

Recommendations for removal of the upper age limit for regular whole blood and component donors

These recommendations have been prepared by Drs Dorothy Stainsby and Mark Butler, at the request of the UK Blood Services Forum.

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1 Remit

The remit of this project was to evaluate available evidence of the safety or otherwise of accepting blood donors beyond the age of 70, and make appropriate recommendations.

We have **not** considered the need for any changes to existing legislation

2 Summary of recommendations

2.1 Following a review of available evidence outlined below we conclude that regular donors of whole blood and blood components can safely continue to donate beyond the age of 70, with no absolute upper age limit, provided that they meet UK Blood Services' donor acceptance criteria as assessed by routine procedures. (Grade B recommendation). We do **not** recommend any additional pre-donation screening or clinical observations for elderly donors.

2.2 We do not at present recommend a change to the upper age limit of 66th birthday for new and lapsed donors.

2.3 Implementation of this change of policy must be supported by monitoring and regular review of adverse events, together with a prospective study of recognised and previously unrecognised adverse events in elderly donors.

3 Background

Current UK legislation and guidance on age limits for whole blood and component donors are outlined in Appendix 1^{1,2}. Regular whole blood donors are obligatorily retired on reaching their 70th birthday, component donors on their 66th. Whilst the Age Discrimination Act 2006 does not apply to volunteers³, it has focussed attention on ageism, and an arbitrary upper age limit for blood donation is increasingly hard to justify.

Written complaints received by the National Blood Service indicate that there is a considerable degree of donor dissatisfaction with the obligatory upper age limit. Between April 2005 and March 2008, 107 complaints were received on this issue, including one from a Member of Parliament, and one from a donor who wished to lobby for a change in policy (Andrew Pearce, personal communication).

The prevalence of cardiovascular and cerebrovascular disease increases with age^{4,5}; this knowledge accounts for the cautious approach by the UK and other blood services to accepting older donors, who may theoretically be less able to tolerate the haemodynamic changes resulting from removal of a unit of blood, though an alternative view is that older subjects may be haemodynamically more stable¹⁵.

In assessing the advisability or otherwise of accepting donors beyond the age of 70, we have considered the following questions;

- Would raising the upper age limit increase the incidence of adverse reactions?
- Are any additional screening procedures or clinical observations necessary?
- Approximately how many donations might be gained?
- Should the same upper age limit apply to whole blood and component donors?
- Should the upper age limit for new donors be retained?

4 Methods

Evidence was obtained from the following sources;

4.1 Demographic data

4.1.1 Population life tables

4.1.2 Population projections

4.2 Blood service data

- 4.2.1 Donor age retirements
- 4.2.2 Age profiles of NBS blood donors
- 4.2.3 NBS data on donor adverse events

4.3 Review of key literature

4.4 Information from other blood services

4.5 Independent clinical advice

5 Results

5.1 Demographic data

5.1.1 Population life tables.

Data published by the Office of National Statistics indicate that healthy life expectancy is increasing, such that in 2004 a 65 year old male could expect to remain well for a further 12.5 years and a 65 year old female for a further 14.5.⁶ This trend towards healthy longevity seems set to continue.

5.1.2 Population projections

These tables predict numbers of people in various age bands over time, and take account of migration as well as birth and death rates. The data in Table 3 are extracted from the Office of National Statistics News Release 23rd October 2007⁷ and indicate predicted increases in the population aged 65-74 and >75 of 43% and 76% respectively in the 25 years from 2006

5.2 Blood Service data

5.2.1 Donor age retirements.

Estimated age retirements range from 8,000 to 10,000 per year from NBS, 400-500 from SNBTS. The effect of these is cumulative; each retirement loses potentially 3 donations per year, for possibly a 10 year period.

5.2.2 Age profiles of regular and new blood donors

It should be noted that caution is needed in interpreting these data, as there may be a degree of duplication of records of regular donors.

5.2.2.1 The age profile of the NBS active donorbase (Fig 1) suggests that annual age retirements will increase as the post-war population 'bulge' reaches 70+.

5.2.2.2 The age profile of new NBS donors (Fig 2) indicates that new donor recruitment tails off with increasing age.

5.2.3 NBS data on donor adverse events

Results of a retrospective study was undertaken, reviewing all vasovagal events recorded following whole blood and component donations during 2007, are presented in Table 4. The rate of vasovagal episodes per 1000 donations shows a downward trend with increasing age for all subclasses of reaction.

