International Forum on Mitigation Strategies to Prevent Faint and Pre-faint Adverse Reactions in Whole Blood Donors

 Responses

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Norway

Lise Sofie H. Nissen-Meyer

Question 1
There are national regulations about predonation weight, blood pressure, pulse and hemoglobin levels, and also regulations about donor information, but not more specific measures to prevent complications. In the questionnaire, the donor is asked about previous (repeated) fainting episodes, which will be carefully considered.

The Norwegian Directorate of Health “Helsedirektoratet” has issued standards of transfusion medicine including standards about blood donation.

Question 2
All donor reactions are reported in the local hospital system for adverse events. Serious reactions are reported online to the national haemovigilance system (Hemovigilans.no). Hemovigilans.no publish statistical reports every year.

The following are reported to Hemovigilans:

- reactions with injuries
- faint reactions
- pre-faint reactions; only if prolonged or requiring treatment
- reactions reported by donors post-donation, if serious
- Local reactions are recorded within the hospital system, if serious also to Hemovigilans. Mild and moderate systemic reactions are reported locally within the hospital system

Question 3
No

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Question 4

Yes, general written information for donors provided before donation is in accordance with the specific standard.

- The information provided as a written pamphlet pre-donation, oral form by staff, website link, and we are preparing an information movie.
- Information is routinely given before first donation, and in an ad hoc way at later donations.
- The following elements are included:
  - description of the donation process
  - information about hydration
  - There is no information about salt intake or Applied Muscle Tension (AMT)

Question 5

The minimum age for whole blood donation is 18 years (specific standard) without extra criteria except 5 minutes extra on donation chair.

Question 6

The maximum age for whole blood donors:

- First time donors are allowed until 65 (new donors above 60 are interviewed by MD; specific standard)
- Repeat, regular donors above 65 are annually medically evaluated using an extra questionnaire (specific standard). Very healthy individuals can be allowed to donate also above 75 years
  - Donors above 65 are annually evaluated with a questionnaire containing 12 questions to reveal possible age-dependent health issues. If completely healthy they are approved for another year or until a health issue presents.
Question 7

All donors are offered drinks throughout their stay at the donation site, without distinguishing between pre/post donation.

- We offer a variety of drinks, from water to coffee, including soda water, soft drinks with or without sugar, ice tea. Not milk. We strongly encourage them to drink at least 0.5 l liquid (of their own choice) during their stay at the donation site.

Question 8

i.) Only donors who have not eaten for several hours, are routinely offered food. They are offered a sandwich/crispbread or two before donation. For others, snacks are freely available.

- We offer sandwiches, crispbread, bananas, sweet biscuits and sometimes salty crackers.

- The snacks are simply available and have not been specifically chosen for their salt content.

ii.) Post-donation on the donation site, no routinely offers but snacks are available as described.

Question 9

We do not encourage donors to perform applied muscle tension exercises (AMT).

Question 10

As a local policy, we have work instructions about how long the donor should stay on the donation chair before going to the refreshment area, or to an additional rest chair before the refreshment area:

- Repeat donors are encouraged to stay on the donation chair for 10 min

- First-time donors for 15 min

Question 11

We have not performed any local studies to inform our policies, or evaluate post-implementation results.
In a study of donors using antihypertensive medication, we asked how much they drink in connection with blood donation. Almost everybody drink >0,5 l and the mean intake was 0,65 l.

Lise Sofie H. Nissen-Meyer

Blodbanken i Oslo

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Question 1

There is no national standard or regulation that specifically covers mitigation strategies to prevent faint or pre-faint complications. We follow those mitigation strategies in Standards for Blood Banks and Transfusion Services of AABB to develop our local measures.

Question 2

All post donation adverse reactions are documented according to the classification of ‘Standard for Surveillance of Complications Related to Blood Donation’ of ISBT in 2014 with slight modifications.

The categories of the complications are summarized in below table:

<table>
<thead>
<tr>
<th>Generalized Symptoms (Vasovagal Reactions)</th>
<th>No loss of consciousness</th>
<th>Loss of consciousness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Duration</td>
</tr>
<tr>
<td></td>
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<td>Duration: &lt; 60 seconds</td>
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<td>Duration: &gt;= 60 seconds</td>
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<td></td>
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<td>2. Convulsion or Incontinence</td>
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<td></td>
<td></td>
<td>Without convulsions or incontinence</td>
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<tr>
<td></td>
<td></td>
<td>With convulsions or incontinence</td>
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<td>3. Injury</td>
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<td></td>
<td>Without injury</td>
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<td></td>
<td></td>
<td>With injury</td>
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<tr>
<td>Localized Symptoms</td>
<td></td>
<td>Blood outside vessel</td>
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<tr>
<td></td>
<td></td>
<td>Hematoma</td>
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<td></td>
<td></td>
<td>Arterial Puncture</td>
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<td></td>
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<td>Delayed Bleeding</td>
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<tr>
<td>Arm pain</td>
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<td>Nerve injury / irritation</td>
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<td>Duration &lt; 12 months</td>
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<td>Duration &gt; 12 months</td>
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<tr>
<td></td>
<td></td>
<td>Other arm pain</td>
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<tr>
<td>Localized infection / inflammation of vein or soft tissues</td>
<td></td>
<td>Superficial thrombophlebitis</td>
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<tr>
<td></td>
<td></td>
<td>Cellulitis</td>
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<tr>
<td>Apheresis related</td>
<td></td>
<td>Citrate reactions</td>
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<tr>
<td>Haemolysis</td>
<td>Air embolism</td>
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<td>------------</td>
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<td></td>
</tr>
<tr>
<td>Allergic reactions</td>
<td>Localized</td>
<td></td>
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<tr>
<td></td>
<td>Generalized</td>
<td></td>
</tr>
</tbody>
</table>

Question 3

Yes.

Screening nurses shall assess all young repeat donors who aged from 16-17 if they have any adverse reaction after their previous donation and record on the blood donation form. For other repeat donors, adverse reactions recorded are reviewed through the blood management system or being enquired while deciding the donation volume.

Question 4

Donation related information is provided in the form of pamphlet at all blood drives and in electronic format via official website, Facebook and mobile apps.

The related information will be given to all donors before each donation.

The following elements are included:

- Donor preparation for blood donation including adequate rest the night before donation, adequate fluid intake, etc
- Description of the donation process
- Introduction of Applied Muscle Tension (AMT)
- Information of post donation advice

Question 5

The minimum age for whole blood donation is 16.

Question 6
The first time whole blood donor can join blood donation till the day of 66th birthday.

With the annual health assessment and approval by the Blood Transfusion Service medical staff donors aged 66 or above who have completed any donation in the last 2 years, can be accepted for whole blood donation up to their 76th birthday.

Question 7

i.) Yes.

