Non-vCJD exposed blood donors and recipients: a self-sufficient supply chain?

1. Executive Summary

Individuals who were born on or after 1st January 1996 are considered to have received minimal primary exposure to vCJD. These individuals started to be eligible to give blood at the beginning of 2013. UK blood services are therefore considering the possibility of using these 'low vCJD risk' donors to supply blood components to transfusion recipients who were also never exposed to the primary epidemic. In this report, we consider when this would be feasible for different blood components and different sub-patient groups (we do not consider potential costs and benefits in making such a change or potential problems with matching of rare groups).

We used NHSBT data regarding whole blood donations from donors of different ages to determine the percentage of different blood components that we expect to be issued from non -exposed donors in future years. In 2013 we estimate that 0.2%, 0.3%, and 0.1% of all red cell, platelet, and FFP / cryoprecipitate units could be supplied by low vCJD risk repeat donors. By 2017, this rises to 4.5%, 6%, and 7.5% respectively. We assume that all platelets would be supplied by whole blood donations and not apheresis, since apheresis donors would not be able to donate whole blood, which could be used for all blood components.

We used data from HES database and the John Radcliffe hospital trust to estimate the proportion of blood components required by patients of different ages. This was used to estimate the percentage of different blood components that we expect to be required for low vCJD risk recipients in future years. In 2013, we estimate that 5%, 9%, and 5% of all red cell, platelet, and FFP / cryoprecipitate units would be required for low vCJD risk recipients. By 2017, this rises to 7%, 12%, and 7% respectively.

We also considered different groups of recipients as defined by red cell specification or age group to see if these could be supplied sooner. These groups were: fetuses (intrauterine transfusions; IUTs); neonatal exchange recipients; neonatal red cell recipients; neonatal and infant 'large volume transfusion' (LVT) recipients; and 'paediatrics' (recipients $\geq$ 1 yr old, and under 16 year of age; see the Definitions Document for a fuller set of definitions for patient groups and components covered by this document). From current issues data, we estimate that 0.02%, 0.04%, 0.48% and 0.53% of total red cell issues would be required for first four of these patient groups, respectively. Note that as neonatal red cells and LVTs both have a neonatal/infant specification and may be used for all ages of infant, provision of these red cells should cover all recipients < 1 year old. However, the use of LVTs for infants is currently variable between paediatric hospitals with some infants receiving 'adult' specification red cells and a smaller number using LVTs for children older than 12 months, so current LVT issue data may underestimate the requirement for infant red cells. For the current modelling, we assume demand for LVTs will continue at its current level, as we have no reliable indication of the likely impact of any changes to current practice on this demand.

Using information from John Radcliffe, we estimate that 3.2% of total issues will be required for paediatric patients.

We estimate that 1.2% and 7.8% of total platelet issues would be required for recipients of neonatal and paediatric platelets respectively[1]. For FFP and cryoprecipitate, 4.4% of total issues would be required for neonatal and paediatric FFP recipients combined[2].

The dates when the needs of specific groups will be met will depend on what priority is attached to them. At the meeting of 3 September 2012, Club 96 working subgroup considered which group should be given highest priority. The following table shows the outcome of the discussion.

Prioritisation List I	**Prioritisation List II**
1. IUT and neonatal exchange recipients 2. Neonatal red cell recipients 3. LVT recipients 4. Low vCJD risk haemoglobinopathy patients 5. Paediatric (low vCJD risk haemoglobinopathy patients and neonates/infants excluded) 6. Other multiple transfused 7. Other haemoglobinopathy patients (i.e., low vCJD risk excluded)	1. low vCJD risk haemoglobinopathy patients 2. IUT and neonatal exchange recipients 3. Neonatal red cell recipients 4. LVT recipients 5. Paediatric (low vCJD risk haemoglobinopathy patients and neonates/infants excluded) 6. Other multiple transfused 7. Other haemoglobinopathy patients (i.e., low vCJD risk excluded)

Transfusions to haemoglobinopathy patients require a greater degree of matching than other patients, and so more detailed information is required to assess when their needs could be met. Information on existing patients is currently being collected. We aim to consider this group in more detail once the data are collected. For the purpose of the following analysis, the demand from low vCJD risk haemoglobinopathy patients is included, but treated in the same way as demand from other patients receiving the same type of unit.

This paper only considers the ability of low vCJD risk donors to meet the demand for blood components from low vCJD risk patients. In the light of limited information on haemoglobinopathy patients, it uses the following priority list:

[1] The proportion of demand for neonatal platelets is derived from issues data, whereas the proportion of paediatric platelets is estimated using information on the age of recipients.
[2] The proportion of demand for both neonatal and paediatric FFP is derived from issues data

Prioritisation List
1. fetuses and neonatal exchange recipients 2. Neonatal red cell recipients 3. LVT recipients 5. Paediatric patients 6. Other low vCJD risk patients

To illustrate possible options, we compare our estimate of blood components donated by and required for low vCJD risk individuals to estimate when low vCJD risk donors would be able to supply enough blood to recipients for different blood components by the following years (**see Figures 4.1a to c**). The years indicated in the table below show dates when supply would meet demand for a combination of different patient groups.

The first column indicates the year when demand would be met, if we only use repeat donations where appropriate, and the second column indicates the corresponding year if we allow first donations to be used.

Red cells

	Repeat donations only	Repeat and first donations
IUT recipients	2014	2013
IUT+ neonatal exchange red cell recipients	2015	2014
IUT+ neonatal exchange red cell and Neonatal red cell recipients	2022	2019
IUT+ neonatal exchange red cell and Neonatal red cell and LVT recipients	2025	2022
IUT+ neonatal exchange red cell and Neonatal red cell and LVT and Paediatric recipients[3]	2025	
All low vCJD risk red cell recipients	2025	

[3] This is inclusive of units used for low vCJD risk haemoglobinopathy patients but not additional matching requirements

Platelets[4]

	Repeat donations only	Repeat and first donations
Neonatal platelet recipients	2036	2026
Neonatal platelet and Paediatric platelets		2028
All low vCJD risk platelet recipients		

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Our analysis suggested that the provision of platelets for paediatric recipients from repeat male donations, and for low vCJD risk recipients from all male donations, from low vCJD risk donors would not be possible within the timescale investigated.

FFP and cryoprecipitate

	Repeat donations only	Repeat and first donations
Neonatal and paediatric FFP and cryoprecipitate recipients	2021	2017
All low vCJD risk FFP and cryoprecipitate recipients	Around 2030	2020

The table below summarises the dates when supply would meet demand for each patient group for all blood components. These correspond to the years in which the demand for all blood components will be met. The table shows the results of **cumulative strategies**:

	Repeat donations only	Repeat and first donations
IUT (red cells only)	2014	2013
IUT+ neonatal exchange recipients (red cells only)	2015	2014
IUT+ neonatal exchange and Neonatal (incl. red cells, platelets, FFP and cryoprecipitate, but not LVT) recipients	2036	2026
IUT+ neonatal exchange and Neonatal and LVT recipients	2036	2026
IUT+ neonatal exchange and Neonatal and LVT and Paediatric (incl. red cells, platelets, FFP and cryoprecipitate) recipients		2028
All components used for low vCJD risk recipients		

We have not provided dates for the blank boxes due to not having identified a date when platelet demand would be met from male donations.

[4] These figures present the “best case scenario” for matching of low vCJD risk donations for platelet production

These data are based on NHSBT data, and therefore relate to England and North Wales. Corresponding data for other parts of the UK may differ, depending on their donor and usage profiles. The paper does not consider any safety aspects of using low vCJD risk donors. In particular, SaBTO would need to consider the implications regarding any changes to importation of FFP.

The results in this analysis can be considered a base-line scenario in which no extra effort is employed to recruit young donors.

Also, the paper does not consider the risk of using pooled platelets for paediatrics (compared with the current practice of using apheresis where possible). It also does not consider the risk of infection from donations from younger donors compared to the general donor population, which is being considered elsewhere.

2. Background

Individuals who were born on or after 1st January 1996 are considered to have received minimal exposure to the dietary causes of vCJD (hereafter, referred to as 'low vCJD risk') and at the beginning of 2013, they started to become eligible to donate blood. The use of blood donations from this group may therefore represent an alternative measure to reduce the risk of vCJD transmission by blood transfusion. If low vCJD risk donors could supply blood components to their peer group, this would effectively create a firewall against secondary exposure for any individual born after 1995.

UK blood services would like to know when it would be feasible to implement such measures. In this analysis, we therefore consider the following questions:

- How many blood components do we expect to be donated by individuals born on or after 1st January 1996 in each year over the next 10 years?
- How many blood components do we expect to be transfused to individuals born on or after 1st January 1996 in each year over the next 10 years?
- In what year could all patients born on or after 1st January 1996 be supplied with blood components from their peers?

We perform this analysis for the following blood components: red cells, platelets, Fresh Frozen Plasma (FFP), and cryoprecipitate.

3. Methodology

We estimated the number of units of blood components donated by and transfused to those born after the 1st January 1996 in each year in England and North Wales over the next 10 years. To compare donated and transfused units, any wastage that occurs between the two needs to be taken into account. Our comparison is therefore done at the point of issue from NHSBT to hospitals: any wastage within NHSBT is applied to donations to convert to issues. A comparison of these issues as a proportion of the total issues was then used to estimate when this cohort's blood supply chain could become self-sufficient.

3.1 Blood Donations

3.1.1 Whole blood donations

To estimate the percentage of blood donations that will be issued from those young enough to be considered low risk to vCJD (low vCJD risk donors) in different years, we obtained data from NHSBT regarding the number of whole blood donations from new and repeat male and female donors in different age groups and the total number of donations in 2011. Instead of actual age at the time of donation, we used the donor's age on 1st January 2011. For future years, we can determine the corresponding age of low vCJD risk donors. Someone born on 1st January 1996 (the assumed cut off for exposure to BSE) would be eligible to give blood from 1st January 2013 (when they reach 17 years old).

We divided the number of donations from each age group by the total number of donations. The percentage of whole blood expected to be donated by low vCJD risk donors in each of the specified years was then calculated as the cumulative percentage of low vCJD risk to total donated units for each age group up to and including the age at which the donors are considered to be low vCJD risk in that year.

This calculation assumes that the age distribution of donors will not change with time. To assess the validity of this assumption, we compare the age distribution of donors over the last three years and find little change. We also estimated the effect of changing demographics on the fraction of young to older donors in each year using population projections from the Office of National Statistics (ONS).

The results in this analysis can be considered a base-line scenario in which no extra effort is employed to recruit young donors.

3.1.2 Donations of different blood components

So far, we have only considered the policy of taking whole blood donations from low vCJD risk donors – we have not considered alternative approaches such as inviting some low vCJD risk donors to become apheresis platelet donors. However, we are interested in the fraction of different components donated by low vCJD risk donors.

Red cells

For red cells, one unit of red cells can be extracted from one unit of whole blood. Because red cells account for the largest demand from whole blood, the fraction of red cells donated by low vCJD risk donors can therefore be assumed to be the same as that of whole blood. By comparing to the total number of donations instead of the total number of issues, we are effectively including any wastage within NHSBT within the calculation.

For IUT and neonatal exchange red cells, donated units are required to be Group O, phenotype rr, CMV-, PANTS-, HbS-, HT-, and K-. They are also required to be repeat donations. Therefore, it is estimated that 8% x 70% x 100% x 100% x 90% x 90% = 4.5%[5] of repeat red cell donations would be suitable for these groups. To estimate the number of donations that are suitable for these groups, we therefore multiply the number of available repeat donation red cell units by 0.036.

Table 3.1a shows the distribution by blood group of donations collected; of neonatal red cell units issued; and of LVTs issued in 2011. By comparing the proportion of donations collected to the proportion of the different components issued across the groups, we can determine the blood group that will take longest to be supplied by UK Blood Services in order to meet the current demand for neonates and for infants receiving LVTs. We identify that this blood group is O-, for both neonatal red cells and

[5] The figure of 8% for the proportion of donations which are O rr is derived as follows: 8.2% of the 2012 whole blood donations from people who turned 17 or 18 in 2012 were of group O-, and approximately 98% of Rhesus D donors are of phenotype rr. 8.2% x 0.98 = 8.0%

LVTs. Therefore, we shall focus on O- in order to estimate the number of donations that are suitable for neonates and LVTs.

Table 3.1a. The proportion of different blood types collected and issued as neonatal red cells and LVTs in 2011.

Blood Groups	% of low vCJD risk donations collected[6]	% of neonatal red cells	% of LVTs
O-	9.0%	78.28%	34.11%
O+	38.1%	14.65%	34.97%
A-	7.3%	2.60%	7.21%
A+	32.0%	3.33%	18.71%
B-	1.8%	0.10%	0.75%
B+	8.3%	1.05%	4.25%
AB-	0.7%	0.00%	0.00%
AB+	2.8%	0.00%	0.00%

For both neonatal red cells and LVTs, donated units are required to be CMV-[7], PANTS-, HT- and K-, and from repeat donations. Also, as indicated above, we focus on O- to identify when the demand from all groups will be met. It is estimated that 10.8% of donations from low vCJD risk donors will be O- (see Table 3.1a), that 70% of these will be CMV negative, 100% will be PANTS-, 90% will be HT- and 90% will be K-. Therefore, it is estimated that 9.0% x 70% x100% x 90% x 90% = 5.1% of repeat red cell donations would be suitable for these groups. To estimate the number of donations that are suitable for O- neonatal red cells and LVTs, we therefore multiply the number of whole blood units by 0.051.

There are no specific red cell requirements for paediatric patients (defined here as 1 to 15 yrs old inclusive, referred to as 'paediatric'). However, if we wish to meet demand from both this group and IUTs/neonates/infants, the demand for O- red cells will be the most difficult to meet, given the profile of demand for IUTs, neonatal exchanges, neonatal red cells and LVTs. For simplicity, we shall therefore assume that the recipients of Neonatal red cells and LVTs (neonates/infants) are prioritised by UK Blood Services and should be supplied with units suitable for these recipients before paediatrics. Once the supply meets the demand for neonates/infants, the O- paediatric recipients can start to receive units which are CMV-, HT- and K- (which previously were all supplied to the neonates/infants) as well as other O- units. It is estimated that 9% of all red cell donations will be suitable for O- paediatrics once the demand for the higher priority components has been met, (prior to this point, the CMV-, HT-, K- units were required elsewhere, leaving 9% - 5.1% = 3.9% available for paediatric demand). This year will be estimated in Figure 4.3a.

The approach for paediatric recipients is also used for low vCJD risk recipients who are aged 16 or over.

[6] This column shows the percentage of 2012 whole blood donations from donors who were aged at most 21at the end of that year that were of each blood group.

[7] It is operationally feasible for NHSBT to supply CMV- for all LVTs (ie both neonates and infants) but not to supply CMV- units for LVT neonates and CMV+ units for LVT infants. Therefore all neonatal/infant spec blood will still be provided as CMV neg despite the SaBTO recommendations that this is not necessary beyond 28 days post the expected date of delivery)

Platelets

Platelets are either obtained by extraction from whole blood donations or via apheresis donations. We assume here that all platelets from low vCJD risk donors are obtained from whole blood. This is because, although more platelets could be obtained via apheresis, this would reduce the number of low vCJD risk whole blood donors that would be available for the other blood components.