5.3 Literature review

Key references were obtained from the recent paper by Goldman et al⁷. The majority of these publications come from the US, where the upper age limit for blood donation was abolished by the FDA in the 1980s.⁸

Personal communication with Dr Mindy Goldman and a further Medline search yielded a further 5 relevant papers^{9,12,13,14}.

Data from 11 papers^{7,8,9,10,11,12,13,14,15,16} are summarised in chronological order in Table 1, and the level of evidence of safety has been evaluated.

There were four cohort studies^{7,8,13,14} in which the response to blood donation in elderly donors was compared to that in younger donors. These showed no excess of adverse reactions in older donors (up to age 78), and no significant difference in physiological compensatory mechanisms. One of these studies included a preliminary retrospective review of donor adverse reactions by 5 year age band and reported a statistically significant decrease of mild vasovagal reactions with advancing age, and a reduction in moderate and severe reactions after age 45⁸.

A randomised controlled trial comparing a group of elderly donors with non-donors¹⁰ found no difference in pulse and BP measurements after postural shift from lying to standing. The study group had not given blood for a year or more and this was the only study that included some subjects who could be regarded as novice donors. This study also included longitudinal observation of 900 donations from these elderly donors and reported no severe reactions, 73 mild reactions, and a progressive decrease in frequency of reactions as the number of donations increased.

Two retrospective observational studies were reported^{9,12} and raised no safety concerns. A further uncontrolled observational study of regular blood donors (aged 55-69) concluded that removal of 450ml blood is tolerated in older, cardiovascularly asymptomatic people without impact on microcirculation.

A case-controlled retrospective multicentre study of 1890 donors with syncope found no increase of incidence of adverse reactions with increasing age and concluded that older repeat donors were unlikely to experience syncopal reactions¹⁵. First-time donors of all ages were 5 times more likely to faint than repeat donors.

Only one of these investigations indicated an adverse effect on donor health¹¹; this was a subgroup of the RCT¹⁰ which monitored the iron stores of 57 donors, all of whom had given 5 donations over a 12 month period. Four donors became

iron deficient and one developed anaemia. This donation frequency exceeds that allowed by UK guidelines.

Two studies addressed the issue of external medical assessment of fitness to donate^{7,10}. One¹⁰ concluded that there was no need to design special or additional questionnaires or to create special restrictions for elderly donors, the other⁷ concluded that extra steps in the donation process, such as an external medical enquiry, may not be necessary.

A retrospective review¹⁴ of 4.1 million donations, of which 3.9 million were allogeneic, found 33 very severe outcomes (VSOs), defined as requiring hospitalisation. Sixteen (48.5%) of these VSOs occurred in donors >60 years old and the authors commented that the frequency of severe reactions among older donors was 'striking, given the relative under-representation of such donors'. It should however be noted that only 5/16 older donors with VSOs were allogeneic.

In addition, there are numerous publications confirming the safety of autologous donation in the elderly. These donors are by definition not fully fit, and most are novice donors, therefore these studies are not directly relevant to this paper. Because there are ample good data relating to volunteer donors, we have not reviewed the literature on autologous donation. If in the future the upper age limit for new donors is re-evaluated, then the literature on autologous donation should be reviewed.

5.4 Information from other blood services

Information regarding other blood services' upper age limit for donation and their experience of older donors was obtained via NBS International and from websites. Results are summarised in Table 2.

Two blood services have documented experience of elderly donors. The Canadian Blood Services have only recently removed the upper age limit, following a careful pilot study⁷. The American Red Cross has long experience of elderly donors and has recently initiated a comprehensive haemovigilance programme including complications of blood donation. Their analysis of donor adverse events reported in 2006 (Dr Anne Eder, personal communication) provides compelling evidence of the safety of whole blood and apheresis donation by elderly donors.

The incidence of various complications of donation analysed by age range is shown in Figs 3 and 4.

Complication rates decreased with increasing age for both first-time and repeat donors (data not shown), however donors 80 years or older had a small but significant increase in the overall rate of complications at the venepuncture site compared to donors aged 70-79, accounted for by an increase in the incidence or small haematomas.

It is also of note that there was no recorded delay in haemoglobin recovery between consecutive donations at standard time intervals. (Dr R Benjamin, personal communication)

5.5 Independent clinical advice

Independent advice was sought from Prof James Barrett, Honorary Professor of Healthcare of Older People, Liverpool John Moore's University and from Prof Pali Hungin, Dean of Medicine and Professor of Primary Care, Durham University.

Prof Barrett advised that there is no requirement for an upper age limit for blood donation (for either existing or new donors) based on health concerns, and that no additional precautions are required when managing blood donors aged over 70. He did not consider that blood donation was likely to accelerate clinical manifestation of covert cardiovascular or cerebrovascular disease.