- For blood donation at mobile units where young donors, first time donors and infrequent donors are the majority, isotonic and packed drinks would be provided for pre and post hydration.
- For blood donation at centres, water, packed drinks and hot beverage would be offered.
- The hydration status of blood donors will be assessed and donors are always recommended to be well hydrated before proceeding to blood donation.

ii.) A drink will be routinely offered to donors after donation.

Question 8

i.) Yes.

- Biscuits are offered as snacks at all blood drives.
- If donors do not have any food consumption within 4 hours, they are recommended to take some snacks and drinks before proceeding to blood donation. Otherwise, snacks are simply available for enjoyment before blood donation.

ii.) Yes.

- Biscuits are offered as snacks at all blood drives.
- Snacks are simply available for enjoyment after blood donation.

Question 9

Yes.

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Nurses and phlebotomists would introduce AMT during the preparation of venipuncture and advise blood donors to practise during blood donation.

Question 10

Yes.

- Blood donors are recommended to stay in the donation chair for at least 5 minutes for haemostasis as well as resting. And after that, staff would position the donor to upright position and accompany the blood donor to refreshment area if there is no adverse reaction.

- Blood donors are recommended to stay in refreshment area for 15 minutes before leaving the venue.

- If the blood donor is a first time donor or has past history of post donation adverse reaction, s/he would be suggested to stay in the donation area for a longer period of time with individual assessment.

Question 11

Local studies (1-3) have confirmed that young age, first time donation status, female gender and low body weight were significant vulnerable factors for vasovagal reactions, and those with reactions were significantly less likely to return.

Less collection per donation as a preventive measure for young first time donors has shown promising result. Another recent small study on effects of AMT also reveals positive outcome with good acceptance to donors.

Given that high risk groups can be identified and the availability of evidence-based techniques, prevention strategies can be tailor-made to the local setting with the aim to assure a safe, sufficient and sustainable blood supply.
References:


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Question 1

Yes, we have procedures to mitigate adverse events at blood collection in our SOP.

Question 2

Yes, we record adverse donor reactions into our nationwide system and follow the reaction rates regularly. We record reactions with injuries, faint reactions, pre-faint reactions and reactions reported by donors post-donation. We also record allergic reactions, hyperventilation, cardiac arrest, seizure, etc, with timings and locations.

Question 3

No, we don’t ask the donor every time, but our national computer system, which staff at each donation site check for every donor, shows up to five adverse events from that donor’s previous donations.

Question 4

Yes, we give donors an information paper and a pamphlet pre-donation, each time, which they have to read before their donation. We verbally explain about adverse events during and after blood collection.
every time, too. And we give a card with information about adverse events and blood centre contact information.

The materials contain information about hydration, together with information about rest/exercise and the blood centre contact information. During blood collection, we show a card with information about Applied Muscle Tension (AMT) and ask for their participation.

Question 5

The minimum age for whole blood donation is 16 years old for 200mL whole blood. For 400mL whole blood the minimum age is 17 years old for males and 18 years old for females.

There is no extra criteria in place for younger donors or first-time donors, regardless of their age.

Question 6

The maximum age for a whole blood donation is 64 years old, including first time blood donors. But for donors who have donated blood between 60 and 64 years of age, we accept whole blood donations up to 69 years old.

Question 7

i.) Yes, all the donors are offered water or isotonic fluids pre-donation on the donation site. The volume is not definite, usually between 200mL and 500mL, and we strongly encourage the
donors to drink. Also, this information is included in the pamphlets they read before the donation.

ii.) Yes, all donors are routinely offered water or isotonic fluids post-donation on the donation site. The volume is usually >200mL. The fluid intake is encouraged on the site and this information is also included in the pamphlets they read before the donation.

Question 8

i.) No, we ask donors if they are hungry pre-donation on the donation site, and offer snacks when they are hungry. They are not strongly encouraged to eat them. The snacks are cookies and sometimes also donuts and are not chosen for their salt content.

ii.) Yes, at fixed donation rooms for all donors we offer snacks post-donation in the refreshment area. The donors are asked to eat them, but are not strongly encouraged. The snacks are cookies and sometimes also donuts and are not chosen for their salt content. For mobile sites we offer food at most but not all.

Question 9

Yes, we encourage donors to perform applied muscle tension (AMT) exercises during the donation, near the end, and after the donation. It is explained to every donor with a card which includes pictures of AMT.
Question 10

We have no regulation on the duration of stay on the chair/bed after a blood donation. Our instruction is to keep the donor for at least 10 minutes at the donation site including their time in the refreshment area. We do have a procedure to check the blood pressure and pulse after the blood donation and send the data to our IT system, so the donor stays on the chair/bed for around 3 minutes. Included in our instructions is to chat with the donor more when it is their first time to make a blood donation.

Question 11

Yes, we did studies about water intake and AMT at various locations before implementing our policies in the SOP nationally.

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Canada

Mindy Goldman & Jennifer McKay

Question 1
There are standards from the Canadian Standards Association, Blood and Blood Components, that state that the status of the donor shall be such that the donation will not harm his or her health, and that there should be procedures to educate and inform prospective donors about risks of donation and post-phlebotomy care. However, there are no specific requirements regarding mitigating strategies such as more stringent criteria for younger donors, or fluid and salt loading.

Question 2
We do record reactions with injuries, faint reactions, and reactions reported by donors post-donation. Pre-faint reactions are recorded if the donors contact us post-donation to report symptoms. ISBT harmonized definitions are used to categorize donor reactions, and rates are reported in our annual surveillance report.

Question 3
We do not routinely ask returning donors if they had a complication at their last donation. However, first-time donors are called approximately 1 week post-donation to assess their on-clinic experience and how they are feeling post-donation.

Question 4
We provide donors with written pre-donation information in the mandatory pamphlet “What you must know to give blood: Making donations safe for you, and for those who receive your blood”. The pamphlet describes the donation process and provides information about hydration and salt intake as well as applied muscle tension (AMT). The pamphlet is available on our website at:


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and water immediately pre-donation and AMT is also provided by staff and volunteers on the donation site (see responses to questions 7, 8, and 9).

Question 5
The minimum age for whole blood donation is 17. First-time donors age 17-23 (up to 23<sup>rd</sup> birthday) must have an estimated blood volume (EBV) greater than 3.5 L, which is calculated based on sex and reported height and weight. All first-time donors remain on the donation chair for 5 minutes post-donation before sitting up and proceeding to the refreshment area. First-time donors also receive a follow-up call approximately 1 week post-donation, as noted in question 3.

Question 6
There is no maximum age for first-time or repeat whole blood donors. No extra criteria are in place for older donors.

Question 7
i) In the pre-donation pamphlet, donors are encouraged to hydrate and eat a non-fatty meal before donation. The pamphlet also mentions that they will be encouraged to drink water pre-donation. For donors who provide us with their e-mail address and permit us to communicate with them by e-mail (over 65% of donations), an e-mail reminder is sent to the donors a few days before donation with the same information. On the donation site, donors are strongly encouraged to drink 500 mL of water by both staff and volunteers, the water is placed in a prominent location near the waiting area. There are also video screens in the waiting areas of our fixed sites (over 55% of collections) that include this messaging.

ii) Post-donation, donors are encouraged to hydrate and drink water, juice, tea or coffee. This is less formal than our pre-donation process, and the amount is not specified.