To calculate the number of units of pooled platelets that could be donated by each age group, we divided the number of whole blood donations for each age group by four (since four units of whole blood are needed to manufacture one unit of pooled platelets). To calculate the fraction of pooled platelets that could be issued from each age group, we divided this by the total expected platelet issues plus the expected wastage within NHSBT in each corresponding year. We need to include a forecast for future platelet demand, since we are concerned with the fraction of whole blood that could meet this demand (this is not the case for red cells, since collections of whole blood must roughly meet any increase in demand).

IUT platelets need to be CMV-, PANTS-, HT- and from male donors (or HLA screened female donors, although we do not assume any screening will take place). They also need to be HPA-1a- and HPA5b-. Therefore, it is estimated that 70% x 100% x 90% x 40%[8] x 2.1% x 80.3% = 0.4% of repeat platelet donations would be suitable for IUTs.

For neonatal platelets, the donated units need to be CMV-, PANTS-, HT- and from male donors (or HLA screened female donors). Therefore, it is estimated that 70% x 100% x 90% x 40% = 25.2% of repeat platelet donations would be suitable for neonates. NHSBT data for 2011 shows that 19% of neonatal platelets issued are O- and 23% are A-. By comparing these figures to the percentage of blood group donations in Table 3.1.a, we identify that the blood group A- will take longest to be supplied. We shall focus on A- in order to estimate the year when all demand for neonatal platelets would be met. Therefore, we estimate that 25.2% x 7.3% = 1.8% of donations will be suitable for neonatal platelets for A- patients.

There are no specific requirements for paediatric platelet units. There are no blood groups predominantly needed for production of paediatric platelet units. However, if we wish to meet demand from neonates, the demand for A- platelets will be the most difficult to meet, given the profile of neonate demand. For simplicity, we shall therefore assume that the neonatal recipients are prioritised by UK Blood Services and should be supplied with units suitable for these recipients before other paediatrics. It is estimated that 7.3% of all platelet donations will be suitable for A- neonates and paediatrics (from the donation percentages in table 3.1a). The year in which the supply would meet the demand for neonates will be estimated in Figure 4.3b.

The approach for paediatric recipients is also used for low vCJD risk recipients who are aged 16 or over.

[8] the proportion of male donors varies depending on the age group. Using 2012 donations, we would estimate that the proportion of male donors will vary between 43% and 45%. We use a figure of 40% to be conservative.

FFP and Cryoprecipitate

The plasma extracted from whole blood is needed for the manufacture of fresh frozen plasma (FFP), plasma for suspension of platelets, and cryoprecipitate. A unit of cryoprecipitate for patients under 16 years old requires one unit of FFP. A pooled adult unit of Cryoprecipitate requires five units of FFP. Since 2009, NHSBT have produced their FFP from male donors only, since antibodies that are thought to increase the risk of transfusion related acute lung injury (TRALI). We assume that this policy would continue to apply.

To calculate the fraction of units of FFP and Cryoprecipitate that could be issued from each age group, we divided the number of whole blood donations from males in each age group by the expected number of FFP units to be issued plus the expected wastage for either FFP alone or FFP for the manufacture of Cryoprecipitate in the corresponding year. We reduce the number of suitable donations by the number of donations suitable for platelet production in order to account for plasma used for the suspension of platelets. We also include a forecast for future FFP and Cryoprecipitate demand.

For neonatal plasma, the donated units need to be PANTS-, HT- and from male donors. Therefore, it is estimated that 100% x 90% x 40% = 36% of repeat FFP donations would be suitable for neonates.

There are no specific requirements for paediatric plasma units, and we are not aware of any blood groups predominantly needed for production of neonatal or/and paediatric plasma units (though AB might be more widely used). Therefore, the number of plasma units suitable for paediatrics is not reduced by any percentage (as has been done for the red cell units). It will be assumed that the plasma units from low vCJD risk donors will be firstly used for the neonatal ?plasma recipients until the supply of units equates the plasma demand in a given year after 2013, and then used for the paediatric recipients. This year will be estimated in Figure 4.3c.

The approach for paediatric recipients is also used for low vCJD risk recipients who are aged 16 or over.

3.2 Blood Transfusions

To estimate the percentage of transfused blood components that will be needed for those young enough to be considered at low risk to vCJD (low vCJD risk recipients) in different years who do not receive a specific age-related component, the age distribution of those receiving blood components in England and North Wales is required. This is not directly available, so instead we estimated this using transfusion data from the John Radcliffe hospital trust. Although this trust comprises only approximately 1.6% of the total units transfused nationally, it is likely to be reasonably representative of the whole country.

For each blood component, we determined the total number of bags transfused within the trust from June 2010 to July 2011 for patients in different age groups. As a check

on this, we also estimated the age distribution for red cells from national hospital episode statistics (HES) data and obtained a very similar age distribution. Because they have different assumptions, this suggests that these assumptions do not significantly affect the results.

The estimated percentage of blood components required for low vCJD risk recipients was calculated as the sum of the percentages in each age group not receiving a specific age-related component up to and including the age at which the patients are considered low vCJD risk in that year.

For neonates and very young patients requiring of LVTs we use NHSBT data for the number of issues in 2011.

3.3 Comparison of blood donations and transfusions

We compared our estimates of the percentage of compatible blood components that will be issued from, and required for, those young enough to be considered low vCJD risk in future years for all blood components. We estimated the year in which low vCJD risk donors would be able to supply blood components to low vCJD risk recipients as the year in which the expected percentage of supply from low vCJD risk donors is greater than required for low vCJD risk recipients.

4 Results

4.1 Donations

4.1.1 Whole blood donations

Table 4.1.1a shows the total number of whole blood donations from repeat donors in different age groups in 2011. The number of whole blood donations from new donors in different age groups is not included in the table as many of the components under consideration require a repeat donation. We also show the year that corresponds to the oldest age at which repeat donors are still considered to be low vCJD risk. In 2013, only 0.16% of whole blood donations could be considered to come from low vCJD risk repeat donors. In 2017, this rises to approximately 1.14%.

Table 4.1.1a: Number of whole blood donations from different age groups in 2011 and expected percentage of total donations that will be obtained from low vCJD risk repeat donors in future years

Year low vCJD risk donors can donate in	Age	Number of WB donations			% of total donations	% of total donations from low vCJD risk donors by year
		Female	Male	Total		
2012	16	0	0	0	0.00%	**0.0%**
2013	17	1803	1288	3091	0.16%	**0.16%**
2014	18	9197	7575	16772	0.87%	**1.03%**
2015	19	12397	10112	22509	1.17%	**2.20%**
2016	20	12439	9575	22014	1.14%	**3.34%**
2017	21	13175	9489	22664	1.18%	**4.51%**
2018	22	13232	8877	22109	1.15%	**5.66%**
2019	23	13711	8941	22652	1.17%	**6.84%**
2020	24	13853	8980	22833	1.18%	**8.02%**
2021	25	13598	8886	22484	1.17%	**9.19%**
2022	26	13647	9000	22647	1.17%	**10.36%**
2023	27	13169	8931	22100	1.15%	**11.51%**
2024	28	13189	9125	22314	1.16%	**12.66%**
2025	29	12932	9063	21995	1.14%	**13.80%**
2026	30	13409	9801	23210	1.20%	**15.01%**
	All	995327	932892	1928219		

Table 4.1.2a shows the total number of whole blood donations from new and repeat donors in different age groups in 2011. The number of donations from 17 year olds is approximately half that of the other age groups, since the average person in this age group will reach 17 (the age that they are eligible to donate) half way through the year. We also show the year that corresponds to the oldest age at which new and repeat donors are still considered to be low vCJD risk. In 2013, only 0.7% of whole blood donations could be considered to come from low vCJD risk repeat donors. In 2017, this rises to approximately 1.5%.

The expected percentage of total donations that will be obtained from these donors in future years is compared with the expected percentage of total donations obtained from repeat donors in order to illustrate the effect of an increase in collections due to the donations from new donors.

Table 4.1.2a: Number of whole blood donations from different age groups in 2011 and expected percentage of total donations that will be obtained from low vCJD risk donors (inc. new donors) in future years

Year low vCJD risk donors can donate in	Age	Number of WB donations			% of total donations	% of total donations from low vCJD risk donors by year
		Female	Male	Total		
2012	16	0	0	0	0.00%	**0.00%**
2013	17	8085	5703	13788	0.72%	**0.72%**
2014	18	18419	14808	33227	1.72%	**2.44%**
2015	19	17646	14254	31900	1.65%	**4.09%**
2016	20	16467	12689	29156	1.51%	**5.60%**
2017	21	16988	12229	29217	1.52%	**7.12%**
2018	22	16692	11320	28012	1.45%	**8.57%**
2019	23	16984	11241	28225	1.46%	**10.04%**
2020	24	17666	11720	29386	1.52%	**11.56%**
2021	25	16446	10997	27443	1.42%	**12.98%**
2022	26	16402	11115	27517	1.43%	**14.41%**
2023	27	15709	11020	26729	1.39%	**15.80%**
2024	28	15594	11033	26627	1.38%	**17.18%**
2025	29	15281	10864	26145	1.36%	**18.53%**
2026	30	15622	11554	27176	1.41%	**19.94%**
	All	995327	932892	1928219		

4.1.2 Donations of different blood components

Table 4.1b, 4.1c, 4.1d, 4.1e and 4.1f shows the percentage of compatible issues of red cells, platelets, just FFP (excl. FFP for cryoprecipitate), FFP for cryoprecipitate production and FFP (inc. FFP for cryoprecipitate) respectively for different groups expected from low vCJD risk donors in future years. We also include the effect of an increase in collections due to the donations obtained from new donors.

Red cells

Table 4.1b: Expected percentage of compatible issues that will be obtained from low vCJD risk donors in future years: **red cells**

Year	% of total compatible donations from low vCJD risk donors			
	IUT (repeat donors)	IUT (incl. first-time donors)	IUT + neonatal exchange (repeat donors)	IUT + neonatal exchange (incl. first-time donors)
2012	0.0%	0.0%	0.0%	0.0%
2013	0.0%	0.0%	0.0%	0.0%
2014	0.0%	0.1%	0.0%	0.1%
2015	0.1%	0.1%	0.1%	0.1%
2016	0.1%	0.2%	0.1%	0.2%
2017	0.2%	0.3%	0.2%	0.3%
2018	0.2%	0.3%	0.2%	0.3%
2019	0.2%	0.4%	0.2%	0.4%
2020	0.3%	0.4%	0.3%	0.4%
2021	0.3%	0.5%	0.3%	0.5%
2022	0.4%	0.5%	0.4%	0.5%
2023	0.4%	0.6%	0.4%	0.6%
2024	0.4%	0.6%	0.4%	0.6%
2025	0.5%	0.7%	0.5%	0.7%
2026	0.5%	0.7%	0.5%	0.7%

Year	% of total compatible donations from low vCJD risk donors			
	IUT + neonatal exchange + neonates (repeat donors)	IUT + neonatal exchange + neonates (incl. first-time donors)	IUT + neonatal exchange + neonates + LVTs (repeat donors)	IUT + neonatal exchange + neonates + LVTs (incl. first-time donors)
2012	0.0%	0.0%	0.0%	0.0%
2013	0.0%	0.0%	0.0%	0.0%
2014	0.1%	0.1%	0.1%	0.1%
2015	0.1%	0.3%	0.1%	0.3%
2016	0.2%	0.3%	0.2%	0.3%
2017	0.3%	0.4%	0.3%	0.4%
2018	0.3%	0.5%	0.3%	0.5%
2019	0.4%	0.6%	0.4%	0.6%
2020	0.5%	0.7%	0.5%	0.7%
2021	0.5%	0.8%	0.5%	0.8%
2022	0.6%	0.9%	0.6%	0.9%
2023	0.7%	1.0%	0.7%	1.0%
2024	0.7%	1.0%	0.7%	1.0%
2025	0.8%	1.1%	0.8%	1.1%
2026	0.9%	1.2%	0.9%	1.2%

Year	% of total compatible donations from low vCJD risk residual donors	
	paediatrics	Low vCJD risk over 1 year
2012	0.0%	0.0%
2013	0.1%	0.1%
2014	0.2%	0.2%
2015	0.3%	0.3%
2016	0.4%	0.4%
2017	0.5%	0.5%
2018	0.6%	0.6%
2019	0.7%	0.7%
2020	0.8%	0.8%
2021	0.8%	0.8%
2022	0.9%	0.9%
2023	1.0%	1.0%
2024	1.1%	1.1%
2025	1.2%	1.2%
2026	1.3%	1.3%

For IUT and neonatal exchange units, the fraction is only 3.6% of the adult fraction.
For IUT and neonatal exchange units + neonatal units, 70% of adult units are eligible due to the CMV- requirements.
Then, we use 9% of 70% to account for O- patients because they take longest to provide. The same assumptions hold for IUT and neonatal exchange units + neonatal units + LVTs.
For IUT and neonatal exchange units + neonatal units + LVTs + paediatric units, we use 6.3% of the adult fraction to consider CMV- O- supply before 2021, and 9% of the adult fraction to consider O- supply thereafter (see Figure 4.3a). The same assumptions hold for low vCJD risk recipients.

Platelets

Table 4.1c: Expected percentage of compatible issues that will be obtained from low vCJD risk donors in future years: **platelets**

Year	% of total compatible donations from low vCJD risk donors			
	Neonates (repeat donors)	neonates (incl. first-time donors)	neonates + paediatrics	Low vCJD risk
2012	0.00%	0.00%	0.00%	0.00%
2013	0.00%	0.02%	0.02%	0.00%
2014	0.03%	0.07%	0.07%	0.03%
2015	0.06%	0.12%	0.12%	0.06%
2016	0.09%	0.15%	0.15%	0.09%
2017	0.12%	0.19%	0.19%	0.12%
2018	0.14%	0.21%	0.85%	0.55%
2019	0.16%	0.24%	0.96%	0.64%
2020	0.18%	0.27%	1.06%	0.72%
2021	0.20%	0.29%	1.14%	0.79%
2022	0.22%	0.31%	1.22%	0.85%
2023	0.23%	0.32%	1.29%	0.91%
2024	0.24%	0.34%	1.35%	0.96%
2025	0.25%	0.35%	1.40%	1.01%
2026	0.26%	0.36%	1.45%	1.05%

For platelets, we assumed that 265,000 units were required in 2011 (these were the actual issues in 2011/12). We also assumed that demand will increase by 4% each year. This increase is in line with the historical trend, and is the increase projected in longer-term forecasts produced as part of the 'demand drivers' project. We assumed a wastage rate within NHSBT of 10.1% per year (the actual difference between produced and issued platelets in 2011/12). Although the volume of issues is similar to that of FFP, four whole blood units are required to manufacture one unit of platelets. The percentage of donations that could be obtained from low vCJD risk donors in any given year is therefore lower than that of FFP.