Prof Hungin's opinion was that 70 need not be a cut-off age provided the donor does not have inter-current problems. He considered it highly unlikely that a donor would have completely covert cardiovascular disease and was not aware of blood donation accelerating the course of disease. With regard to additional precautions required, he expressed some concern regarding the risk of postural hypertension, but considered that this could be addressed by appropriate clinical management at the time of blood donation.

6 Discussion

6.1 Would raising the upper age limit increase the incidence of adverse reactions?

Evidence from published and unpublished experience with older donors is that vasovagal reactions are less common in older donors^{7,8,9,10,12,13,15,16,17} and expert opinion is that there are no other major health concerns that might discourage a change in policy.

There is some evidence to suggest that haematoma formation may be more common in very elderly donors (Dr Anne Eder, personal communication).

Risks of adverse reactions to component collection are discussed in para 6.4

We found no documentation of delayed haemoglobin recovery with age based on standard donation intervals. In the single study that reported falling iron stores in elderly donors¹¹, the study group were bled five times in 12 months.

6.2 Are any additional screening procedures or clinical observations necessary?

The UK blood services rely on rigorous donor selection procedures to ensure the safety of donors and recipients. These procedures should be equally effective across all age groups, with external referral required only in exceptional circumstances when additional clinical information is required.

The value of routine external medical referral was assessed as part of the implementation of acceptance of older donors by the Canadian Blood Services⁷. Following referral to the family physician, 18/862 (2%) of prospective donors were deferred. The authors concluded that it was 'likely that the conditions noted as reasons for deferral would have been elicited on donor health examination' and that external medical enquiry 'may not be necessary'.

Some blood services routinely measure blood pressure pre-donation, however there is no consensus on acceptable limits, and moreover the phenomenon of 'white-coat hypertension' is well recognised. Endorsement of current UK policy not to routinely measure blood pressure pre-donation was obtained in 2002 by Dr Frank Boulton from Prof Bryan Williams, Professor of Medicine, University of Leicester Faculty of Medicine and Biological Sciences, and President of the British Hypertension Society, and from Prof Eoin O'Brien, Professor of Cardiovascular Pharmacology in Dublin (Dr Virge James, personal communication).

6.3 Approximately how many additional donations might be gained?

Calculation of possible donations gained is a complex mathematical exercise incorporating several unknown factors. If 9,000 donors are retained each year in England and Scotland, and each donor attends twice a year, then the maximum possible donations gained would be 18,000 in year 1, 36,000 in year 2, 54,000 in year 3, 72,000 in year 4 and 90,000 in year 5. Deferrals and 'drop-outs' have not been factored into this estimate, and its validity is uncertain!

6.4 Should the same upper age limit apply to whole blood and component donors?

The American Red Cross group (Dr Anne Eder, personal communication) found that, across all age groups, the incidence of systemic reactions was lower for automated plateletpheresis and slightly (but significantly) higher for double red cell collections compared to whole blood donation, whilst the rate of major reactions was significantly lower for both platelet and double red cell collection. Differences between successive age bands after age 30 were not statistically significant.

6.5 Should the upper age limit for new donors be retained?

Although some of the above studies included both first-time and repeat donors, it has not been possible to extract good data on reaction rates in elderly first-time donors.

The age profile of new donors suggests that removal of the upper age limit for first-time donors would not result in a large number of new recruits.

Finally, whilst removal of the upper age limit for repeat donors in the UK would allow the service gradually to gain experience with an ageing donor population, removal of the upper age limit for new donors would require some difficult clinical decisions by session staff.