Question 8
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Donors are strongly encouraged to have a salty snack immediately pre-donation, which contains approximately 400 mg of salt. Pretzels and chips are offered on all donation sites, other types of packaged snacks are offered on some sites as well. Both before and after donation, we aim to have some snacks that are gluten-free, vegan, or kosher to cater to the needs of our donors.

Snacks are also offered post-donation, in a less structured way. They include both salty snacks (as above) and sweet snacks such as cookies.

Question 9

Yes, we specifically encourage AMT, giving donors an information card about it when they sit in the donation chair. Donors are instructed to do the AMT exercises after the needle is removed and while they rest in the donation chair, prior to sitting up and going to the refreshment area. They also may do the exercises at any time during or after donation if they feel lightheaded. AMT is also mentioned in the donor pamphlet, on the video screening in our fixed sites, and in the e-mail reminder to donors.

Question 10

First-time donors are encouraged to stay on the donation chair for 5 minutes post-phlebotomy. Repeat donors may get up from the donation chair 2 minutes post-phlebotomy, providing that they feel well.

Question 11

We follow reaction rates in our donors when policy changes are introduced [1].

We assessed risk factors for donation by evaluating our donor reaction database and performing a post-donation survey of donors. In the survey, we were able to capture more baseline information that we don’t routinely collect, such as donor height and weight, and more reaction information than we routinely collect, such as off clinic reactions and mild reactions. The study contributed to adoption of our policy for more stringent EBV criteria in 17-23 year old donors [2].

We assessed vasovagal reactions in older donors (over 71st birthday) and the contribution that an annual external medical assessment of these donors made to donor safety. After this evaluation, we
decided to eliminate the need for the outside medical assessment. Since reaction rates in older donors were no higher than in middle aged donors, we also dropped the upper age limit for infrequent and then for first-time donors [3,4].

We performed a donor survey assessing how much attention donors pay to the mandatory pre-donation pamphlet. Results were sobering, in that many donors, particularly repeat donors, admit to a very cursory look at the pamphlet. Based on this information, we have streamlined the pamphlet, trying to remove unessential information. We also try and repeat the information in the pamphlet regarding donor health in multiple other channels (website, e-mail reminders, on clinic video screen, oral messaging from staff, AMT card) to improve donor participation in mitigation strategies [5].

References:


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Sweden

Maria Kvist

Question 1
The National Board of Health and Welfare regulates blood donation in Sweden. They stipulate that blood donation should be performed in a safe way for donors and that persons that have health issues making them prone to adverse reactions should not be chosen as donors.

Question 2
Yes.

- reactions with injuries - yes
- faint reactions - yes
- pre-faint reactions - often recorded locally but not reported to the national donor vigilance system
- reactions reported by donors post-donation - yes
- other - faint reactions are reported as immediate or delayed, as well as grade of severity of outcome. (The donor vigilance system also records adverse reactions following international standards).

Question 3
Not in the DHQ but many of the staff ask this during the predonation interview.

Question 4
At the donation site, we have only oral information and encouragement on drinking before donation. Our pamphlet will be updated shortly to include advice on drinking before donation. Our website has information of the donation process with recommendations on drinking.

Oral encouragement on drinking is given by staff before each donation.
The following elements are included on the website:

- description of the donation process
- information about hydration

Question 5

The minimum age for whole blood donation is 18 years.

No extra criteria are in place for younger donors, or first-time donors, regardless of their age.

Question 6

Regulations follow the EU directive on senior donors. No maximum age for experienced donors stipulated in regulations. In Stockholm and many parts of Sweden there is no maximum for repeat donors but some counties apply their own maximum age.

For first time donors, the national regulation follow the EU directive that stipulates that first time donors over the age of 60 can be approved at the discretion of the physician in the blood establishment. In practice, no approvals are made for first time donation over the age of 65.

For repeat older donors, the national regulation follow the EU directive that stipulates that repeat donors over the age of 65 can donate with permission of the physician in the blood establishment, given annually.

Question 7

i.) All donors are routinely offered water, juice or other fluids.

- Blood donation centers have a small café with drinks such as water, tea, coffee, milk and juices, sandwiches, fruit etc. Donors can take what they want at liberty, before or after donation. Most often the donors are offered a portion of non-carbonated fruit soft drink of 250-300 ml, packaged with a straw so that they drink during the donation. This drink is often the only option at mobile donation services.
Drinks are available but most often also encouraged.

ii.) All donors.

- At their liberty.

- Drinks are available but most often also encouraged.

Question 8

i.) Yes, but not at all mobile donation services.

- Sandwiches, fruit, cookies.

- No.

- Available.

ii.) Yes, but limited at mobile donation services.

- Sandwiches, fruit, nuts, cookies. Limited at mobile donation services.

- No.

- Available.

Question 9

No

Question 10

Yes.

- A few minutes in the donation chair.

- First time donors are recommended to rest 5-10 min in the donation chair.

Question 11

No.
Canada – Quebec

Nancy Robitaille & Jessyka Deschênes

Question 1

In Canada, the Canadian Standards Association (CSA) issues standards on blood and blood components every 5 years and Health Canada published the Blood Regulations, in 2014. Although the CSA standards CSA -Z902-15 have eligibility criteria for donor selection for allogeneic blood collection, there is no clause covering mitigation strategies to prevent faint or pre-faint reactions.¹ The Blood Regulations has no specific clause on mitigation strategies. However, it does require that: “An establishment that has reasonable grounds to believe that a donor has experienced a serious adverse reaction during a donation or within 72 hours after a donation must notify the Minister of the adverse reaction within 24 hours after it learns of the death of the donor or within 15 days after it learns of the adverse reaction in any other case.”²

Question 2

In 2015, Héma-Québec, the sole blood center for the province of Quebec, implanted a new donor hemovigilance system using the definitions from the “Standard for surveillance of complications related to blood donation” issued by ISBT, AABB and IHN.³ All information pertaining to adverse reactions related to blood donations is collected either during donation by Héma-Québec personnel or reported post-donation by donors. Reactions are reported using a standardized form and an annual report is produced. Both local and systemic reactions are recorded. Local reactions include ecchymosis/hematoma, arterial puncture, re-bleeding, allergic reaction at puncture site, immediate and delayed nerve injury and painful arm. Systemic reactions consist of the following: vasovagal reactions (VVR: including faint and pre-faint reactions with or without loss of consciousness (LOC)), major cardiovascular, apheresis specific reactions and delayed local reactions (local inflammation/infection, thrombophlebitis, deep venous thrombosis, arteriovenous fistula, compartment syndrome and pseudoaneurism of the brachial artery).
Question 3

The donor questionnaire contains the following question: “Did you have complications after your last blood donation (fainting or allergy at puncture site)?” This question is asked to repeat donors for whole blood and apheresis donation.