For IUT platelets, the demand is very small (19 units in 2011). However, the proportion of donors who meet the specified requirements (most notably HPA 1a-) is also very small (around 0.4%), ignoring the need for ABO group and Rhesus D compatability. As a result, the number of donors who meet these criteria in the first two years will be very small. While we would normally expect there to be sufficient low vCJD risk donors to meet demand in 2015, the small numbers involved make it less certain that there will be enough donors for each of the required groups donating at the right time. As a result, we assume that these units will continue to be supplied from the general donor pool, rather than low vCJD risk donors.

For neonatal units 25.2% of units are eligible due to the special requirements. Then, we use 7.3% of 25.2% to account for A- patients because they take longest to provide. For neonatal units + paediatric units, we use 1.8% of the total number of donations to consider CMV- A- supply before 2016, and 7.3% of the adult fraction to consider A-

supply thereafter (see Figure 4.3b). The same assumptions hold for low vCJD risk recipients.

Table 4.1d: Expected percentage of compatible issues that will be obtained from low vCJD risk donors in future years: **FFP only**

Year	% of total compatible donations from low vCJD risk donors			
	Neonates (repeat donors)	neonates (incl. first-time donors)	neonates + paediatric	Low vCJD risk recipients
2012	0.0%	0.0%	0.0%	0.0%
2013	0.4%	1.9%	1.9%	1.9%
2014	2.9%	6.8%	6.8%	6.8%
2015	6.2%	11.5%	11.5%	11.5%
2016	9.3%	15.6%	17.3%	17.3%
2017	12.3%	19.5%	21.6%	21.6%

Table 4.1e: Expected percentage of compatible issues that will be obtained from low vCJD risk donors in future years: FFP for **cryoprecipitate**

Year	% of total compatible donations from low vCJD risk donors			
	Neonates (repeat donors)	neonates (incl. first-time donors)	neonates + paediatric	Low vCJD risk recipients
2012	0.0%	0.0%	0.0%	0.0%
2013	0.8%	3.4%	3.4%	3.4%
2014	5.0%	11.7%	11.7%	11.7%
2015	10.4%	19.1%	19.1%	19.1%
2016	15.0%	25.0%	27.8%	27.8%
2017	19.1%	30.2%	33.6%	33.6%

Table 4.1f: Expected percentage of compatible issues that will be obtained from low vCJD risk donors in future years: **FFP (incl. FFP for cryoprecipitate)**

Year	% of total compatible donations from low vCJD risk donors			
	Neonates + paediatric (repeat donors)	Neonates + paediatric (incl. first-time donors)	neonates + paediatric (repeat donors)	Low vCJD risk recipients (incl. first-time donors)
2014	0.0%	0.99%	0.00%	1.11%
2015	0.8%	3.78%	0.59%	4.20%
2016	3.5%	6.15%	2.58%	6.83%
2017	6.0%	8.33%	4.48%	9.25%
2018	8.3%	10.24%	6.17%	11.38%
2019	10.5%	12.06%	7.79%	13.40%
2020	12.6%	13.89%	9.36%	15.43%
2021	14.6%	15.50%	10.83%	17.22%

2022	16.6%	17.05%	12.26%	18.95%
2023	18.4%	18.51%	13.60%	20.57%
2024	20.1%	19.90%	14.92%	22.11%
2025	21.8%	21.18%	16.15%	23.53%
2026	23.6%	21.79%	17.45%	24.21%
2027	25.3%		18.77%	
2028	27.1%		20.04%	
2029	28.5%		21.14%	
2030	30.0%		22.23%	

For FFP, we assumed that there will be 259,000 units required in each year (the number of issues in 2011/12). For cryoprecipitate, we assumed 135,000 units of FFP will be needed for issues in each year (the number of FFP units needed to manufacture cryoprecipitate in 2011/12). We assumed a wastage rate of 3.7% and 7.5% for FFP and cryoprecipitate respectively within NHSBT (the difference between produced and issued volumes in 2011/12). We also assumed a yearly increase in demand of 0.5% and 4% for FFP and cryoprecipitate respectively (the average forecasted increase for the next 2 years provided by Sue Holdsworth).

For neonatal units, we assumed that 12,598 donations (which are the neonatal platelets issued in 2011) are used for suspension of platelets and remove them from the number of donations suitable for neonatal plasma units. The new number of suitable donations is multiplied by 36.0% to account for the special requirements. For neonatal units + paediatric units, no fraction of adult plasma units is required, since no blood group is predominantly used for their production. The year in which the prioritisation of donations for neonates will be relaxed is 2016 (see Figure 4.3c).

We implicitly assume no change in red cell demand. Because of the far lower volumes needed, the percentage of FFP that could be obtained from low vCJD risk donors in any given year is higher than for red cells.

4.2 Transfusions

4.2.1 Red cells

Figure 4.2a shows the estimated percentage of red cells transfused to patients of different ages using data from the John Radcliffe trust and from hospital episode statistics. The two methods produce very similar age distributions. The distribution peaks at ages 75 to 79, and declines at older and younger ages. There is a slight increase in the 0 – 4 years age group compared to the 5 – 14 years age group due to red cells transfused to neonates.

Figure 4.2a: Percentage of red cells transfused to patients in different age groups.

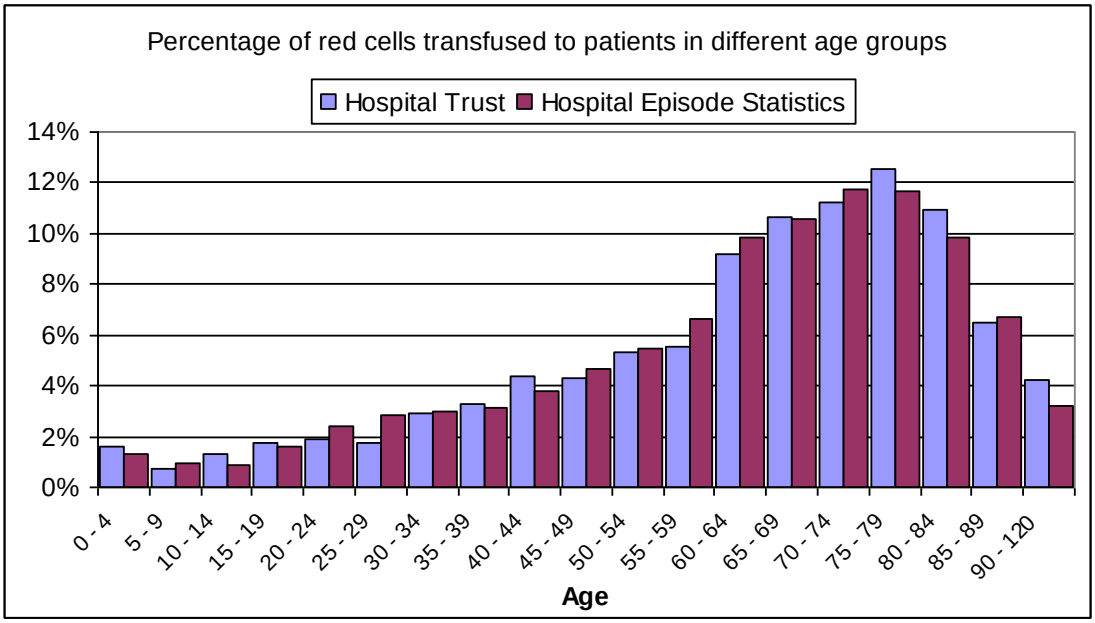


Table 4.2.a. shows the expected percentage of red cells that will be required for low vCJD risk patients in future years. We assumed an average wastage of 5% of all red cell issues within hospitals.

Table 4.2a: Percentage of red cells required for low vCJD risk patients in different years assuming the two different age distributions.

Year	Hospital trust	HES
2012	4.4%	4.0%
2013	4.8%	4.3%
2014	5.2%	4.7%
2015	5.6%	5.1%
2016	6.0%	5.6%
2017	6.4%	6.2%
2018	6.7%	6.7%
2019	7.1%	7.3%

The two different methods used in calculating the age distribution result in very similar estimates for the percentage of red cells that will be required for low vCJD risk patients. This provides a greater confidence in the results. We assume that other blood components would also have similar age distributions, and so only calculate the age distributions from the John Radcliffe trust.

In 2011, NHSBT issued 309 and 814 units for IUT and neonatal exchange patients respectively. This corresponds to a fraction of 0.02% of the overall number transfused for IUTs and 0.06% for IUTs and neonatal exchange combined.

We use NHSBT issues data from 2011 to estimate that the percentage of red cells required to produce neonatal red cells, and assume that this proportion will not significantly change over time. In 2011, NHSBT used 8761 adult units to create

neonatal red cell units out of a total of 1.92m units of whole blood, giving a proportion of 0.48%. For neonatal red cells, we are focusing on O- to identify when all groups needs will be met, giving a proportion of total demand of 0.38% (= 0.48% x 78.3%). This fraction will be compared with the fraction of donated units that are CMV-,HT-, K- and O- in order to estimate the year in which the neonates will be supplied from low vCJD risk donors (see Figure 4.3a).

In 2011, NHSBT issued 3027 LVTs which were O-, CMV-., PANTS-, HT- and K- This corresponds to a fraction of 0.17% of the overall number transfused. This fraction will be compared with the fraction of donated units that are[5] CMV-, PANTS-, HT-, K- and O- in order to estimate the year in which the neonates and infants receiving LVTs will be supplied from low vCJD risk donors (see Figure 4.3a).

The fraction of O- IUTs, neonatal exchange and neonatal red cells and LVTs is 0.60% (= 0.05 % + 0.38% + 0.17%) This will be compared with the fraction of donated units that are both CMV- and O- in order to estimate the year when the neonates, together with IUT and neonatal exchange patients and infants receiving LVTs, will be supplied from low vCJD risk donors.

For paediatric red cells, we use the John Radcliffe data to estimate the fraction of units transfused to those aged 1 to 15 to be 3.2%. Again, we assume that this fraction will not change significantly over time. This will be compared with donations of whole blood in order to estimate the year in which the paediatrics will be supplied from low vCJD risk donors.

4.2.2 Platelets

Figure 4.2b shows the percentage of platelets transfused to patients of different ages in 2010/11 in the John Radcliffe trust, the percentage of platelets transfused to patients of different ages in 2010/11 from the Hospital Episode Statistics (HES) database and the percentage of platelets transfused to patients of different ages in 2010 from Pendry's study on the use of platelets[9]. From the John Radcliffe trust (see the histograms in blue), the smaller overall volume of platelets (3258 units) compared to that of red cells (21,000 units) results in a less smooth age distribution. The platelet age distribution peaks at a slightly younger age than the red cell distribution. There are also a much larger percentage of platelets transfused to patients under 5 years of age (ie, ~ 10%). This is due to the large volumes of platelets used for childhood haematological conditions because the JR trust is a specialist centre. From the HES database and Pendry's study (see the histograms in dark red and the histograms in white, respectively), the percentage of platelets transfused to patients under 5 years of age is much smaller (ie, ~ 4%). Though, it is not so different from the percentage of platelets transfused to patients older than 5 years of age and younger than 30 years of age from the JR trust. We shall use in the analysis the age distribution from Pendry study to estimate the percentage of platelets transfused to paediatrics and low vCJD risk patients in different years

[9] "*Where do Platelets go in the North West of England and North Wales? An audit of the use and wastage of platelets*" (2010) by Dr. Kate Pendry, Regional Transfusion Team and Transfusion Teams in Hospitals / Trusts in the North West of England and North Wales

Figure 4.2b: Percentage of platelets transfused to patients in different age groups.

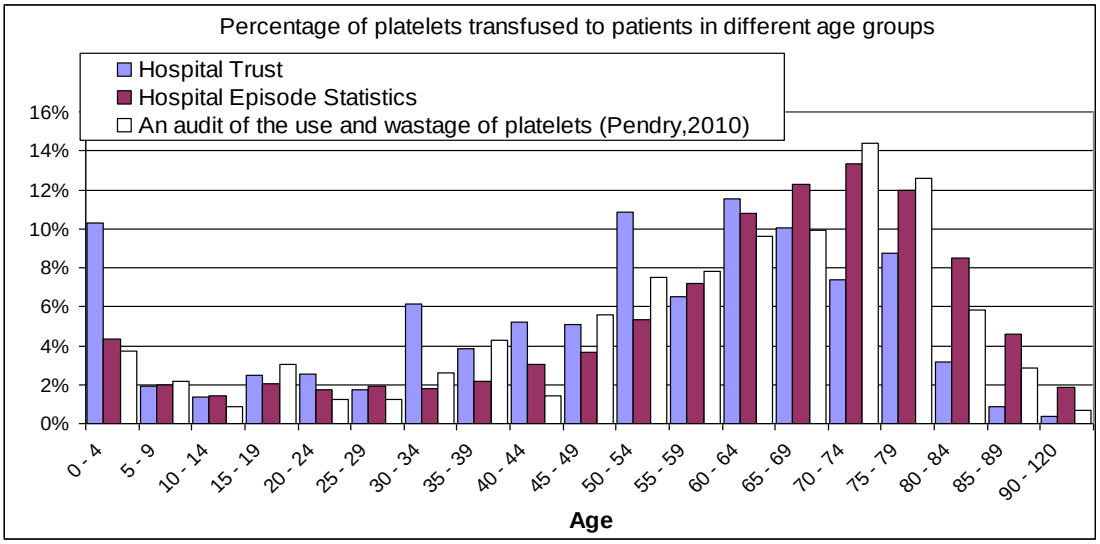


Table 4.2b shows the expected percentage of platelets that will be required for low vCJD risk patients in future years. The larger percentage of platelets required for younger patients results in a much larger percentage of platelets required for low vCJD risk patients than is found for red cells.

Table 4.2b: Percentage of platelets required for low vCJD risk patients in different years.

Year	Percentage of platelets from Pendry study	Percentage of platelets from the HES data	Percentage of platelets from the JR trust[10]
2012	**6.0%**	8.4%	13.9%
2013	**6.4%**	8.8%	14.3%
2014	**7.1%**	9.2%	15.0%
2015	**8.1%**	9.6%	15.8%
2016	**8.5%**	10.0%	16.3%
2017	**8.7%**	10.3%	16.9%
2018	**9.0%**	10.7%	17.5%
2019	**9.4%**	11.0%	17.8%
2020	**9.7%**	11.4%	18.3%
2021	**9.7%**	11.7%	18.6%
2022	**10.1%**	12.1%	18.7%

We use NHSBT data from 2011 to estimate that the percentage of platelets required for neonates and assume that this will not significantly change over time. In 2011, NHSBT issued the equivalent of 3150[11] adult units as neonatal units, and considering this as a fraction of the 265,000 platelet issues in 2011/12, we obtain a fraction of 1.19%. for neonatal platelets.

[10] The percentages of issues in the John Radcliffe trust in different years are for information only. These percentages were used to estimate the years when the issues from donors would meet the issues for recipients. The results were discussed at the Club 96 Working Group meeting in June 2012.