Table 1: Summary of literature relevant to safety of older donors

Reference	Year of publication	Type of study	Methods	Results	Level of evidence of donor safety
8	1987	Cohort study	<p>Preliminary study: donor adverse reactions reviewed by 5 year age bands</p> <p>2 groups of previous donors recruited & assessed as eligible by normal selection criteria</p> <p>504 aged 66-78 (study group)</p> <p>510 aged 52-65 (controls)</p>	<p>5123 donations reviewed</p> <p>Mild vv reactions decreased with advancing age ($p < 0.0001$)</p> <p>Moderate and severe vv reactions less frequent after age 45 ($p < 0.0001$)</p> <p>8/504 older donors had mild reactions, no severe reactions</p> <p>7/510 control donors had mild reactions. One of controls had fatal MI 2 days post-donation</p>	<p>2b</p> <p>2b</p>
9	1987	Observational study (retrospective)	Retrospective review of donor adverse reactions	1145 donations from volunteer donors aged 66-78, no adverse reactions recorded	4
10	1991	RCT	<p>325 healthy volunteers >63 yrs who had not donated blood for >1 yr were assessed according to donor eligibility criteria and randomised into donors and controls. Mean age 68 (range 63-77)</p> <p>Assessed at 8-10 week intervals for 1 year; at each visit 1 unit of blood taken from donors, 7ml sample from controls Iron status monitored in both groups (see 6)</p> <p>Clinical assessment at each visit; BP and pulse lying and standing, repeated following venesection.</p>	<p>325 potential subjects; 51 disqualified, 23 dropped out. After additional medical screening a further 2 excluded. 244 randomised. 31 dropped out during study, 13/31 due to illness</p> <p>900 donations taken from donor group. 51 occasions when donation deferred</p> <p>No severe reactions, 10 moderate reactions, 73 mild reactions; frequency decreased as number of donations increased.</p> <p>Both groups had reduction in pulse and BP after shift from lying to standing; no difference between donors and controls</p>	1b
11	1991	RCT	<p>Subgroup of study 8. Iron stores observed in donors and non-donors</p> <p>57 healthy volunteers aged 63-77</p> <p>Each donated 5 units of blood over 12 months.</p>	<p>At entrance, iron stores averaged 724mg in women, 875 in men. After 5 donations, mean iron stores had fallen to 67mg in women, 362mg in men. 4 women became Fe deficient and 2 developed anaemia.</p> <p>Concluded that 5 donations a year is</p>	n/a

Reference	Year of publication	Type of study	Methods	Results	Level of evidence of donor safety
			Control group of non-donors gave 7 ml sample.	excessive!	
12	1991	Observational study (retrospective)	Retrospective review of adverse reactions in 50,000 donations from donors over 65 since 1978	2 major cardiac problems; 68 yo woman with history of angina had massive MI 4 d post-donation 74 yo man had MI at session but before donation.	4
13	1992	Cohort study	Cardiovascular response to phlebotomy measured in previous blood donors, both normal and hypertensive; 464 aged 52-65 and 532 aged 66-78. BP and pulse rate measured supine and sitting, before and after removal of 500ml of blood.	No serious adverse effects; mild effects rare in both groups (<2%) Age was not an independent predictor of BP change after either phlebotomy or postural change. 25% of both groups lowered their systolic BP by =10mm Hg. More older subjects (15.2%) than controls (6.9%) had a drop of =20mm Hg post-phlebotomy, but this did not persist after correcting for higher initial systolic BP in older group.	2b
14	1995	Observational study (retrospective)	Retrospective review of very severe outcomes (requiring hospitalisation) in 4.1 million donations, including 218,190 autologous.	33 VSOs occurred, of which 16 (48.5%) were in donors >60 years old. 11 of these were autologous donors.	n/a
15	1998	Cohort study	Investigated effects of 450ml blood donation on physical fitness (assessed by treadmill exercise tolerance) and haemorheology (assessed by plasma viscosity) of 24 regular elderly allogeneic blood donors (aged 63-69 mean=65). Results compared to 23 younger donors (aged 55-62, mean=58) and 7 elderly non-donors (63-68 mean=65)	Mean exercise tolerance increased on day+1 in all groups but was only significant in the younger group and there was no significant difference between the groups. PV decreased significantly after donation in both groups of donors. Concluded that older donors and younger controls showed similar compensating mechanisms.	2b
16	1999	Case-controlled multicentre study	Retrospective case-controlled study of 1890 blood donors with syncope. Case controls and random population controls used to determine the significance of individual variables	Young age is the most significant variable, followed by low weight and first time donation. Study concluded that older repeat donors are unlikely to experience syncopal reactions.	3b

Reference	Year of publication	Type of study	Methods	Results	Level of evidence of donor safety
			variables		
17	2001	Uncontrolled observational study	Effect of 450ml blood loss on red cell count, plasma viscosity, protein concentration, haematocrit and tissue perfusion (using laser Doppler) in 42 regular blood donors aged 55-69	Median rapid water shift of 208ml. Haemodilution led to a decrease in hct, protein conc and pv. No changes in cutaneous microcirculation. Concluded that moderate blood loss is tolerated in older cardiovascularly asymptomatic people without impact on microcirculation.	4
7	2007	Cohort study	Regular donors permitted to continue whole blood or apheresis donation past their 71 st birthday conditional on external medical assessment. Rates of adverse reactions and deferrals compared to other age groups	961 donors (54% of those contacted) volunteered. 862 were assessed; 98% considered fit. 659 donors attended, 93% successfully donated. None deferred for high risk activities and no pos viral markers. One mod/severe donor reaction from 3137 donations. Reaction rates in donors over 71 not significantly different from rates for all other donors.	2b