Question 4

Written information about the donation process, hydration and salt intake is provided to all donors at registration, prior to the blood donation. Similar information can be found on Héma-Québec’s website. No information about applied muscle tension is provided. Regular reminders about hydration and salt intake are provided by staff to blood donors at different check points during the donation process (registration, donor questionnaire, pre-donation and post-donation).

Question 5

The Civil Code of Québec forbids blood donation by minors. Therefore, the minimum age requirement for whole blood donation is 18. Héma-Québec has specific criteria in place to prevent VVR. All donors must weigh at least 50 kg to be eligible to donate. For donors aged between 18 and 22, the total blood volume (TBV) is calculated. A minimum TBV of 3200 ml is required to donate. Those with a TBV between 3200 ml and 3500 ml are allowed to donate a maximum of 450 ml whole blood. Those with a TBV ≥ 3500 ml can donate 485 ml whole blood. A TBV ≥ 3500 ml is required for apheresis donation for all donors and the annual volume limit is established according to the donor’s weight.

Question 6

As of December 2019, there is no maximum age limit for either first-time or repeat donors. No other eligibility criteria are in place specifically for older donors. However, it is worth mentioning that data from Héma-Québec’s donor vigilance system shows that older donors, defined as those ≥ 71 years of age, have the lowest rate of VVR (mild to severe). In 2018-2019, the VVR rate in older donors following
whole blood donation was 0.93 per 100 donations. In comparison, the highest rate was for donors aged 18-22 years at 14.32 per 100 donations and the rate for all donors was 4.32 per 100 donations.4

Question 7
All donors are routinely offered 500 ml of water pre-donation and staff is instructed to strongly encourage donors to drink the recommended amount (500 ml) throughout the donation process. In addition, water, juices or other beverages are available post-donation in the refreshment area. For environmental reasons, donors are encouraged to bring a reusable water bottle.

Question 8
All donors are offered a salty snack containing 450 mg of sodium pre-donation and are strongly encouraged by staff to eat it before their donation or throughout the donation process. Pre-donation snacks are chosen specifically for their salt content. Additionally, various snacks, sweet or salty, are also offered post-donation at the refreshment area however no specific salt content is required.

Question 9
At the present time, applied muscle tension exercises are not proposed nor advertised.

Question 10
Donors in permanent donor clinics are instructed to rest for five minutes on the donation chair before going to the refreshment area. Donors at mobile drives also have a five minute rest period but this will take place in a chair located in a rest area supervised by volunteers.

Question 11
A local retrospective study was performed to evaluate the impact of pre-donation hydration and salt intake on mild and severe VVR. We compared the rates of occurrence of VVR with LOC and without LOC 6
months before and after the implementation of prevention measures. The data shows that 6 months after implementation, the risk of VVR with LOC was reduced by 11.60%, and the risk of VVR without LOC was reduced by 12.60%. More than a year later, these risk reductions were decreased even more at 21.29% and 14.55% respectively, demonstrating the effectiveness and relevance of this practice. Furthermore, additional data on the rates of VVR according to total blood volume (TBV) has led us to reconsider the minimum TBV required to be eligible to donate blood for donors of all ages. Our objective is that a minimum TBV of 3500 ml be required for donation in order to further decrease the incidence of VVR in our donors.

References:


United Kingdom

Emanuele Di Angelantonio, Amy McMahon & David Roberts

Question 1

National Health Service Blood and Transplant (NHSBT) – only one blood donation service for the whole of England.

Question 2

Yes, as indicated below:

- reactions with injuries - YES
- faint reactions - YES
- pre-faint reactions - YES
- reactions reported by donors post-donation - YES

Question 3

Donors are routinely asked, “Did everything go well with your last donation?”

Question 4

Yes, in the form of written pamphlet pre donation, written pamphlet post donation and oral form by staff.

- Yes, prior to each donation
- We include the following elements:
  - description of the donation process
  - information about hydration
  - information about Applied Muscle Tension (AMT)

Question 5

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The minimum age for whole blood donation is 17 years old.

- Women under 20 years old are expected to have an estimated blood volume of more than 3500ml.

First time donors must be aged between 17 and 66 years old

Question 6
- First time donors – 66 years old.
- Repeat, regular donors – none.
- If a donor is over 70 years old, they must have donated blood in the previous 2 years.

Question 7
i.) Yes.
   - encouraged to drink 500ml water pre donation
   - encouraged
ii.) Yes, water, juice, tea or coffee
   - Encourage to have at least two drinks
   - Encouraged

Question 8
i.) No
ii.) Yes
   - Potato chips, biscuits, fresh fruit
   - Yes
   - Encouraged

Question 9
Yes.

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– During and post donation.
– A handout is provided during the donation.

Question 10

Yes.
– 2 minutes following needle withdrawal.
– Same for all donors.

Question 11

One ongoing national study.
– In progress.

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Iran
Mahtab Maghsudlu

Question 1
The national standards of Iranian Blood Transfusion Organization (IBTO) require all blood centers to ensure the safety of blood donors during and after blood donation. The blood centers are also required to have a procedure in place for the prevention of reactions.

It is worthy to note that the donor vigilance program was initially established in 2012 under my supervision.

Question 2
A donor vigilance system was established in 2012 at the national level. Initially, classification of reactions was in accordance with 2008 ISBT standards for surveillance of complications related to blood donation\(^1\). Then it was revised based on 2014 revised ISBT classification\(^2\). Any reactions in donors are documented in blood donor’s information software.

Categories are covered as follows:

- Vasovagal reactions with injury
- Vasovagal reactions without injury
- Adverse reactions reported by donors post-donation

Question 3
Donors are not verbally asked if they had a complication at their last donation, however if they report a complication in their last donation, it will be recorded in blood donors information software. There is a routine procedure to request blood donors to inform the blood center if s/he has any complication during the first 24 hours following blood donation. We believe that asking the donor about his/her reactions may make him/her increasingly sensitive to these issues and imposing stress during his/her current donation.

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Question 4

A general written information focusing on recommendations for mitigation of systemic and local reactions is given to each donor prior to each donation. It is a take home message and focuses on hydration in to avoid fainting. There are different materials (pamphlet, banner, web-based link) in all blood centers focused on donation process available in the registration area.

Following elements are included:

- Description of donation process
- Information about hydration

Because the Iranian populations consume much more sodium than health authorities recommend, this strategy is not used in IBTO.

Question 5

The minimum age for whole blood donation is 18 years and there are no extra criteria in place for them.

Question 6

The maximum age for first-time whole blood donors is 60 years; for repeat and regular donors the maximum age is 65 years and beyond if approved by a blood donor’s physician. There are no extra criteria in place for them.