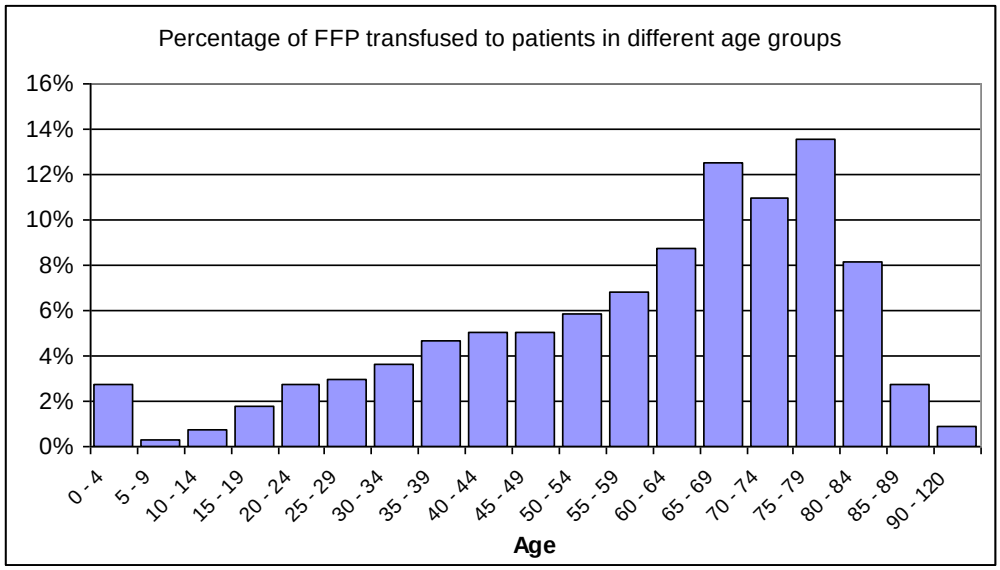
[11] This figure assumes that four donations would result in four neonatal platelet units being issued, in line with the proposed processing of low vCJD risk donations, as opposed to the current average of 2.3. In reality, 5486 adult units were created to produce the neonatal units.

For paediatrics, we estimate the fraction of units transfused to those aged 1 to 15 to be 5.5%, using the Pendry study. Again, we assume that this fraction will not change significantly over time.

4.2.3 FFP and Cryoprecipitate

Figure 4.2c shows the percentage of FFP and FFP for cryoprecipitate that were transfused to patients of different ages in 2010/11 in the John Radcliffe trust. For cryoprecipitate, we use the combined age distribution, since the volumes of cryoprecipitate alone are too low to obtain a reliable age distribution. The percentage of very young recipients is slightly higher than that of red cells (although a smaller fraction is transfused to the 5 to 14 year old age group).

Figure 4.2c: Percentage of FFP transfused to patients in different age groups.



Due to the risk of vCJD transmission through the transfusion of plasma, UK Blood Services import FFP from abroad for patients that were born on or after 1 January 1996. The fraction of total issues to hospitals for this cohort is therefore known and can be used[12]. In 2011, 5.3%, 4.4%, and 4.4% of all FFP only, FFP for cryoprecipitate only, and total FFP issues respectively were to under 16 year olds. Low vCJD risk donors were still under 16 in 2011. The percentages of FFP for low vCJD risk patients in 2011 should therefore match these figures. We use the age distribution for FFP and Cryoprecipitate to determine how this fraction is likely to increase each year.

Table 4.2c shows the expected percentage of FFP only, FFP for cryoprecipitate only, and total FFP that will be required for low vCJD risk patients in future years. Given the long shelf-life of FFP, we assume no hospital wastage.

[12] This calculation does include an allowance for the use of Octaplas, based on the drop in demand from NHSBT at the time that Octaplas started to be used.

Table 4.2c: Percentage of FFP and cryoprecipitate required for low vCJD risk patients in different years.

Year	FFP only	Cryo only	FFP + Cryo
2011	5.3%	4.4%	4.4%
2012	5.8%	4.9%	4.9%
2013	6.4%	5.3%	5.4%
2014	6.7%	5.6%	5.6%
2015	7.2%	6.0%	6.1%
2016	8.1%	6.7%	6.8%
2017	8.9%	7.4%	7.5%
2018	9.9%	8.2%	8.3%
2019	10.9%	9.0%	9.1%

To determine the percentage of FFP and cryoprecipitate required for neonatal and paediatric usage, we use the number of imported FFP and Cryoprecipitate issues in 2011 compared to the total issues. There were 8742 and 7412 units of neonatal and paediatric FFP issued in 2011. Assuming total FFP issues of 257,000 units (and converting the neonatal units to adult units by dividing by 1.4), we estimate that 2.4% and 2.9% of total FFP issues are for neonatal and paediatric usage (excluding neonates) respectively. In 2011, there were 8274 units of cryoprecipitate issued to children. Assuming total Cryoprecipitate issues of 257,000 units (and converting to adult units by dividing by 1.4), we estimate that 4.4% of total Cryoprecipitate issues are required for neonates and paediatrics combined. These numbers can be combined to determine that 4.4% of total FFP and Cryoprecipitate issues are required for neonates and paediatrics.

4.3 Comparison of donations and transfusions

The figures in this section show the percentage of units available for issue from low vCJD risk donors compared to the percentage needed for issue to low vCJD risk recipients (i.e. recipients who were born on or after 1st January 1996) of different types for different blood components.

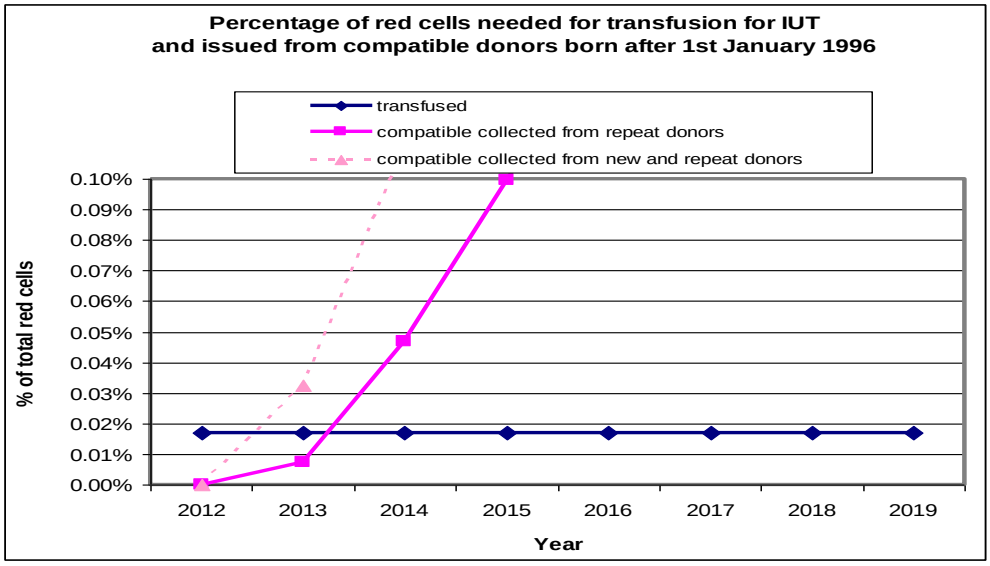
Red cells

Figure 4.3a shows the percentage of red cells needed for transfusion to different groups and issued from compatible low vCJD risk donors. Both the projected donation from repeat donors and the donations from new and repeat donors are shown.

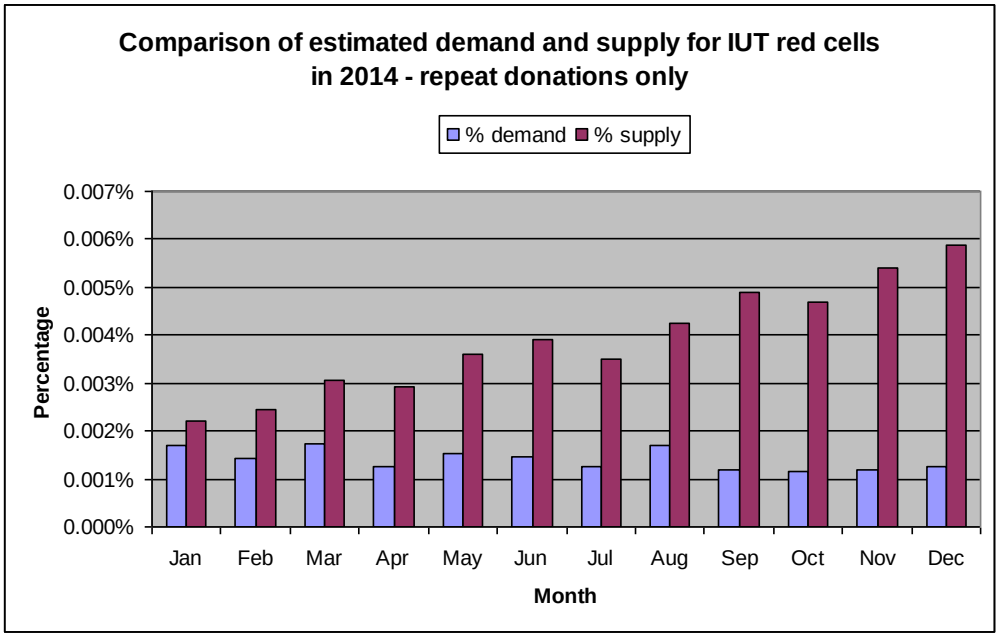
(In this analysis, we include the demand from haemoglobinopathy patients, but treat this demand in the same way as demand from other patients for the same type of unit.

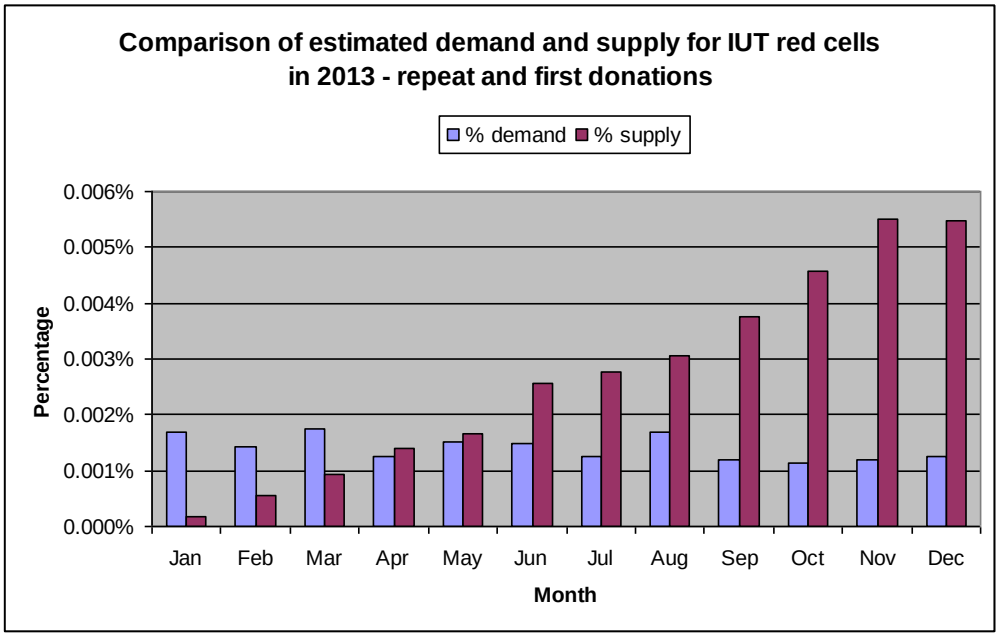
Figure 4.3a: Percentage of red cells needed for transfusion to different groups and issued from compatible donors born on or after 1st January 1996

i) IUT

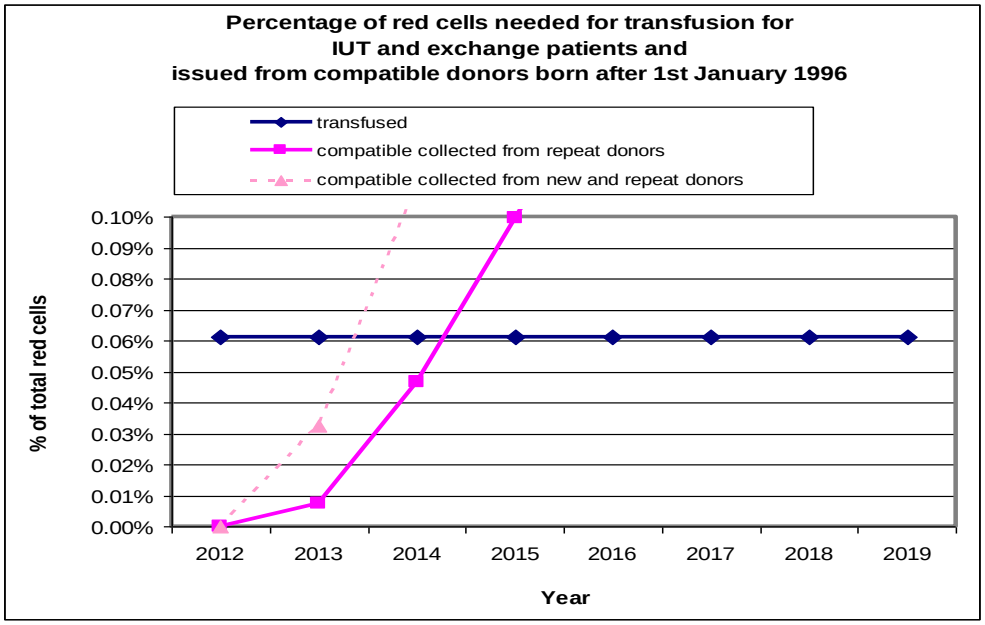


The graph suggests that demand for IUT red cells would be met using repeat donations in 2014. Looking at the monthly profile within 2014 suggests that this should be possible. If we allow first donations to be used, the graph suggests that demand would be met in 2013. Looking at the monthly distribution suggests that demand could be met from roughly half way through 2013.