Table 2

Experience of other blood services

Blood Service	Upper age limit	Experience of donors >71 years of age
American Red Cross ¹⁸	New donors – no upper age limit Repeat donors- no upper age limit Applies to whole blood and apheresis donors	Analysis of donor adverse events reported to ARC donor haemovigilance in 2006. Complication rates decreased with advancing age for first time and repeat donors. Donors aged >80 had small but significant increase in overall complications compared to 70-79, primarily reflecting increase in incidence of small haematomas (see figs 3,4)
Australian Red Cross ¹⁹	New & regular blood donors - to 71 st birthday. New apheresis donors to 61 st birthday Existing apheresis donors to 66 th birthday Thereafter with annual written medical approval. Absolute upper age limit 81	Not documented
Canadian Blood Services ²⁰	New donors – to 61 st birthday Repeat donors – to 71 st birthday. Thereafter at medical discretion. Upper age limit removed in 2004. Pilot study preceded full implementation ³	One mod/severe donor reaction in 3137 donations from donors >70. Reaction rates in donors over 71 not significantly different from rates for all other donors ³ . Change in policy continues to 'go well' (Dr M Goldman, personal communication)
New Zealand Blood Service ²¹	New donors – to 60 Repeat donors –to 71 birthday	none
EFS (France)	New donors – age 60 Repeat donors – up to 66 th birthday	None. Upper age limit for registered donors currently under review (Dr Gilles Follea, personal communication)

