose only one of the following:

- No consent
- · Verbal consent only
- Verbal consent documented in the notes by clinician
- Verbal and written consent from parents (parents have to sign a form)
- Other

Would you be interested in participating in a national / international network to address further research questions in neonatal transfusion practice?

Over the coming year, you may be invited to taking part in a short point prevalence study on neonatal blood transfusions. This would involve collecting data on all neonatal transfusions on your unit for a short period of time.

Choose one of the following answers. Please choose **only one** of the following:

No thank you / Yes

Thank you very much for your time in answering our survey.

Submit your survey.

Thank you for completing this survey.

LIST OF PARTICIPATING NEONATAL (RESEARCH) NETWORKS

To be added after review by national coordinators.