Question 7 (i) & 7 (ii)

All donors are routinely encouraged to drink 2 glasses of water before donation, which is available in the registration area. All blood donors are offered a package after donation which contains a juice drink (200-250 ml). Water is also available to drink.
As previously mentioned, all blood donors receive a package following blood donation that contains a piece of cake and a juice drink. There is no routine to offer snacks before donation. However, all physicians are required to ask blood donors about having eaten during the last 6 hours. If a donor hasn’t eaten anything in the last 6 hours, s/he will be offered snacks.

Question 9
This method is not used in IBTO.

Question 10
Based on the approved working instruction (WOI) of IBTO, a donor must stay on the donation chair for 15 minutes and then s/he is guided to the refreshment area. This is required for all donors, including first-time donors.

Question 11
Monitoring the recorded data and implementing corrective or preventive actions is an important part of a donor vigilance system, therefore monitoring of data is routinely done. However, no study has been conducted so far, since complications appear to be underreported.

References:


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Question 1

Finnish Red Cross Blood Service

Question 2

Yes, as indicated below:

- reactions with injuries - YES
- faint reactions - YES
- pre-faint reactions - YES
- reactions reported by donors post-donation - YES
- others - Convulsions and By every category above; the need of medical care outside of the blood service.

Question 3

NO.

Question 4

Yes.

- Written pamphlet pre-donation, oral form by staff, information on website.
- Oral form by staff prior to every donation, written short information prior to every donation, written more detailed information for first time donors and in an ad hoc way.
- The following are included:
  - description of the donation process - YES
  - information about hydration - YES
- information about salt intake - NO
- information about Applied Muscle Tension (AMT) - YES, in the more detailed
  information leaflet and in an ad hoc way.

Question 5

The minimum age is 18 years.

- YES, extra time on donation chair, information leaflet (more detailed information about AMT
  and hydration).

Question 6

- First time donors – age 59.
- Repeat, regular donors – age 70.
  - In the age group 66-70; you need to donate at least every 24 months.

Question 7

i.) Yes.

- Water, juice or coffee/tea; 1-2 glasses.
- Strongly encouraged.

ii.) Yes.

- For first-time donors staff offer one glass of water/juice/coffee/tea before the donor leaves the
  donation couch.
- For all donors; strongly encouraged.

Question 8

i.) No.

- Snacks have not been specifically chosen for their salt content.

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— There are snacks available.

ii.) Yes.

— Sandwiches, cookies, sweets, nuts.

— Snacks have not been specifically chosen for their salt content.

— Strongly encouraged.

Question 9

Yes.

— All first time donors and donors in an ad hoc way.

— Card, and verbal if needed.

Question 10

Yes.

— For first time donors 10 minutes, for regular donors no time line given.

— See above.

Question 11

Yes.

— Small, non-scientific studies. Changes in the content of the information leaflets. (One on-going study project).

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Question 1
Yes.

ANSM (Agence Nationale de Sécurité du Médicament, the French competent authority) regulations and EFS (Etablissement Français du Sang, the French transfusion public service) standards and instructions. Of note, EDQM (European Directorate for the Quality of Medicines and Health Care of the Council of Europe) guide to the preparation, use and quality assurance of blood components, contains standards that are contributive to the prevention of faint or pre-faint occurrence, and therefore complications (such as maximum volume of blood to be collected, maximum percentage of blood volume collected), standards to which ANSM regulations and EFS standards abide.

Question 2
Yes.

- reactions with injuries
- faint reactions
- pre-faint reactions
- reactions reported by donors post-donation

All grade I (low grade) to grade IV (death) donor adverse events (including those mentioned above) are recorded through a unique French database vigilance system, irrespective of imputability (regulatory requirement for grade II to IV; EFS requirement for grade I to IV).

Question 3
Yes, returning donors are asked about complications, per EFS instructions.

Yes, general written information is provided per EFS instructions.
Pre-donation written pamphlet, digital communication (screens at donor site, EFS website link, and EFS mobile phone application).

- It is given prior to each donation.

- the following elements are included:
  - description of the donation process - Yes
  - information about hydration - Yes
  - information about salt intake - No (except in the event of heat waves)
  - information about Applied Muscle Tension (AMT) - Yes

Question 5

The minimum age for whole blood donation is 18.

- No specific measure for younger donors or first-time donors.

Question 6

- First time donors – Age 70 (after 60, specific MD approval is required), per ANSM regulations
  - For repeat, regular donors – Age 70 (after 65, specific MD approval is required), per ANSM regulations
    - Yes, MD approval after 60 (first time donors) or 65 (repeat donors), per ANSM regulations

Question 7

i.) Yes, all donors, per EFS instructions.

- 500 ml plain water.

- Strongly encouraged.

- Yes, all donors.
— Approximately 500 ml.
— Strongly encouraged.

Question 8

i.) No, (only in case of a heat wave or an empty stomach).
— Cookies, pastries, bread, fruits, chocolate bars, fruit juice.
— No.
— Strongly encouraged.

ii.) Yes.
— Warm plates, sandwiches, cookies, pastries, chocolate bars.
— No.
— Strongly encouraged.

Question 9

Yes, per EFS instructions.
— During donation.
— Written pamphlet, verbal instructions.

Question 10

Yes, per EFS instructions.
— A few minutes (of note donors are required per EFS instructions to stay at least 20 minutes at
collation and 40 minutes for granulocyte collection before leaving the donation site).
— Not specifically, although the EFS instructions, in particular for the first-time donors, strongly
recommend that the donor get up slowly from the donation chair, stay a few minutes sitting on the
donation chair with the legs dangling, and to stand up only if all is ok.
Question 11

Yes.

Evasion study: prospective randomized study evaluating hydration (plain water, isotonic water) and AMT (Morand et al, Transfusion 2016). 

Case-control study examining risk factors for fainting (Narbey et al, Vox Sanguinis, 2016)

- Introduction of AMT.

References:


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USA – Vitalant

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Question 1
No.

Question 2
Yes, as follows:
- reactions with injuries ✓
- faint reactions ✓
- pre-faint reactions ✓
- reactions reported by donors post-donation ✓
- other - needle-stick injuries

Question 3
No.

Question 4
Yes.
- Pamphlet and oral.
- Young donors.
- The following elements are included:
  - description of the donation process ✓
  - information about hydration ✓
  - information about salt intake ✓
  - information about Applied Muscle Tension (AMT) ✓
Question 5

The minimum age for whole blood donation is 16.

- Blood volume ≥ 3500 ml; information about hydration, salty snacks, muscle tensing.

Question 6

- First time donors - no maximum.
- Repeat, regular donors - no maximum.
  - There are no extra criteria in place for older donors.

Question 7

i.) All donors.
  - Water, no volume specified.
  - Encouraged.

ii.) All donors.
  - 8 oz.
  - Encouraged.

Question 8

i.) All donors.
  - Salty.
  - Yes
  - Encouraged.

ii.) All donors.
  - Salty.
  - Yes
— Encouraged.

Question 9

Yes, only young donors.