Figure 1: Profile of NBS active donorbase by age

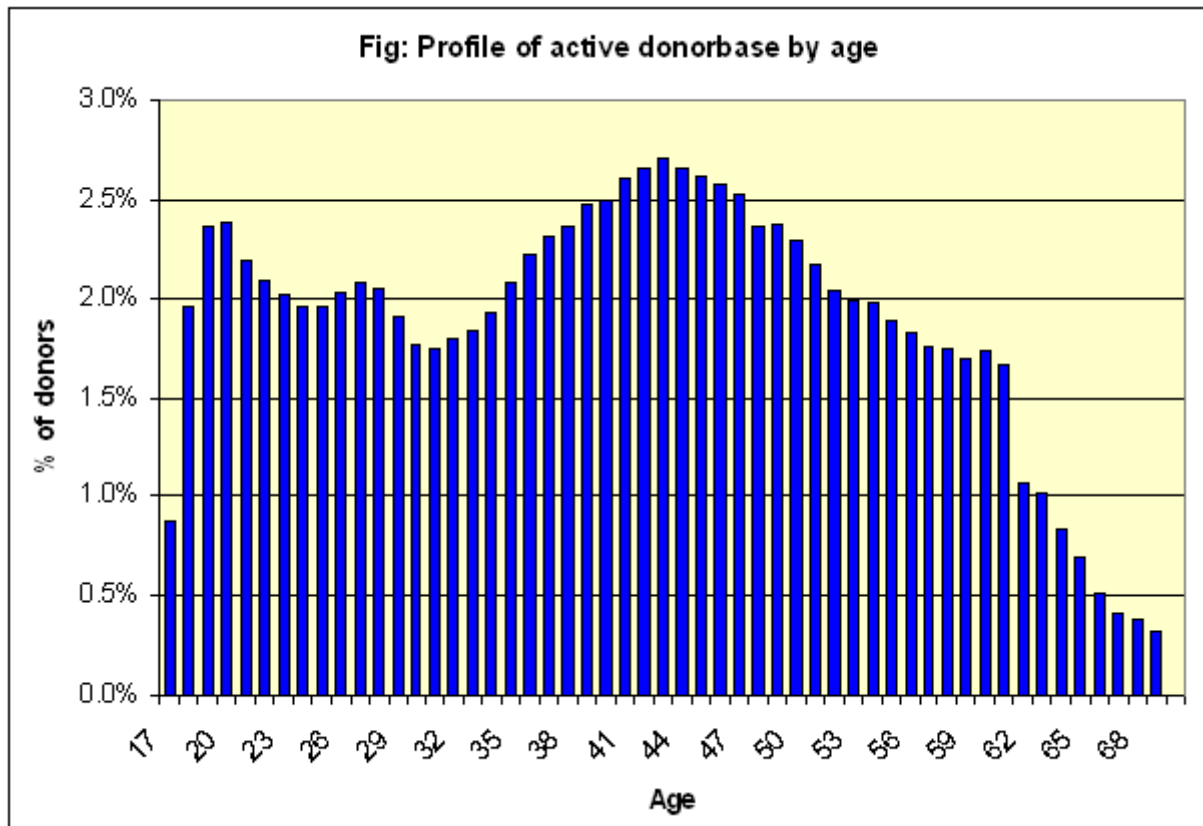


Figure 2: Age profile of new donors

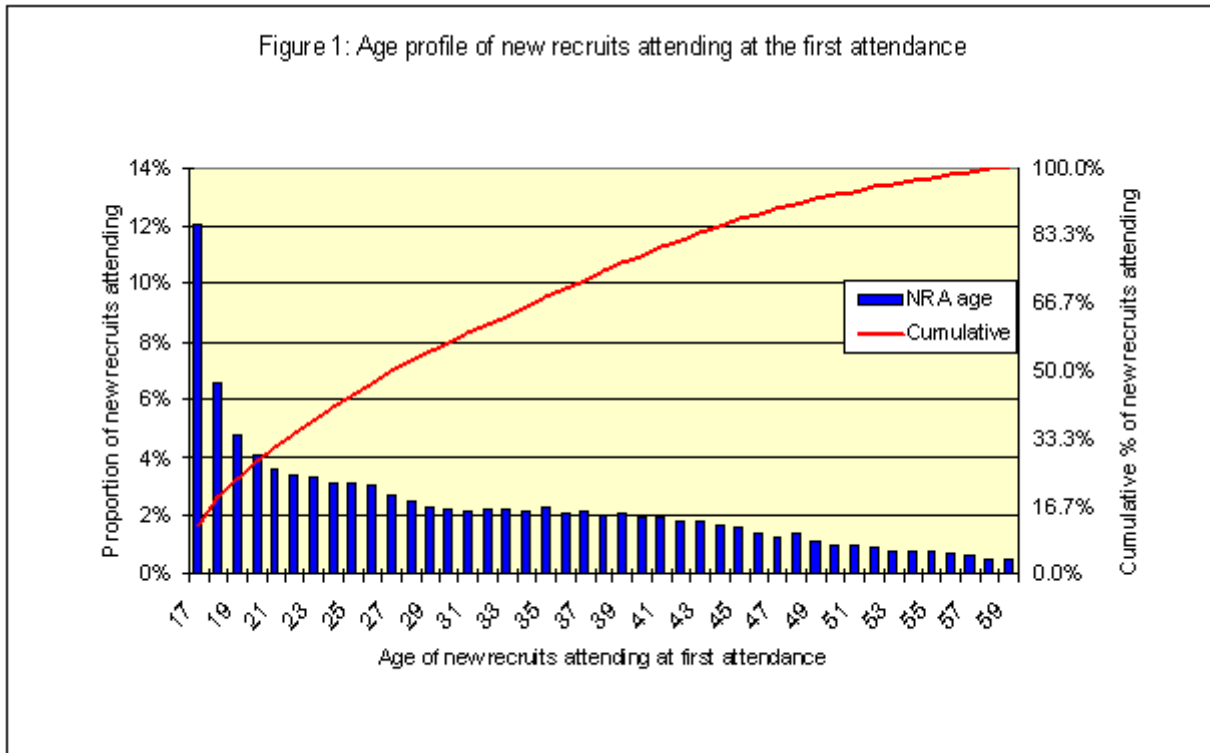
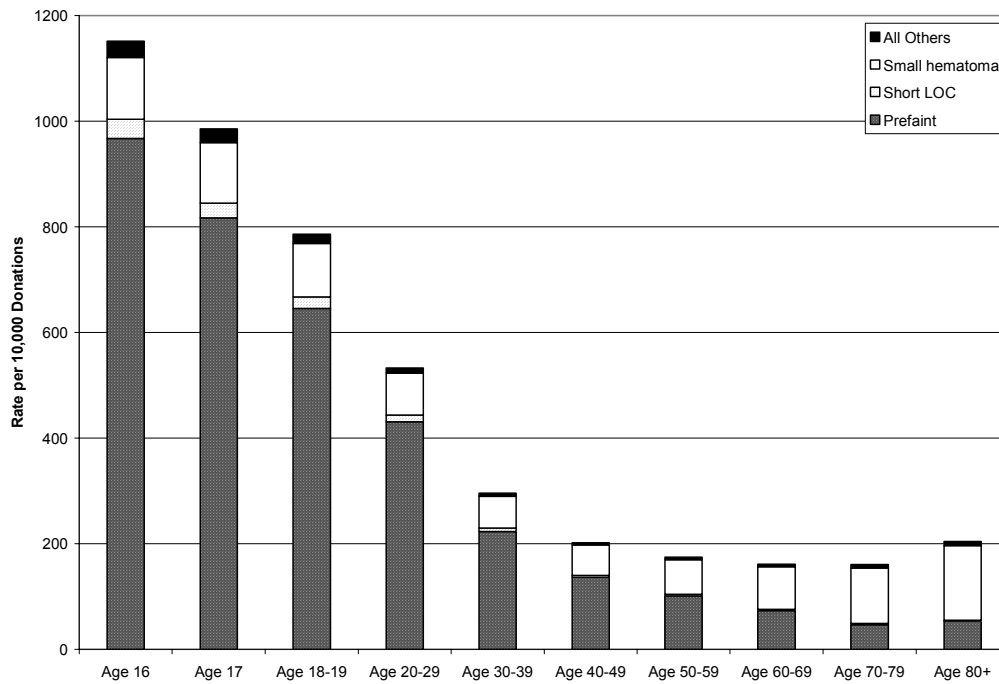