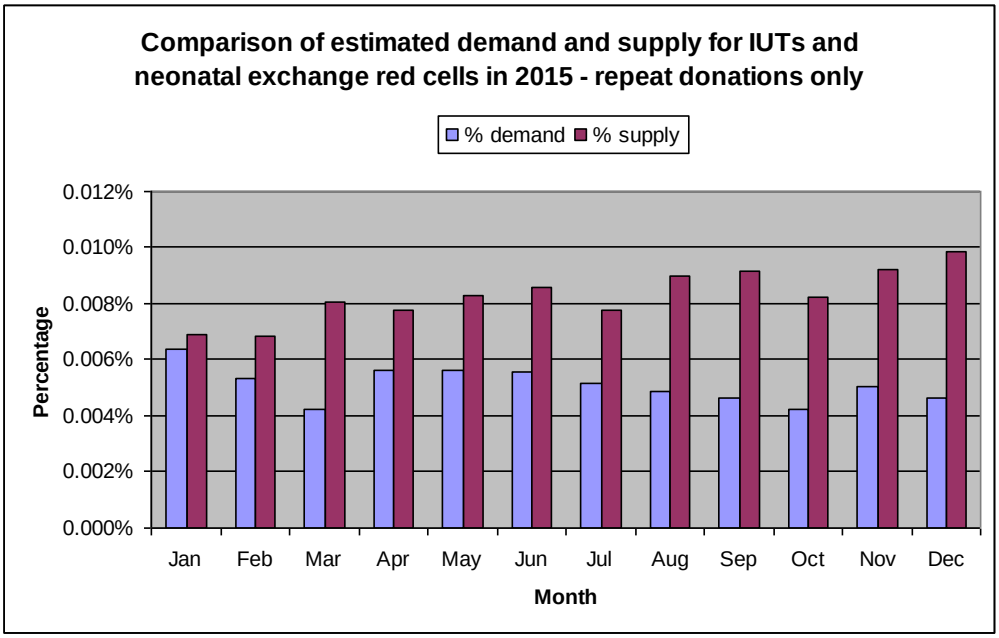


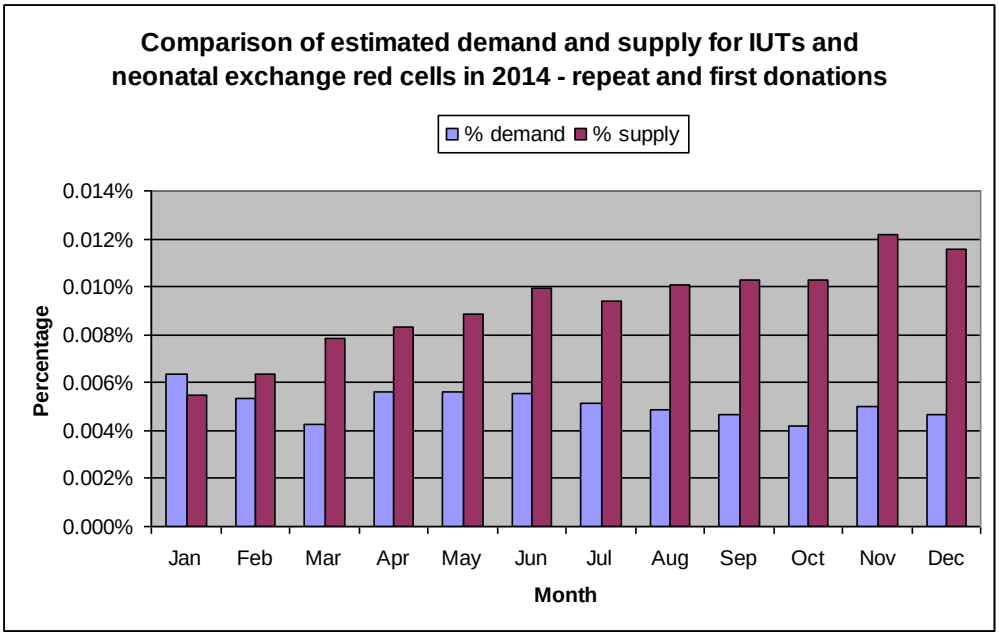


ii) IUT and Neonatal exchange Recipients

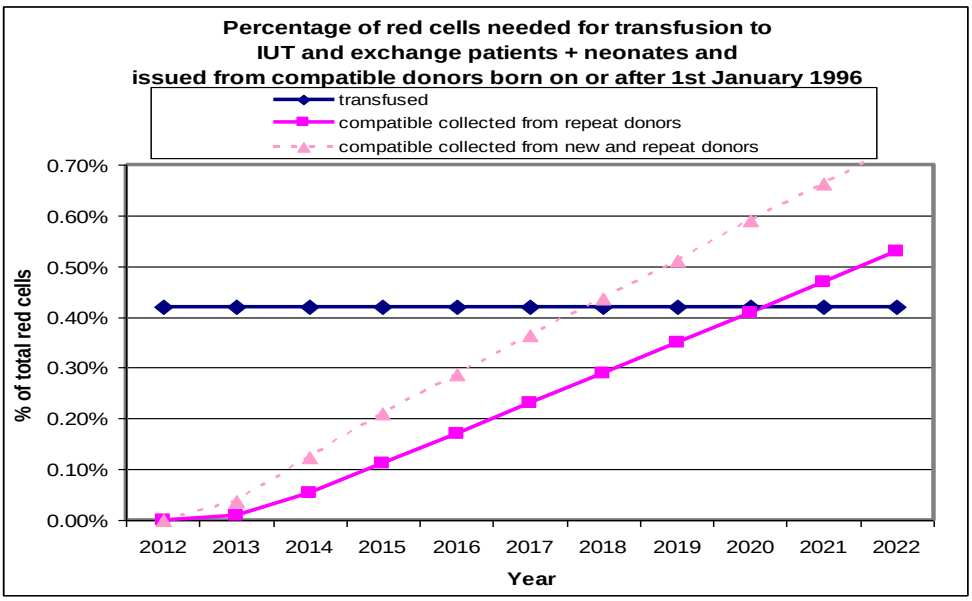


The graph suggests that expanding to include supply of neonatal exchange red cells would be possible in 2015 if we only allow repeat donations, and in 2014 if we also allow first donations. Looking at the monthly breakdown suggests that demand should be able to be met by repeat donations after February 2015, and from first and repeat donations after March 2014.

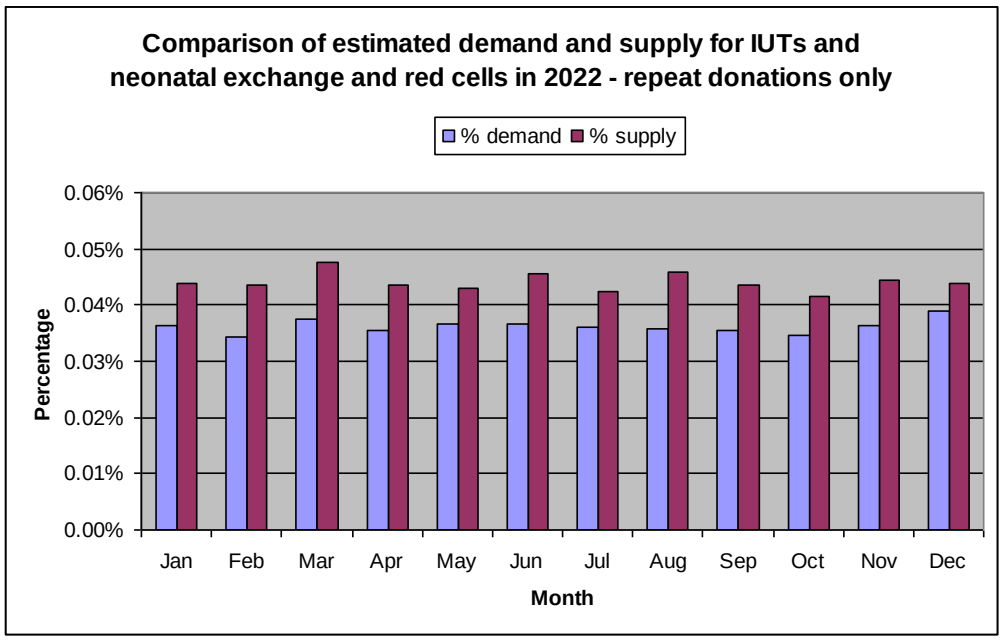

Comparison of estimated demand and supply for IUTs and neonatal exchange red cells in 2015 - repeat donations only
% demand
% supply
0.012%
0.010%
0.008%
0.006%
0.004%
0.002%
0.000%
Percentage
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Month

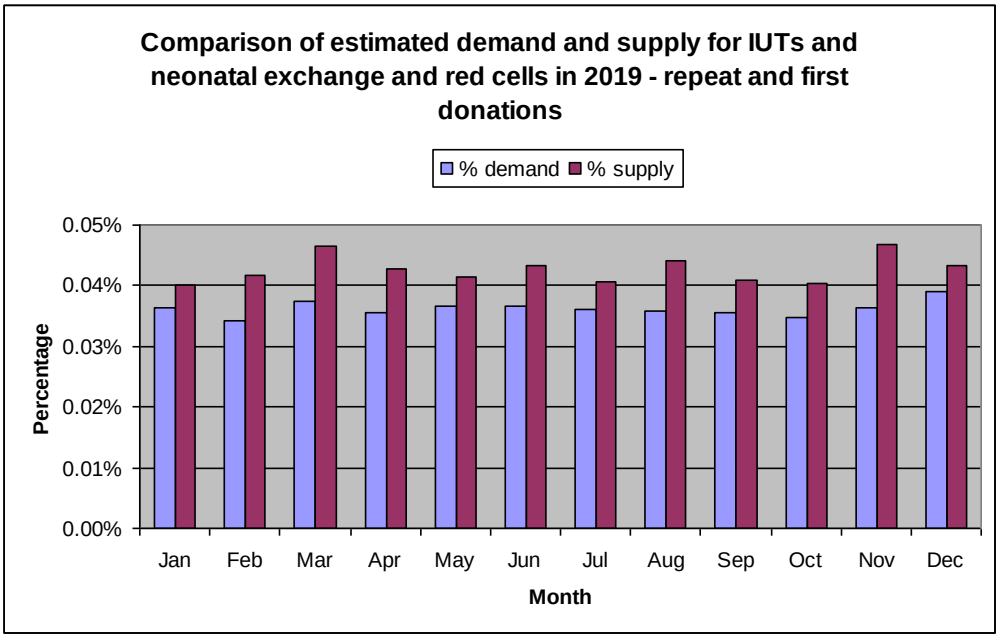

Comparison of estimated demand and supply for IUTs and neonatal exchange red cells in 2014 - repeat and first donations
% demand
% supply
0.014%
0.012%
0.010%
0.008%
0.006%
0.004%
0.002%
0.000%
Percentage
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Month

iii) IUT, neonatal Exchange + Neonatal red cell recipients

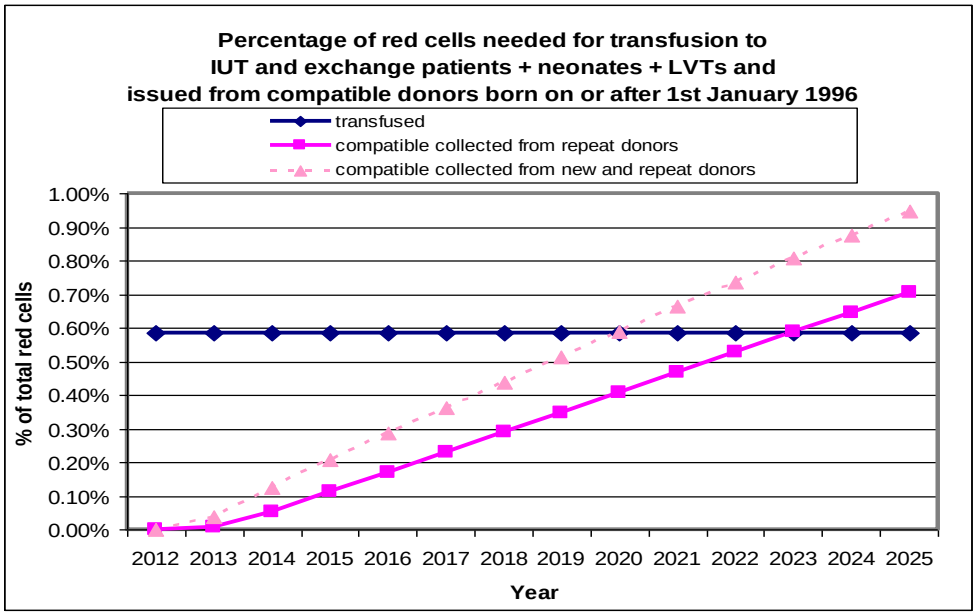


The graph suggests that expanding further to include supply of neonatal red cells would be possible in 2021 if we only allow repeat donations, and in 2019 if we also allow first donations. Looking at the monthly breakdown suggests that demand might be able to be met by repeat donations in 2021, and from first and repeat donations in 2019.

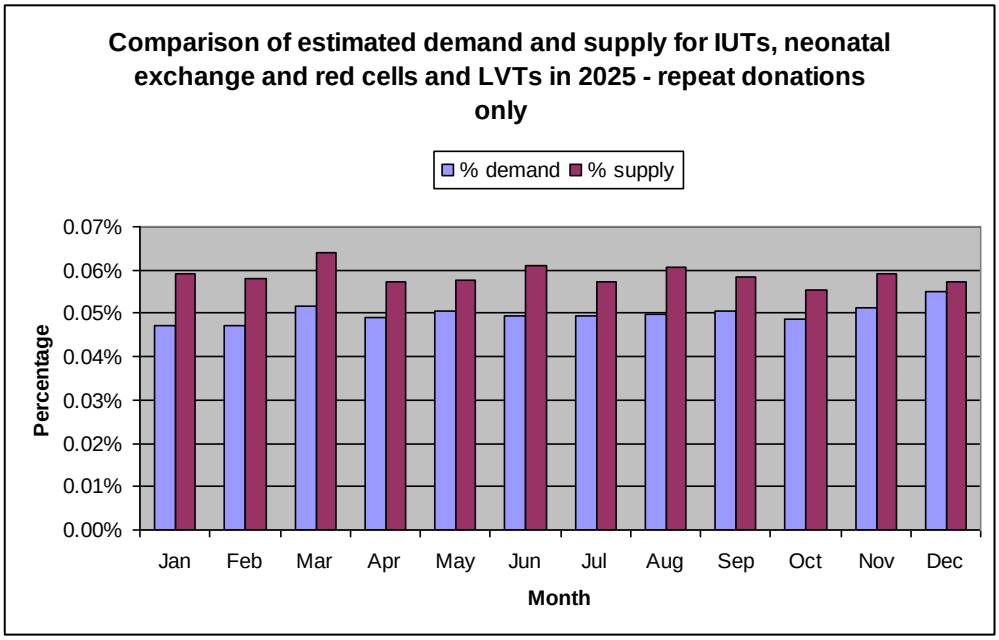


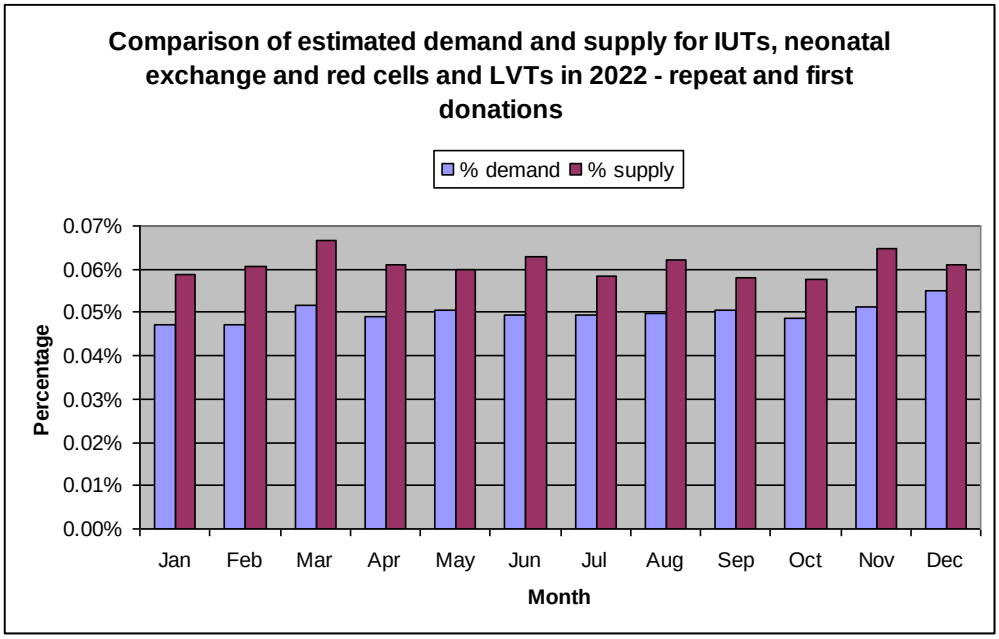

Comparison of estimated demand and supply for IUTs and neonatal exchange and red cells in 2019 - repeat and first donations
% demand
% supply
0.05%
0.04%
0.03%
0.02%
0.01%
0.00%
Percentage
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Month