— Needle insertion, end of donation, needle withdrawal, anytime feeling faint, when standing up.

— Brochure, verbal.

Question 10

Yes.

— One minute with feet dangling off side of bed.

— All donors.

Question 11

Yes.

— Many studies published; we now provide salty snacks and fluids to donors before, during and after donation; we teach muscle tensing to young donors.

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Israel

E. Shinar, V Gendelman & H. Raz

Question 1

Yes.

- The Israeli Ministry of Health.

Question 2

Yes, as follows:

- reactions with injuries ✓
- faint reactions ✓
- pre-faint reactions ✓
- reactions reported by donors post-donation ✓ - upon receiving report from the donors.

Question 3

No.

In cases of severe reaction a deferral is entered into the record system to prevent the next donation.

Question 4

Yes.

- Written information in the Door Health Questionnaire and in MDA website link.
- Each donation.
- The following elements are included:
  - description of the donation process ✓
  - information about hydration ✓
Question 5

Seventeen (17) years with parental permission.

- Younger donors (12-17y) are accepted for autologous units only.

Question 6

There is no maximum age, BUT

- For first time donors: 18-60Y. Above 60y an approval from the treating physician is required and collection should be done in a fix-site, and in the presence of an EMS provider, qualified to provide at least basic CPR.

- For repeat, regular donors: Above 65y an approval from the treating physician is required annually and collection should be done in a fix-site, and in the presence of an EMS provider, qualified to provide at least basic CPR.

  • extra time on donation chair.

Question 7

i.) We suggest they drink 1-2 glasses of water.

- We suggest they drink 1-2 glasses of water.

- Gently encouraged.

ii.) Yes.

- A glass or more.

- Strongly encouraged and served.

Question 8

i.) No.

ii.) Yes, in certain donation sites.

- Cookies.
— No.
— Simply available.

Question 9
No.

Question 10
Post-donation rest of 10 minutes in total.
— About 2-3 minutes.
— No.

Question 11
Analysis of faint reactions is performed yearly.
— Results are presented to MDA blood services management and to the phlebotomists.

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Brazil

Silvano Wendel & Roberta Fachini

Question 1

In Brazil, the Ministry of Health defines the technical regulations to be complied with by all Hemotherapy Services and its compliance is supervised by the National Health of Surveillance Agency.

The technical regulation only defines that each service should have a standard operating procedure with specific instructions for the prevention, identification and treatment of adverse reactions in blood donors, including the availability of medicines and equipment needed to provide the adequate medical assistance to these donors.

Additionally, the training and standardization of health professionals regarding procedures for emergency care follow the guidelines for advanced life support from the Brazilian Society of Cardiology. However, there is not in the national regulation specific mitigation strategies to prevent faint or pre-faint complications (https://portalarquivos2.saude.gov.br/images/pdf/2018/marco/29/PRC-5-Portaria-de-Consolida---o-n---5--de-28-de-setembro-de-2017.pdf).

Question 2

The technical regulation to be complied with at the national level defines that the Hemotherapy Service should record all adverse events that occur during a blood donation, including the medical procedure established for its attendance, as well as notify the adverse events considered serious to the National Health of Surveillance Agency (http://portal.anvisa.gov.br/documents/33868/404938/guia_hemovigilancia15.pdf/495fd617-5156-447d-447d-7211cdbab8a7).

We classify, record and follow the adverse reaction rates according to the categories below:

a. Local reactions: characterized by only local symptoms of blood leakage or pain, caused directly by inserting the needle (blood leakage, pseudoaneurysm, arteriovenous fistula and compartmental syndrome; nerve injury; thrombophlebitis or allergy for locally used solutions).

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b. Systemic reactions: most of these reactions are vasovagals, with symptoms of faint or pre-faint, and which can be triggered by psychological factors such as the blood vision, fear or apprehension, or may constitute a neurophysiological response to the donation.

c. We also registered any reactions reported by donors post-donation.

Question 3

Yes. As part of our clinical screening for every blood donor candidate, the question whether the candidate has previously donated blood and if he/she has had any discomfort or reaction during or after his/her previous donation. Depending on what the donor reports, we provide pre-puncture and post-donation care guidelines to try to prevent recurrence of this reaction.

For example, to increase oral hydration even more during the day, and not to undergo great physical effort, such as gym exercises.

Question 4

Yes. Our Service provides the donor candidate with full details of the entire clinical screening and blood donation process itself. We have a general written information, which is offered before all donations, explaining all the donation process, and the importance of the adequate hydration and of the salt intake, during the day.

This inform is offered by a written pamphlet during the pre-donation period and it is emphasized orally by staff. All of this content is also available in our website link.

Question 5

The blood donor must be between 16 (sixteen) years and 69 (sixty-nine) years old, 11 (eleven) months and 29 (twenty-nine) days.

Candidates for blood donation aged between 16 (sixteen) and 17 (seventeen) years old must have formal written consent from their legal guardian for each donation that they make.
In cases of technically special needs (donors with rare phenotypes, familiar with irregular antibodies whose frequency of negative antigen blood is higher in the same family members), an applicant whose age is under 16 (sixteen) years or over 70 (seventy) years will be accepted for donation purposes after examination by the doctor of the Hemothrapy Service.

Additionally, the limit for the first donation shall be 60 (sixty) years, 11 (eleven) months and 29 (twenty-nine) days.

To be approved for donation, the applicant must have a weight of at least 50 kg (fifty kilograms). Candidates weighing less than 50 kg (fifty kilograms) may be accepted for donation purposes, after medical evaluation, provided that the volume of anticoagulant in the collection bag is proportional to the volume to be collected.

The total blood volume to be collected should be a maximum of 8 (eight) mL / kg weight for women and 9 (nine) mL / kg weight for men. The volume allowed by donation is 450 mL ± 45 mL, to which up to 30 mL may be added for the laboratory tests required by laws and technical standards.

Question 6

To repeat or regular donors, the maximum age for whole blood donation is 69 (sixty-nine) years, 11 (eleven) months and 29 (twenty-nine) days.

In cases of technically justifiable needs, over 70 (seventy) years old donors might be accepted for donation purposes after examination by the doctor of the hemothrapy service, with corresponding risk and benefit assessment. It is necessary to present a report that justifies the need for the donation, recording it in the donor form.

For the first time donors, the maximum age acceptable for donation is 60 (sixty) years, 11 (eleven) months and 29 (twenty-nine) days.

There are no extra criteria in place for older donors.

Question 7
For all donors or a subset of donors (such as first-time donors) are routinely offered water pre-donation on
the donation site. We don’t specify the volume to be drunk, but it is strongly encouraged.

Post-donation, all donors are kept in our service at least 15 minutes and they receive juice, coffee or
milk, depending on their preference. This conduction is strongly encouraged, too.

Question 8
The offering of pre-donation salty snacks does not occur routinely. Our procedure provides for the donor
to be questioned if he has adequately fed and ingested liquid on the date of the donation and, if he reports
that the last meal was more than three hours, the donor is obliged to take salty snacks and to drink enough
liquid at this time, pre-donation.