Figure 3: Rates of Donor Complications Associated with Allogeneic Whole Blood (WB) Donation.

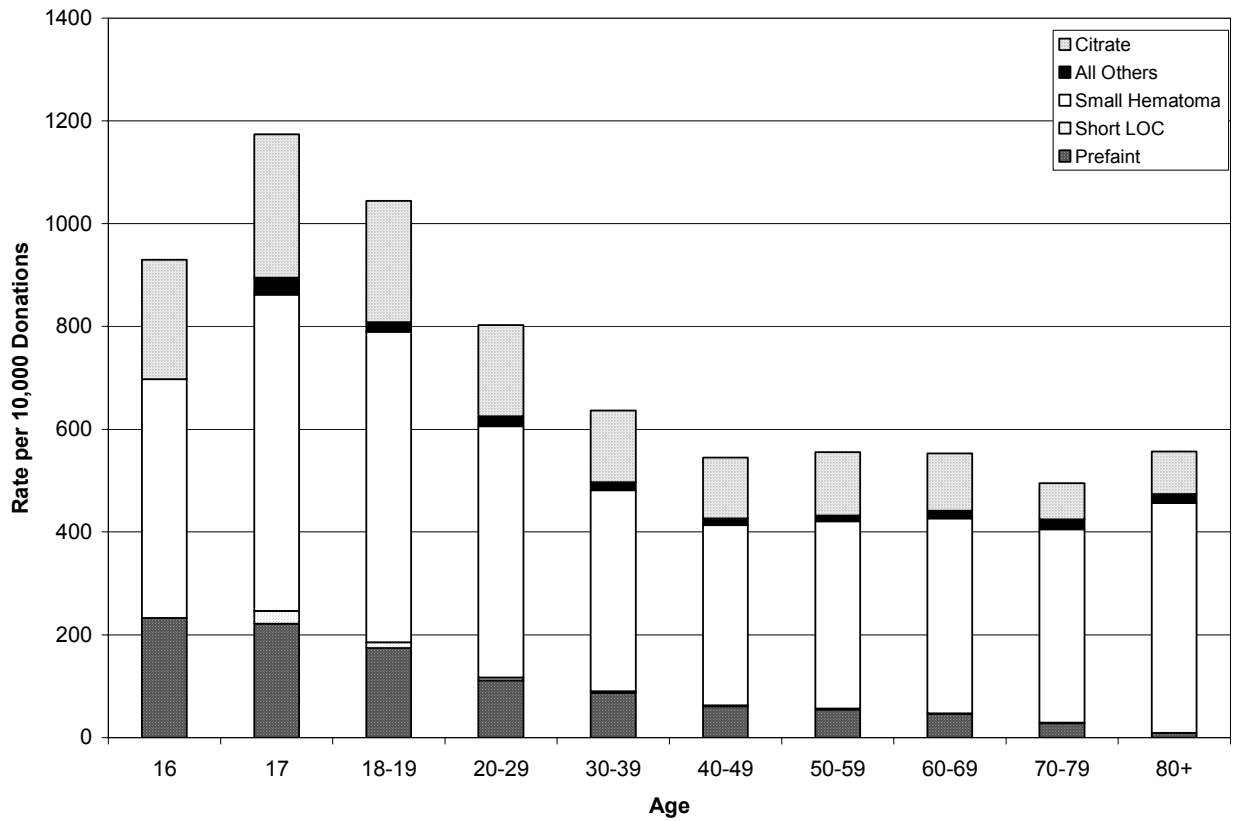
The overall rates are statistically significantly ($p < 0.05$) different between each successive age group, except between 60-69 and 70-79 years. (unpublished data courtesy of Dr Anne Eder)



Total donations	Age 16	Age 17	18-19	20-29	30-39	40-49	50-59	60-69	70-79	80+
	46,275	404,042	424,624	812,196	822,438	1,319,317	1,314,918	616,879	223,185	30,553

Figure 4: Rates of Donor Complications Associated with Apheresis Platelet (PLT) Donation.