iv) IUT, Neonatal Exchange + Neonatal red cells + LVT recipients



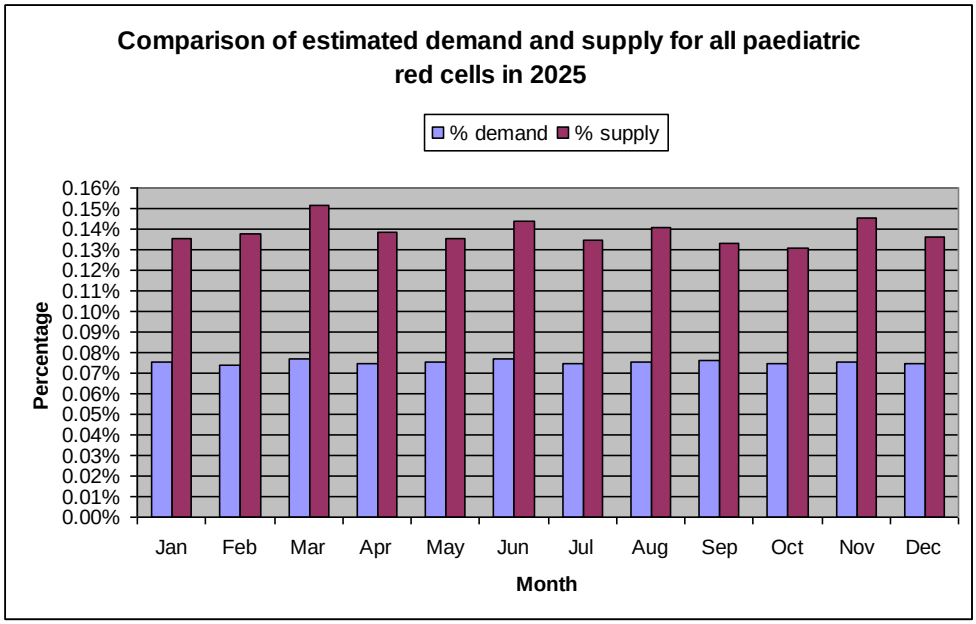
The year-level analysis suggests that extending to cover LVTs (based on current demand) might be met from repeat donations in 2024, but a monthly analysis suggests that we would need to wait until 2025. Similarly, monthly analysis would suggest that including first donations would bring the date forward to 2022 rather than 2021.



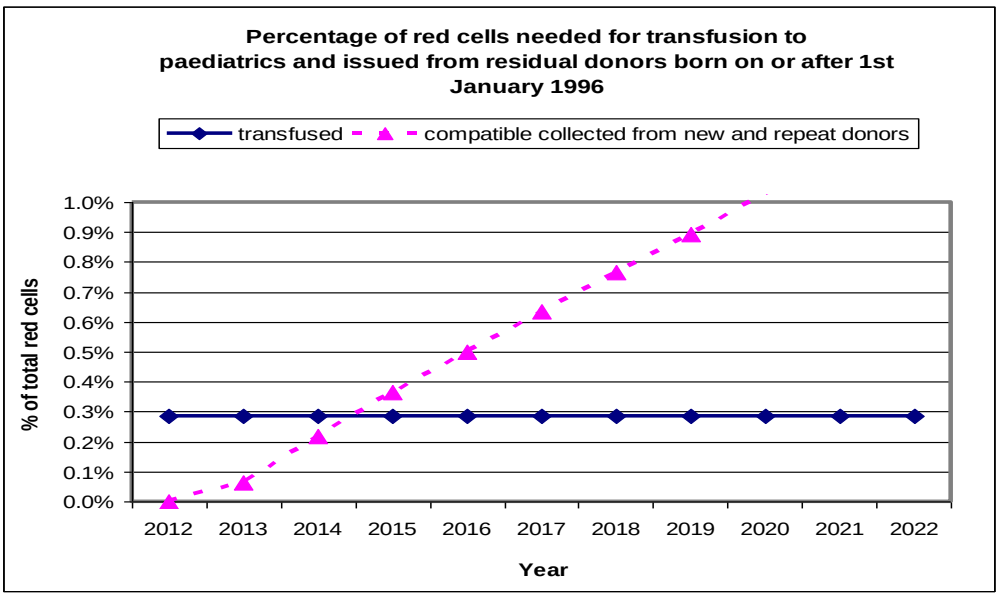


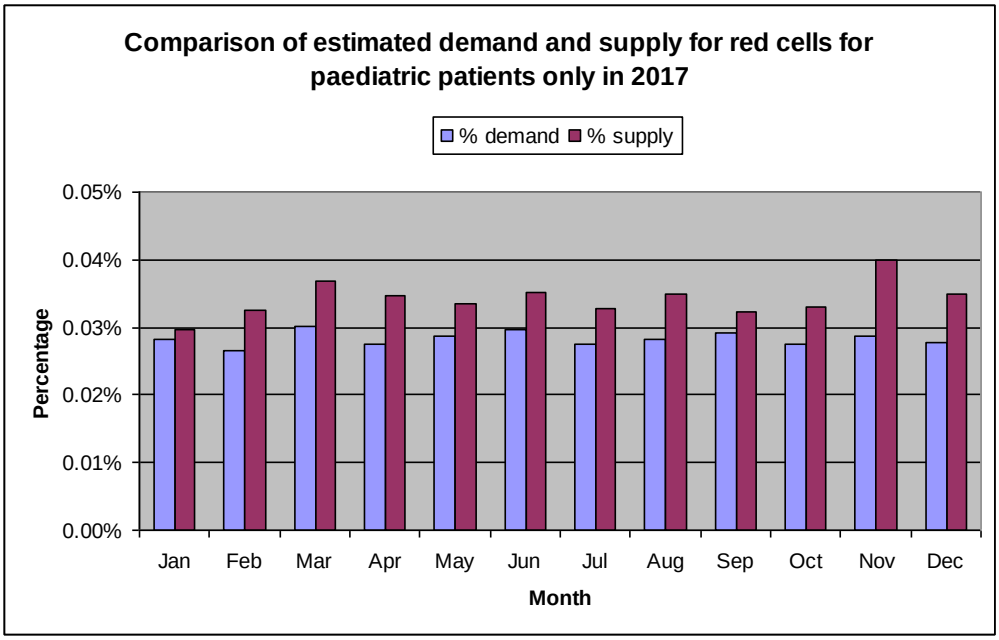
v) Paediatrics

For paediatric patients, we do not require that red cells come from repeat donations. If we continue to require repeat donations for the younger patient groups, we would expect paediatric demand to be met from the unused first donations. The graph below suggests that extending to include paediatric patients would still be possible in 2025 (assuming LVT demand is met).



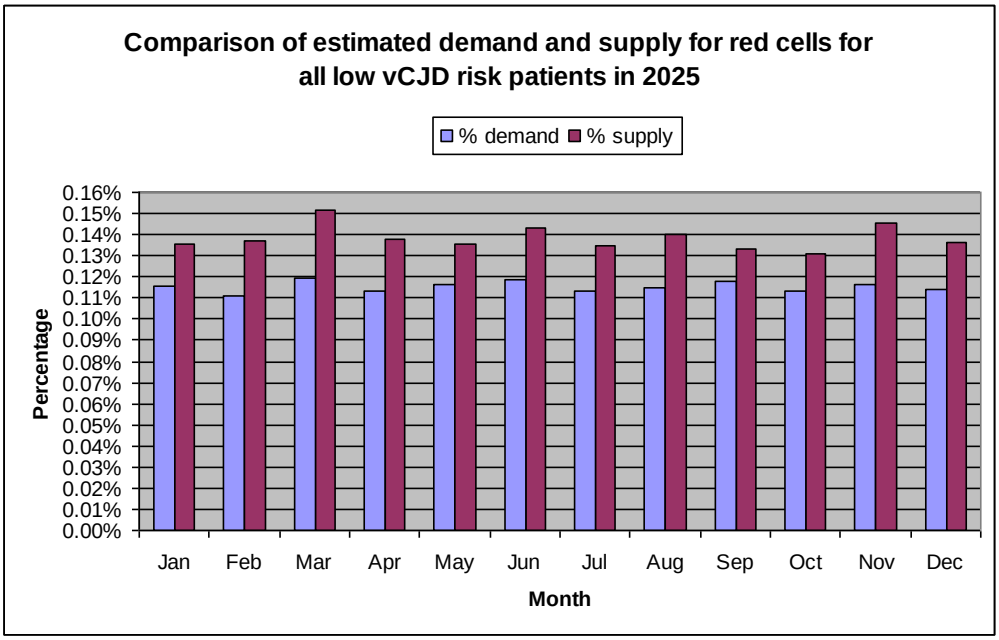
If we continue to supply all IUTs, neonatal exchange and red cells and LVTs from repeat donations, then we would be able to meet the demand from older paediatric patients before 2025 from first donations. Looking at the annual and monthly supply and demand suggests that this might be possible in 2017.



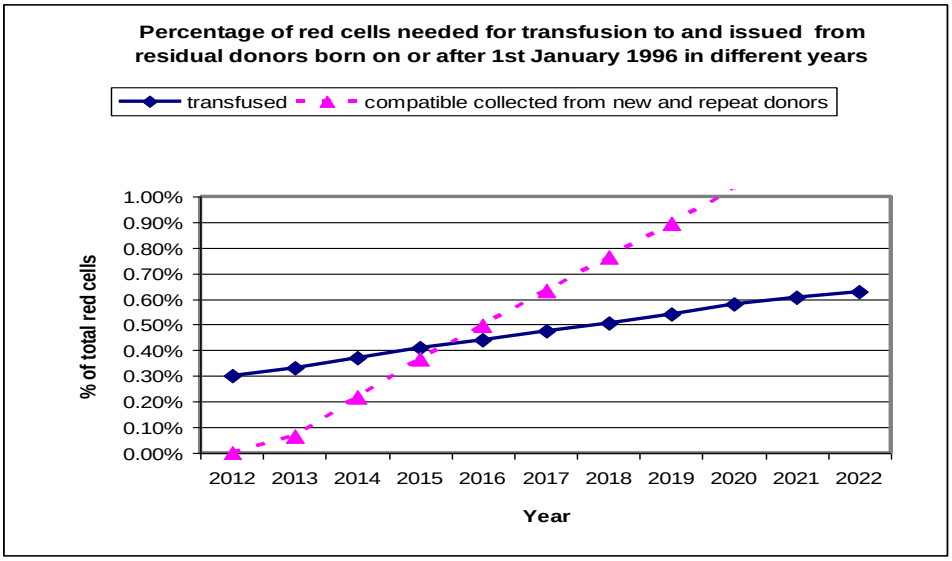


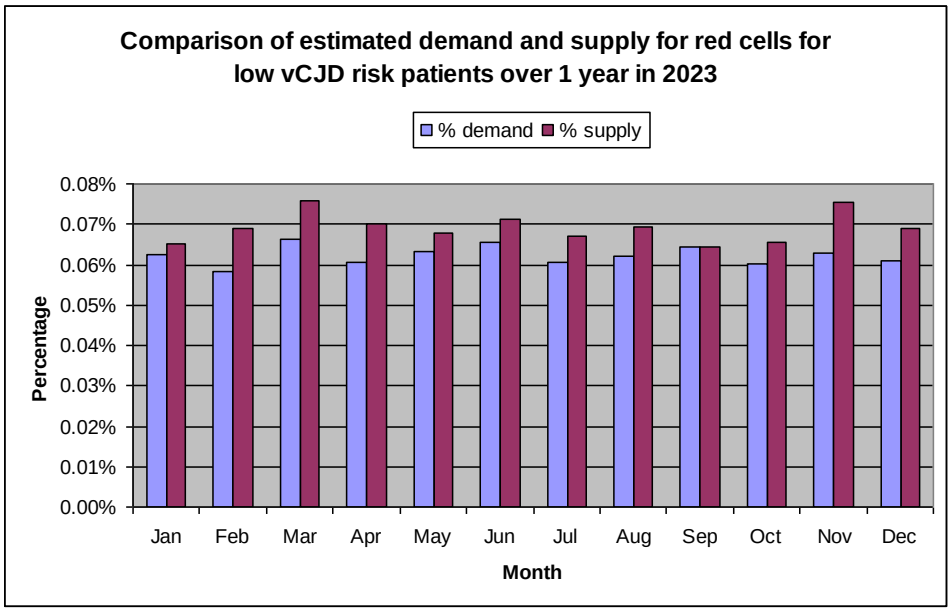
vi) Low vCJD risk recipients

Again, we see that we would be able to extend the provision to cover all low vCJD risk patients in 2025.



If repeat donations were used to meet demand from patients under one year of age, then first donations, annual information would suggest that this demand might be met in 2021, but a monthly analysis would suggest that the demand might met until 2023, although it may be better to wait until 2024 to ensure that September demand is met.