On the other hand, always after blood collection, the donor remains at the Blood Bank for at least 15
minutes. At this time, it is strongly recommended that he/she eats salty snacks and/or drinks water, coffee,
milk or juice, according to his/her preference.

All snack options offered to our donors have the sodium concentration specified, but they were not
chosen from a thorough analysis of what should be the ideal value (reference). Some examples that
demonstrate how this sodium concentration can vary: turkey breast sandwich with 1015 mg of sodium
and cheese sandwich with 102 mg of sodium.

Question 9
The only muscle exercise that the donor is advised to do during the donation is the flexion-extension of
the fingers of the upper limb that has been punctured for blood collection.

This instruction is communicated by the nurse verbally and immediately before the venous puncture.

Question 10
There are no differences regarding first time or repeated donors about how long they should stay on the
donation chair before going to the refreshment area provided the donation went on normally. However,
we always advise donors to stay for approximately 5 minutes in their chair after the end of donation, as an extra safety caution.

Question 11

The practices described in this paper have been instituted for many years, and no case-control studies have been done to justify any of them, as well controlled evaluation post-implementation.

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Question 1
Since July 2019, at Sanquin new and novice donors (up to their 5th donation) are offered a 300 ml cardboard drinking cup with a cartoon picture and text printed on it, encouraging them to drink water before they donate.

Question 2
Yes, we record all of the adverse donor reactions mentioned above in the blood service information system. For all complications we record severity (low degree of morbidity – not life threatening; moderate to severe morbidity – hospital admission, prolongation of disease or disability; life threatening or fatal outcome) and the time at which the complication. For each reaction the code shows when it occurred (during donation, after donation at the blood collection center or after donation outside the collection center). Serious reactions and all cases where outside medical care was required are additionally assessed for imputability to the donation and recorded in the quality management system.

Question 3
We ask returning donors if their last donation went well on the Donor Health Questionnaire, which they all complete before donation.

Question 4
Information about blood donation, including the donation process and avoiding complications, is actively provided to new donors through the website and a short video which is reviewed on a tablet at the collection center immediately before the first interview. Printed and verbal information about planning and preparing for their first donation is given to them on that occasion (in The Netherlands donors attend first for interview and testing only, and are subsequently invited separately for their first donation).

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encourage all donors to eat and drink enough prior to each donation (via invitation and website). New and novice donors (up to 5 donations) are encouraged to drink additional water before donation (at blood collection site). Posters with information about AMT are available at each blood collection site.

Question 5

The minimum age for blood donation is 18 years. New and novice donors (up to 5 donations) are encouraged to drink additional water before donation.

Question 6

Donors can register as blood donors up to the age of 65. Repeat donors can now continue to donate up to and including the age of 79 – the maximum age was raised from 69 in 2018. Donors above the age of 65 must be checked by a donor physician each year.

Question 7

Hot and cold drinks (including water, but no isotonic drinks) are available in cups, mugs or glasses (customary sizes, 120-330 ml) in the refreshment area at the donation site. As mentioned before, 300 ml pre-donation water drinking is actively encouraged up to the fifth donation. In the pre-donation interview all donors are asked about recent drink and food intake and staff will recommend taking a drink or snack before donation as appropriate.

All donors are advised to eat and drink something after their donation. Drinks (as described above) and snacks are offered at the donation site by a staff member or volunteer. Instant soup and broth are also served depending on the donor’s preference.

Question 8

Snacks are not offered pre-donation, but are available at the donation site.

Snacks are available to all donors post-donation and include instant soup or broth, currant buns, bread rolls with ham or cheese, gluten-free muesli/chocolate bars, honey cake, and small or semi-large
Cookies/cakes. The savory snacks have not been chosen based on actual salt content but on practicality and palatability.

Question 9
Posters with instructions on AMT are displayed at the donation sites. The poster images show donors performing AMT during the collection to prevent dizziness. Staff attending donors with (pre)faint reactions verbally give instructions for AMT during recovery as well as later on the day, if necessary, referring to the posters as reinforcement. AMT is also mentioned in website information for donors as well as the above-mentioned video for new donors.

Question 10
Repeat donors can leave the donation chair after checking if they don’t feel faint or dizzy. They are encouraged to eat and drink something in the refreshment area and stay there for 10 minutes or so. First-time donors remain on the donation chair for longer and are offered a cold drink before they are allowed to leave the donation chair. Donors with a previous vasovagal reaction (this information is coded on the printed attendance form) will also be kept in the chair for longer.

Question 11
Yes, the EPISODe study was performed to check if drinking water prior to donation prevented donor complications in younger (up to age 30) new and novice donors (Wiersum et al, Transfusion 2018;00;1-11). The results showed that donors who drank water prior to donation experienced less donor complications. This led to the implementation of the policy in which new and novice donors (up to 5 donations) are offered additional water prior to donation.
Question 1

YES.

Incorporated into our system documents specifically to include:

- Muscle Tension to Prevent Reactions.
- Students Guide to Blood Donation.
- Reference on setting up hydration station for high schools.
- Training for staff on how to identify, manage and prevent further complications.

Question 2

We track all reactions in eBDR and can pull subsequent reports on reaction rates. We also capture all major reactions on Donor Complication Injury Record. All complication types are captured. Data is reviewed and entered into the ARC Hemovigilance data base.

- reactions with injuries - Yes
- faint reactions - Yes, we categorize faint & pre-faint reactions as prolonged recovery if the donor is still experiencing symptoms or low blood pressure for longer than 30 minutes.
- pre-faint reactions – Yes, see above.
- reactions reported by donors post-donation – Yes.
- other – Yes, any and all reactions are recorded.
Question 3

No.

Question 4

YES, AABB ASSOCIATION BULLETIN #08-04.

- Written for students, oral by staff (ex: hydration station and muscle tension) and website links.
  - Students Guide to Blood Donation.
  - Muscle Tension to Prevent Reactions.
  - Reference on setting up hydration station for high schools.

- Given to young donors as part of the pre-reading materials at each donation. Available to all donors on the website.

- Information on elements included:
  - description of the donation process - Yes
  - information about hydration - Yes
  - information about salt intake - No
  - information about Applied Muscle Tension (AMT) - Yes for young donors in the Students Guide to Blood Donation

Question 5

Age 17 – 16 if permitted by state law and with parental permission.

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Yes, (AABB ASSOCIATION BULLETIN #08-04).

- Students Guide to Blood Donation is part of the required reading for donors who are student age (under the age of 19).