Differences in overall rates between successive age groups are not statistically significant ($p < 0.05$) except for between 18-19, 20-29 and 30-39 years. (Unpublished data courtesy of Dr Anne Eder)



Total donations	43	1,218	3,560	26,986	44,812	119,535	156,890	72,477	21,771	2,300
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Table 3

Adapted from Office of National Statistics News Release 23rd October 2007

Table 2

Projected population by age, United Kingdom, 2006-2031

Ages	2006	2016	2026	2031	% rise
60-74	8,269,000	9,824,000	11,035,000	11,802,000	43
75 and over	4,659,000	5,480,000	7,477,000	8,223,000	76

Table 4**Vasovagal reaction rates for whole blood and component donations by donor age band****12 months Jan-Dec 2007**

Age range	17-20	21-30	31-40	41-50	51-60	61-65	66-70	Total
Total attendances	107225	306349	391296	571740	489867	161825	62643	2090945
VV1 (No)	6223	8749	4946	4023	2998	724	179	27842
Rate/1000	58.0	28.6	12.6	7.0	6.1	4.5	2.9	
VV2 (No)	629	744	390	385	347	90	31	2616
Rate/1000	5.9	2.4	1.0	0.7	0.7	0.6	0.5	
VV3 (No)	245	372	171	157	150	35	13	1143
Rate/1000	2.3	1.2	0.4	0.3	0.3	0.2	0.02	
DV1 (No)	59	128	70	111	83	31	10	492
Rate/1000	0.6	0.4	0.2	0.2	0.2	0.2	0.15	
DV2 (No)	73	128	71	78	80	36	16	482
Rate/1000	0.7	0.4	0.2	0.13	0.16	0.2	0.26	
DV3 (No)	19	38	22	19	35	18	5	156
Rate/1000	0.2	0.12	0.05	0.03	0.07	0.1	0.08	

Vasovagal events are classed as either immediate (i.e. occurring at the session venue) or delayed (i.e. after the donor has left the session venue). They are classified according to severity as follows:

VV1/DV1 Felt faint, no loss of consciousness

VV2/DV2 Fainted, loss of consciousness, without complications

VV3/DV3 Fainted, loss of consciousness, with complications (nausea, vomiting, delayed recovery, physical injury)

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20. Canadian Blood Services: Blood donor eligibility guidelines (2008)
http://www.blood.ca/centreapps/internet/uw_v502_mainengine.nsf/page/E_Can_I_Donate
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Appendix 1

Current UK Legislation and guidance on age eligibility of blood donors

Blood Safety and Quality Regulations 2005²¹

Age	18 to 65 years	
	17 years	Where, in the opinion of a qualified health professional, the donor has sufficient knowledge and understanding of what is involved in the process of blood donation to give their informed consent, or otherwise with the written consent of a person with parental responsibility.
	First time donors over 60 years	- at the discretion of the doctor in the blood establishment
	Over 65 years	- with permission of the doctor in the blood establishment, given annually

UK Blood Services Guidelines on Care and Selection of Donors²²

Obligatory

Component Donors.

Must not donate if:

Under eighteen years of age.

They have had their sixty-sixth birthday.

They have not previously given a whole blood donation without untoward effects.

Whole Blood Donors.

Must not donate if:

Under seventeen years of age.

They are a first time donor who has had their sixty-sixth birthday.

They are a donor who has previously given blood and who has had their seventieth birthday.

Additional Information

The lower age limit takes account of national laws on age of consent. Upper age limits have traditionally been set to protect the health of the donor. There is however little evidence to support this and many blood services have now set aside an upper age limit. Whole blood donors have been accepted in the UK until their seventieth birthday since 1998. An audit has shown a decrease in adverse events in older donors compared to younger donors.

Provided older donors remain in good health they may continue to be accepted safely within these guidelines. As with all donors they are

assessed for their fitness to donate at every attendance.

Donors may be accepted on their birthday.

Reason for change

To introduce guidance that is compliant with the Blood Safety and Quality Regulations 2005.

The upper age limit for component donors has been increased in line with the upper age limit for first time whole blood donors. The position regarding donating on birthdays has been clarified.