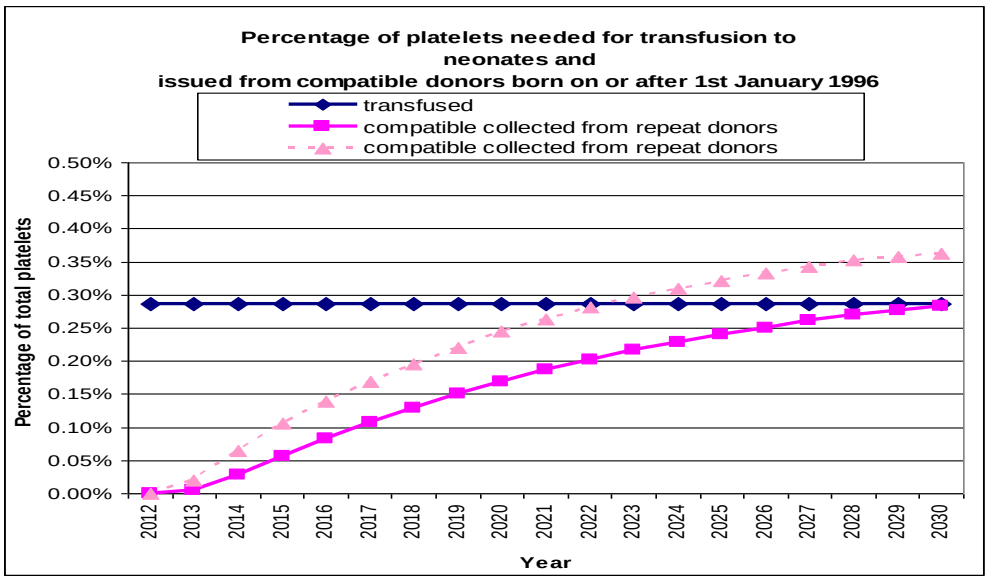


Platelets

Figure 4.3b shows the percentage of platelets needed for transfusion to different groups and issued from compatible low vCJD risk donors. Both the projected donation from repeat donors and the donations from new and repeat donors are shown.

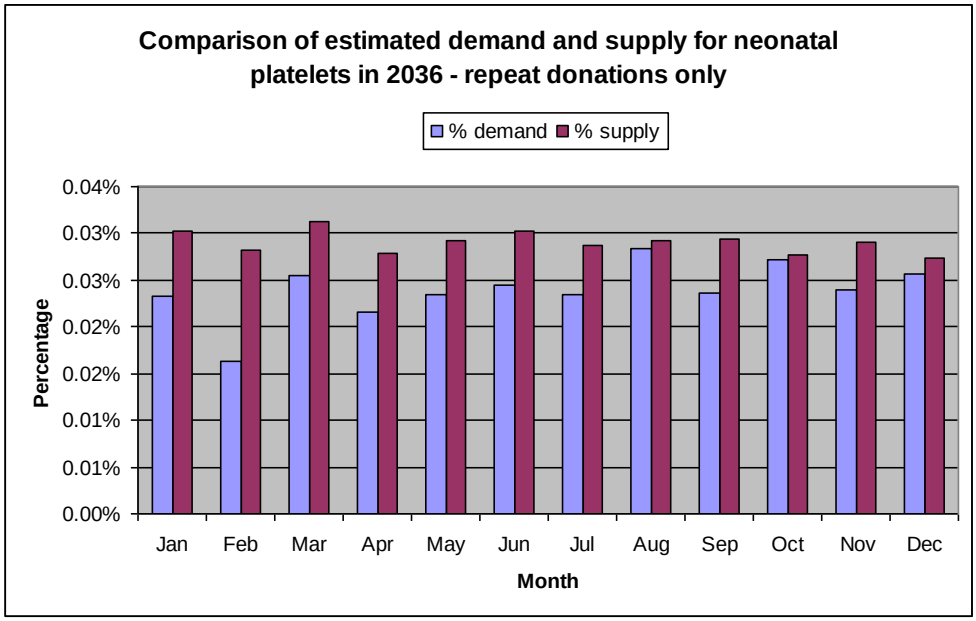
Figure 4.3b: Percentage of platelets needed for transfusion to different groups and issued from compatible donors born on or after 1st January 1996

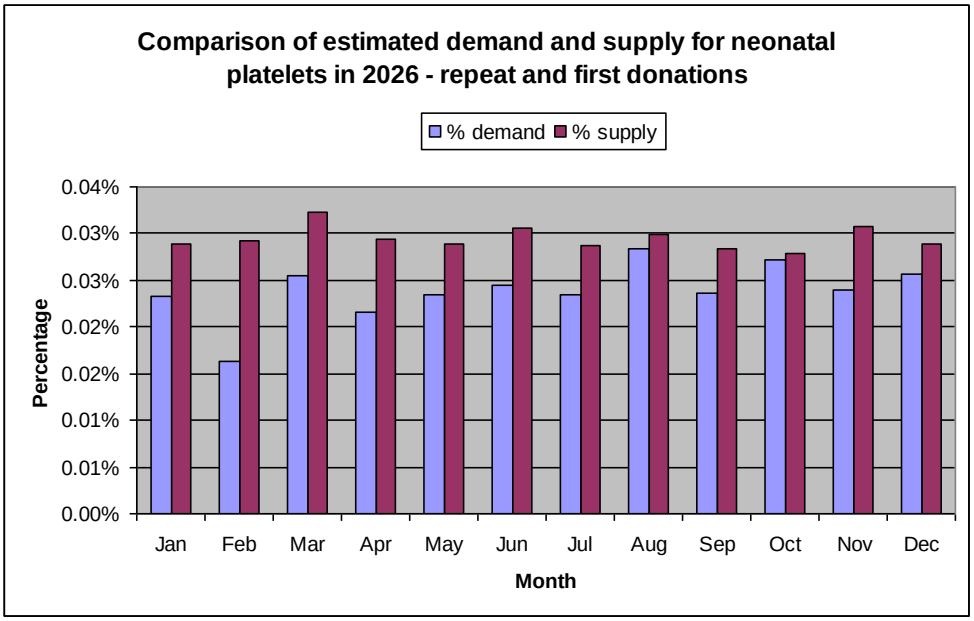
i) Neonates



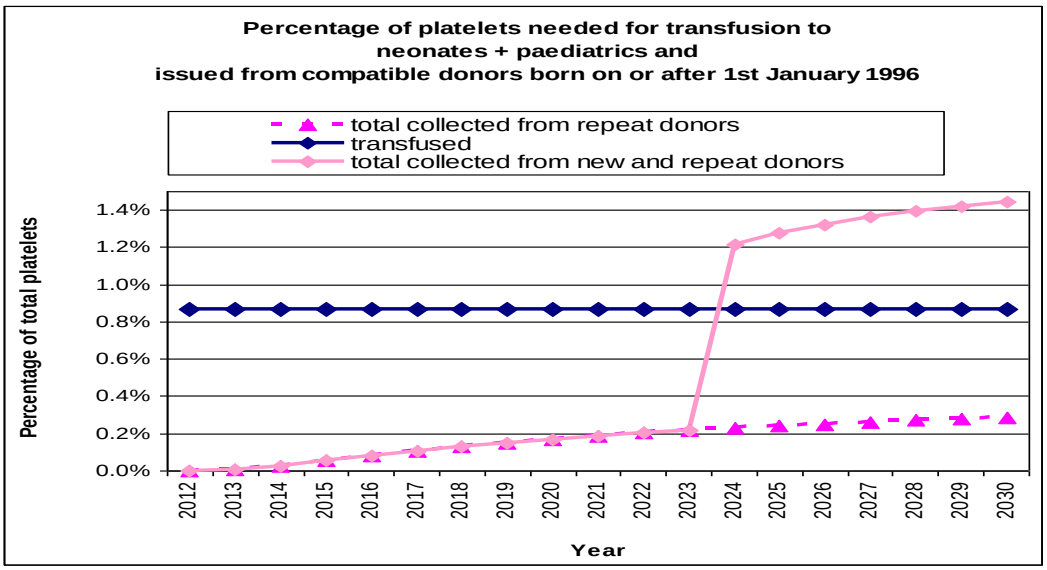
The above graph suggests that demand from neonates might be met by repeat donations in around 2030. However, looking at the month-level supply and demand, we see that the variation means that we would not be able to meet demand within each month.in that year. Meeting the demand in the peak months from repeat donations continues to be a problem in subsequent years, and is not actually achieved until 2036. One significant factor in this is our assumption that demand will increase by 4% each year.

If we allow first donations to be used as well, the annual graph suggests that we might be able to meet the demand in 2022 or 2023. However, looking at the monthly breakdowns suggests that we would not meet demand in peak months until 2026. However, we need to remember that platelet shelf life is very short, and so there may be periods within the peak demand months where supply might still not fully meet demand.



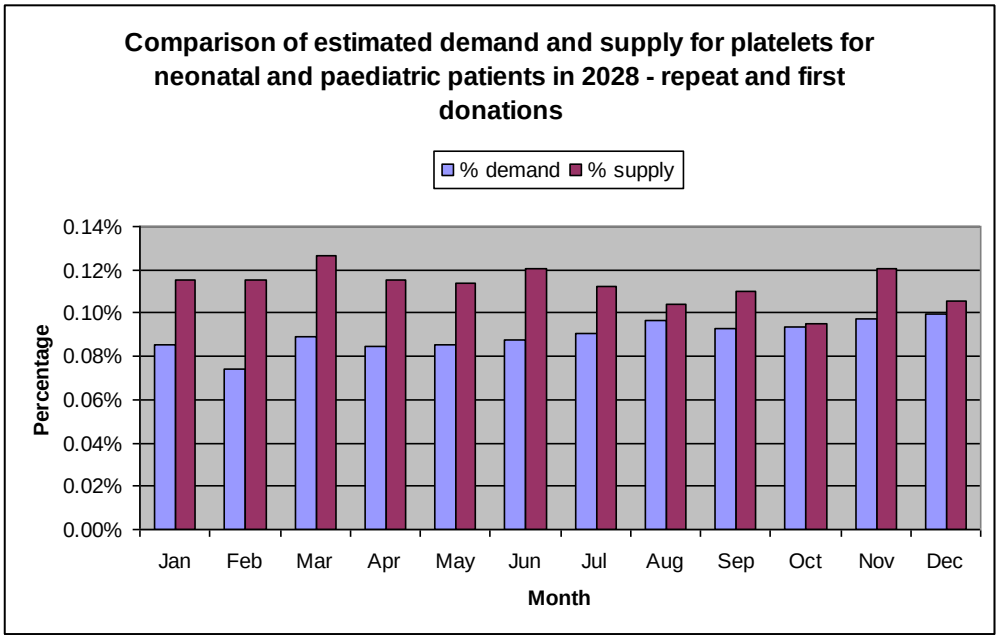


ii) Neonates + Paediatrics

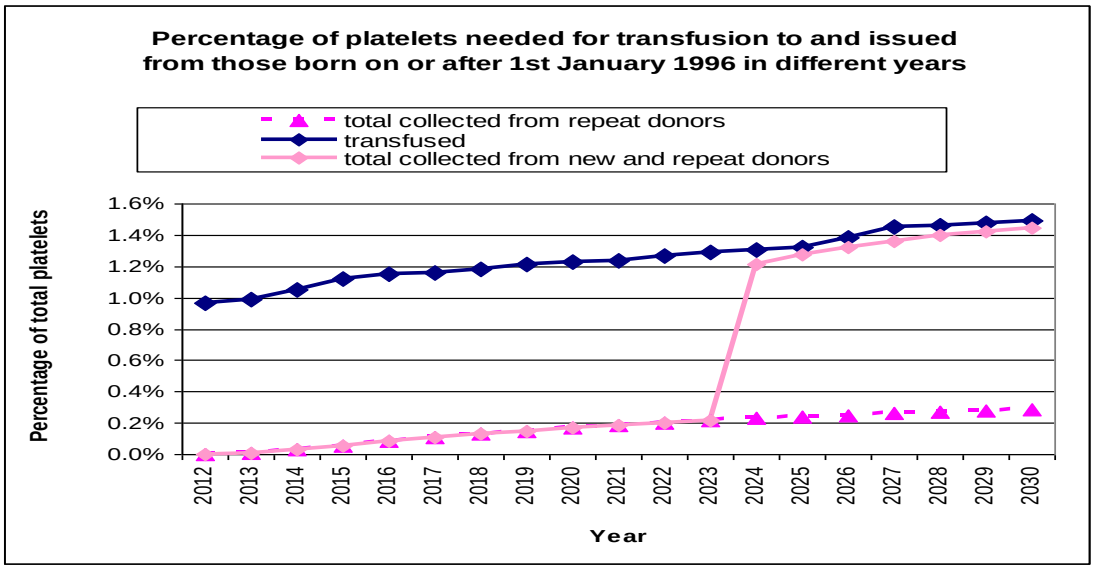


The above graph suggests that supply from repeat donations in 2030 would still be a long way below demand from neonates and paediatrics.

If we allow first donations to be used as well, the annual graph suggests that we might be able to meet the demand in 2024. However, looking at the monthly breakdowns suggests that we would not meet demand in peak months until 2028. However, we need to remember that platelet shelf life is very short, and so there may be periods within the peak demand months where supply might still not fully meet demand.



iv) Low vCJD risk Recipients



As before, the graph suggests that supply from repeat donations in 2030 would still be a long way below demand from all low vCJD risk patients. It also suggests that the supply will also fall short of the demand when we include first-time donations.

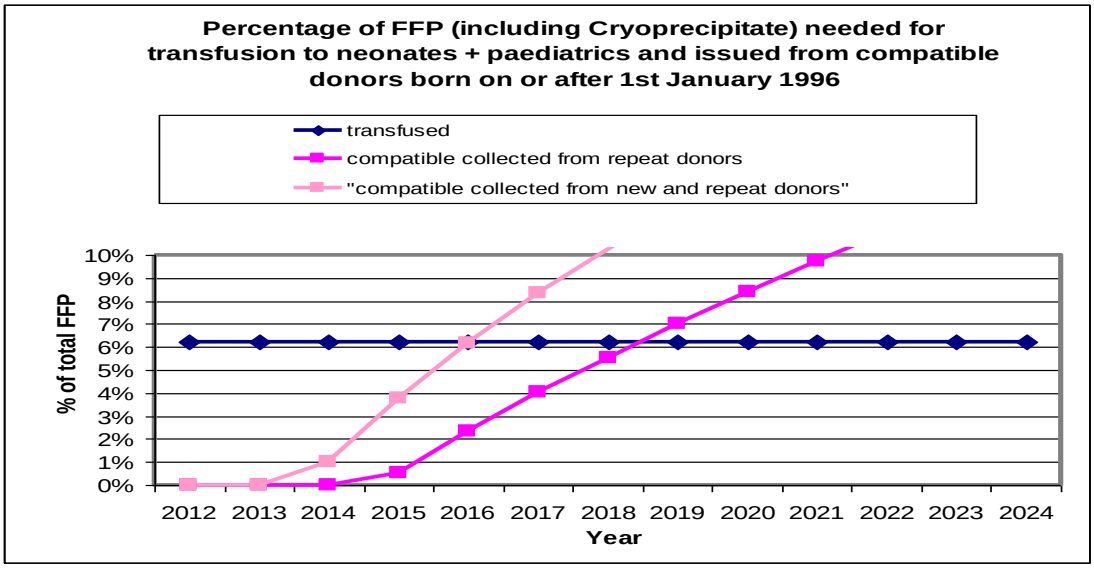
FFP / Cryoprecipitate

Plasma is required in the production of packs of platelets, and so some allowance needs to be make for this when we investigate the ability of low vCJD risk donors to meet demand for FFP and cruoprecipitate. Practically, this will depend on what priority is given to providing FFP compared to platelets. In particular, if platelets are given priority, then there will be a shortage of A- plasma available for a number of years.

For this analysis, we have assumed that a volume of plasma will be required for platelets equivalent to the amount required for meeting neonatal platelet demand, but have not considered at blood group level.

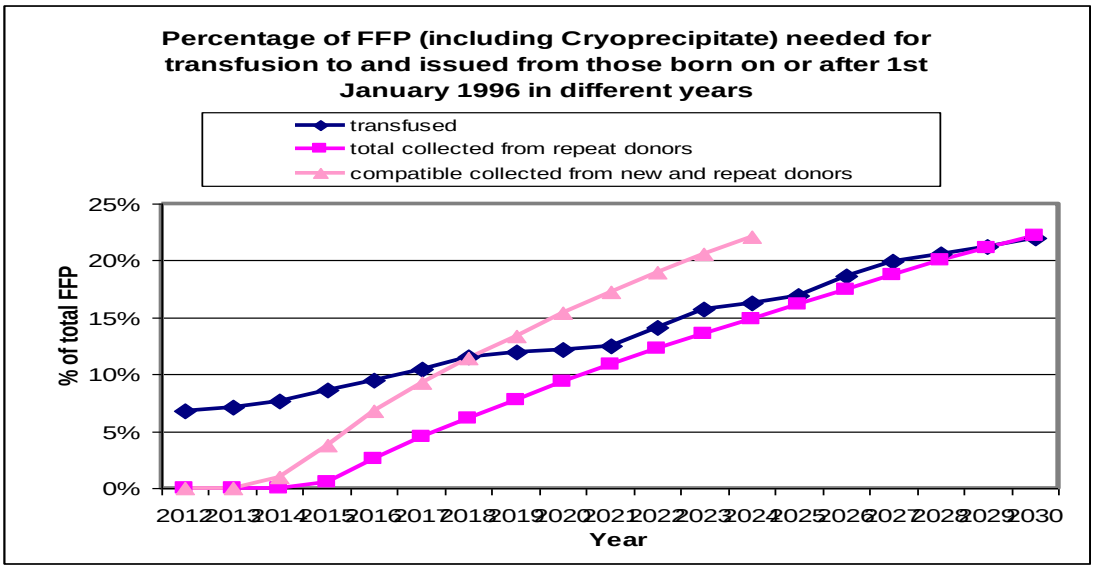
Figure 4.3c shows the percentage of FFP and Cryoprecipitate needed for transfusion to different groups and issued from compatible low vCJD risk donors. Both the projected donation from repeat donors and the donations from new and repeat donors are shown. We do not present a monthly analysis due to the shelf life of these products.

i) Neonates + Paediatrics



Looking at annual figures, the graph suggests that the demand from paediatric and neonate recipients could be met in 2021 from repeat male donations, or in 2017 if first male donations are allowed.

ii) Low vCJD risk Recipients



This graph suggests that the demand from all low vCJD risk recipients may be met from repeat male donors by 2030, or in 2020 if first male donations are allowed.

A number of assumptions and simplifications were made in this analysis. We consider the possible effect of these in Annex A.

5 Conclusions

- In 2013, individuals who were born on or after 1st January 1996 (who are considered have received minimal exposure to BSE) will be old enough to donate blood.
- Our analysis of the age distribution of donors suggests that, assuming no change in the recruitment strategy, ~4.5% of all donated red cells will come from those individuals considered 'low vCJD risk' to vCJD by 2017. The proportion of other blood components and for different patient groups will vary due to a different demand and different restriction on the properties of the donated blood.
- We used the number of red cells issued as IUTs, neonatal exchange, neonatal red cells and LVTs, along with the number of red cells transfused to patients, to estimate that the percentage of O- red cell demand for these components in the future will be 0.02%, 0.03%, 0.48% and 0.17%. We used information on transfusions to patients aged from 1 to the appropriate maximum age in the John Radcliffe trust to estimate that 3.2% of issued red cells will be required by paediatric patients, and to estimate the proportion of red cell demand that will come from patients in each year group from 16 to 30. Bringing these together, we estimate that demand from low vCJD risk recipients will comprise 4.4% of total demand in 2012, rising to 6.4% by 2017.
- The proportion of platelets required by low vCJD risk recipients is estimated to be 6.0% from the Pendry study in 2012 and is rising to 8.7% by 2017. The proportion of platelets required by neonatal recipients is estimated to 0.37% from NHSBT issues data for 2011.
- For FFP and cryoprecipitate, 4.9% of issued units will be required by low vCJD risk recipients in 2012, rising to 7.5% by 2017. 4.1% of FFP and Cryoprecipitate are required by neonates and paediatrics.
- The years indicated in the table below show dates when supply would meet demand for a combination of different patient groups.

Red cells

	Repeat donations only	Repeat and first donations
IUT recipients	2014	2013
IUT+ neonatal exchange red cell recipients	2015	2014
IUT+ neonatal exchange red cell and Neonatal red cell recipients	2022	2019
IUT+ neonatal exchange red cell and Neonatal red cell and LVT recipients	2025	2022
IUT+ neonatal exchange red cell and Neonatal red cell and LVT and Paediatric recipients[13]	2025	
All low vCJD risk red cell recipients	2025	

Platelets[14]

	Repeat donations only	Repeat and first donations
Neonatal platelet recipients	2036	2026
Neonatal platelet and Paediatric platelets		2028
All low vCJD risk platelet recipients		

:

Our analysis suggested that the provision of platelets for paediatric recipients from repeat male donations, and for low vCJD risk recipients from all male donations, from low vCJD risk donors would not be possible within the timescale investigated.

FFP and cryoprecipitate

	Repeat donations only	Repeat and first donations
Neonatal and paediatric FFP and cryoprecipitate recipients	2021	2017
All low vCJD risk FFP and cryoprecipitate recipients	Around 2030	2020

[13] This is inclusive of units used for low vCJD risk haemoglobinopathy patients but not additional matching requirements

[14] These figures present the “best case scenario” for matching of low vCJD risk donations for platelet production

Annex A: Assumptions and their possible effect on the results

A number of assumptions were made in this analysis:

- **Age distribution of donors**

We assume that the age distribution of donors will not change in future years. An analysis of the donor age breakdown in 2009, 2010, and 2011 shows that the relative numbers of younger donors has been declining slightly. The proportion of donations from 16 to 20 year-old compared to total donations dropped by approximately 0.3 percentage points a year over the last 3 years. If this trend continues, the percentage of blood components that could be issued from low vCJD risk donors will be less than projected (by a similar amount).
The assumed age distribution may also not hold if NHSBT pursue an active policy of recruiting more young donors. The results should therefore be treated as a baseline case (i.e. assuming no big changes in recruitment that would boost the proportion).

- **Expected percentages of platelets required for non-exposed patients**

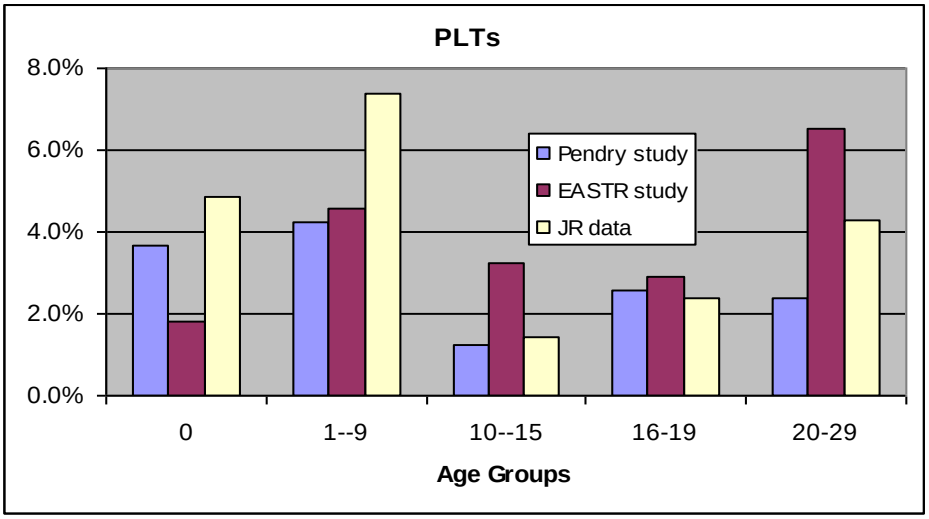
To assess the expected percentages of platelets required for non-exposed patients, we compared the following studies:

(1) Pendry study on the use and wastage of platelets in the North West of England and North Wales[15]. This study covers the period 2009-2010;
(2) EASTR study on the use of platelets in hospitals across England and North Wales.[16]. The volume of platelets transfused in this study is from 2001.
(3) The volume of platelets transfused in John Radcliffe hospital trust only. This data is from 2010/2011.

Figure below shows the expected percentage of platelets that would be required for non-exposed patients in future years as being calculated from these studies

[15] "*Where do Platelets go in the North West of England and North Wales? An audit of the use and wastage of platelets*" (2010) by Dr. Kate Pendry, Regional Transfusion Team and Transfusion Teams in Hospitals / Trusts in the North West of England and North Wales

[16] Llewelyn CA, Wells AW, Amin M, *et al* (2009): The EASTR study: a new approach to determine the reasons for transfusion in epidemiological studies. *Transfusion Medicine*, 19: 89–98



This shows that the distributions from the three different sources vary significantly, and provide no consistent picture. For our analysis we will use the Pendry study to estimate the platelet age distribution in the models as the Pendry study is far more recent than the EASTR study and is more representative on the national level than the study of use of platelets in John Radcliffe hospital trust.

- **Demographics changes in donor population**

We also looked into the effect of changing demographics on the overall population from which donors could be recruited. Donors can begin donating blood from the ages of 17 to 65. We used population projections from the Office of National Statistics to estimate how the proportion of 17 to 65 year olds compared to the whole population will change over the next 10 years. This is estimated to have an effect of less than 0.1% on our results and so for simplicity, is not included in the analysis.

- **Demographics changes and age distribution of recipients**

Blood components are used in many different usage areas in which the age profile of patients can be very different (for example, the age distribution for hip replacements peaks in the early 70's whereas the age distribution for some forms of acute leukaemia peaks in early childhood). If the relative blood usage in different areas changes substantially in the future, this may change the overall age distribution of blood recipients. To investigate the possible effect of this, we used estimates of the changing proportion of different usage areas in future years from our work on 'Demand Drivers'. This also incorporates any expected changes in population demographics. Figure A1 shows how we project the proportions to change between 2010/11 and 2020/21. Surgical usage is expected to decrease relative to usage in anaemia and haematology. We also show the percentage of red cells expected to be transfused to low vCJD risk recipients in different usage areas in 2012 (see Figure A2). A larger proportion of red cells are given for haematology and neonatal in children than in recipients overall. We estimated the overall age distribution in each year by weighting the age distributions in usage area by the changing proportions of blood use in each area. This was then used to determine the proportion of low vCJD risk to total recipients expected in each year.

Our new estimate for the proportion of red cells needed for low vCJD risk recipients is higher by 0.3% by 2016. This is due to the increased proportion of haematological patients of which a larger proportion are children. It is not, however, a large effect because most usage areas have similar patient age distributions. For simplicity, we do not include this modification in our final results: the projections are somewhat uncertain and would not affect the year in which low vCJD risk donors could meet low vCJD risk demand. However, it does provide an idea of the uncertainty in our estimate of the proportion of low vCJD risk recipients.

Figure A1: Percentage of red cells expected to be transfused in different usage areas in 2010/11 and 2020/21.

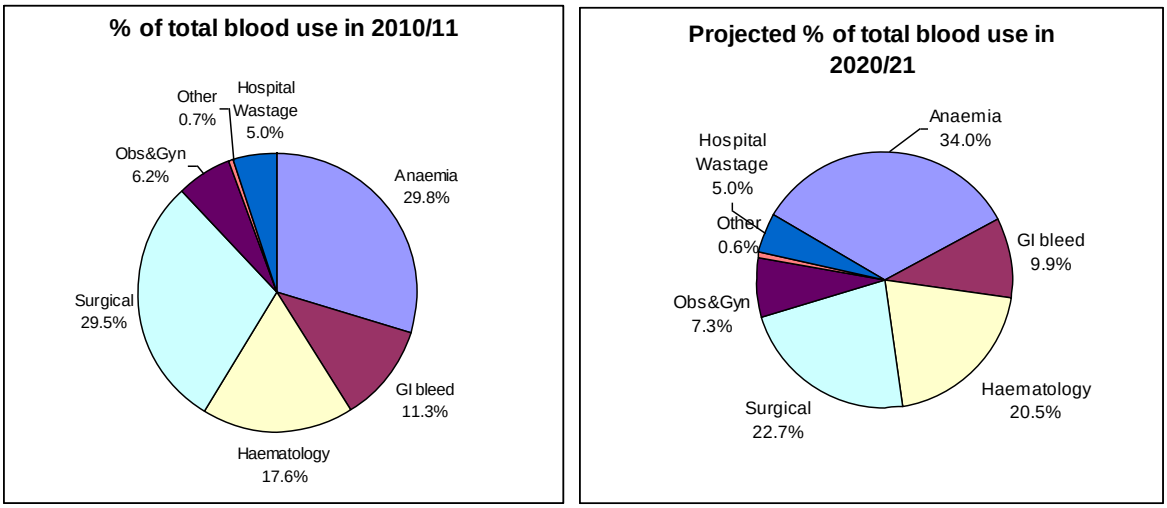
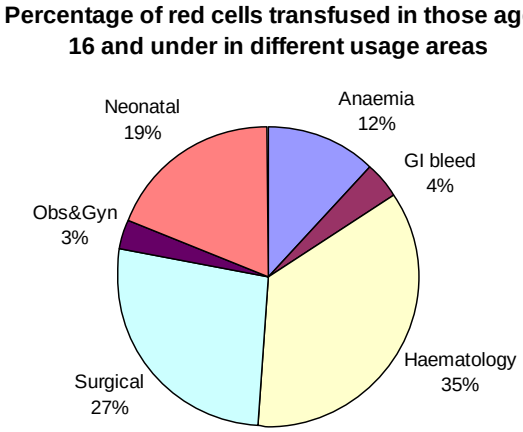


Figure A2: Percentage of red cells expected to be transfused to low vCJD risk recipients in different usage areas in 2012



- **Blood groups**

Where we do not have any specific indication, we assume that the proportions of different blood groups that are donated and transfused are the same. This is not strictly true (mainly because of substitution of different blood groups within hospitals), but should only be a relatively small effect. Meeting the demand for rarer blood groups and more complex matched blood types may be more of an issue due to the inherent variability that comes with lower volumes. NHSBT could

mitigate this effect by ensuring a larger difference between the fraction of low vCJD risk donors and recipients, before implementing any change in their supply chain.

- **Projections for platelet and FFP demand**

To determine the proportion of low vCJD risk donors for platelets and FFP, we require an estimate of the total demand in each year. If the growth is substantially different from that forecast, then this will affect the results.