Higher estimated blood volume is in place for the following:

<table>
<thead>
<tr>
<th>Donor Type</th>
<th>Product Type</th>
<th>Age</th>
<th>Gender</th>
<th>Acceptable Height</th>
<th>Acceptable Weight (lb)</th>
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<tbody>
<tr>
<td>Whole Blood</td>
<td></td>
<td>19 &amp; over</td>
<td>Male or Female</td>
<td>N/A</td>
<td>110 to bed weight limit</td>
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<td>Under 19</td>
<td>Female</td>
<td>4'10&quot;</td>
<td>146 to bed weight limit</td>
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<td>115 to bed weight limit</td>
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<td></td>
<td>5'6&quot; and taller</td>
<td>110 to bed weight limit</td>
</tr>
<tr>
<td></td>
<td>Apheresis except 2RBC</td>
<td>N/A</td>
<td>Male or Female</td>
<td>N/A</td>
<td>110 to bed weight limit</td>
</tr>
<tr>
<td>ALYX 2RBC</td>
<td></td>
<td>N/A</td>
<td>Male</td>
<td>5'1&quot; and taller</td>
<td>150 to bed weight limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>Female</td>
<td>5'5&quot; and taller</td>
<td>175 to bed weight limit</td>
</tr>
<tr>
<td>MCS+ 2RBC</td>
<td></td>
<td>N/A</td>
<td>Male</td>
<td>5'1&quot; and taller</td>
<td>130 to bed weight limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>Female</td>
<td>5'5&quot; and taller</td>
<td>150 to bed weight limit</td>
</tr>
</tbody>
</table>

Question 6

No maximum age except for donors in NY state – 75 is upper limit but are allowed to donate with an additional evaluation.

- First time donors NO – see above.
- Repeat, regular donors? NO – see above.
  - No extra criteria are in place for older donors.

Question 7

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i.) Young donor <19 or at high schools routinely offered water.
   - Water – 1 16.9oz bottle and more if requested.
   - Strongly encouraged.

ii.) All, Yes.
   - 1 bottle – 16.9oz or more if requested.
   - Strongly encouraged.

Question 8

i.) No – only if requested by donor.
   - N/A.
   - No.
   - Simply available upon request.

ii.) Yes.
   - Variety of what is available – usually donated – cookies, pretzels, raisins, crackers.
   - No.
   - Strongly Encouraged.

Question 9

Yes, especially recommended for young donors.
   - During the actual time the donor is donating the unit.
   - Written for young donors and verbal for all others (covered in staff training).

Question 10

No – we ensure the donor is feeling well and allow them to leave after bandaging.

Question 11
Yes.

- Changes in height and weight requirements for young donors reduced reaction rates substantially.

Kathleen M. Grima
American Red Cross
Philadelphia, PA
Email: Kathleen.Grima@redcross.org
Australia

Joanna Speedy

Question 1

In Australia we are required to comply with the Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019. TGO 102 includes that the requirements in relation to blood and blood components are specified in the Guide to the preparation, use and quality assurance of blood components, 19th edition, 207, published by the Council of Europe (CoE Guide).

The CoE Guide includes the following general principles in relation to donor adverse events:

- Prospective donors must be informed of the possible adverse reactions of blood donation and how they can be prevented.
- Training of the personnel collecting blood should include preventing and recognising the (early) signs of adverse reactions and their rapid treatment.
- The source of an adverse reaction should be identified and corrective and preventive measures considered.
- Data should be collected and analysed in order to initiate corrective actions that could prevent or reduce the frequency or minimise the severity of adverse reactions in the future.
- A donor who has experienced vasovagal reactions should be informed about the risk of delayed fainting. The donor should not drive a vehicle or resume work or any hazardous occupation or hobby in the ensuing 12 hours if delayed fainting could put the donor or other persons at risk.

Note: the specification of 12 hours is new in the CoE 19th edition. Lifeblood is in the process of reviewing this gap, as we currently recommend 8 hours for driving based on the known occurrence of greatest risk for delayed VVR.

There are no standards or regulations that cover specific information on hydration, applied muscle tension or meals.

Question 2

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Lifeblood’s donor vigilance system monitors adverse events in blood donors that have a temporal relationship to blood donation. The system underpins Lifeblood’s comprehensive and continuous improvement approach to the mitigation and management of donor adverse events to improve donor safety and experience and is integral to Lifeblood’s Clinical and Quality Governance Framework.

We record both in-centre and off-site reactions. The table below provides a summary of the events recorded for whole blood donors. The vasovagal category refers to all fints and pre-faint events and for each of these events we capture whether there has been loss of consciousness and/or injury.

<table>
<thead>
<tr>
<th>Adverse Event Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasovagal reactions</td>
</tr>
<tr>
<td>Phlebotomy related events</td>
</tr>
<tr>
<td>Arterial Puncture</td>
</tr>
<tr>
<td>Cellulitis</td>
</tr>
<tr>
<td>Delayed Bleeding</td>
</tr>
<tr>
<td>Haematoma</td>
</tr>
<tr>
<td>Nerve Injury/Irritation</td>
</tr>
<tr>
<td>Other injury</td>
</tr>
<tr>
<td>Painful arm</td>
</tr>
<tr>
<td>Thrombophlebitis</td>
</tr>
<tr>
<td>Other Event</td>
</tr>
<tr>
<td>Anaphylaxis</td>
</tr>
<tr>
<td>Chest Pain</td>
</tr>
<tr>
<td>Local Allergic Reaction</td>
</tr>
<tr>
<td>Other event/injury</td>
</tr>
</tbody>
</table>

Question 3

Yes, returning donors are asked if they had any side effects after leaving the donor centre on their previous visit.

If yes and this event has not previously been recorded the event is recorded at this time.
Question 4

Information provided prior to attending:

Appointment SMS reminders often include a reminder about hydration and eating prior to donating and a link to our website lifeblood.com.au where donors can find out more about the donation process and how to prepare for the donation.

Information provided in-centre:

Information on donation risks and mitigation strategies (attached below) is provided in written form to all donors in-centre at the time of completing the donor questionnaire. This includes specific information on the risk of fainting and strategies to reduce this risk, including pre and post donation hydration, snacks, in-centre recovery and post-donation avoidance activities.

All new donors also receive a written information sheet which explains the relevant donation process (ie whole blood, plasma or platelets), ways to reduce the risk of fainting and bruising and who to contact if they have problems or questions after donating.

All donors receive an AMT instruction card.

Question 5

First time donor – maximum age is 75 years for both males and females

Repeat donors –

- Donors aged 76 years or older who have completed a donation of any type in the last two years are permitted to donate whole blood
- Donors aged 76 years who have not donated in the last two years but have made at least one prior donation, can be accepted depending on whether there is a history of a previous faint/pre-faint.

There are no additional criteria in place for older donors.

Question 6

First time donor – maximum age is 75 years for both males and females.
Repeat donors –

- Donors aged 76 years or older who have completed a donation of any type in the last two years are permitted to donate whole blood

- Donors aged 76 years who have not donated in the last two years but have made at least one prior donation, can be accepted depending on whether there is a history of a previous faint/pre-faint.

There are no additional criteria in place for older donors.

Question 7

Pre-donation:

All whole blood donors are provided/offered 500ml water on arrival.

Hydration advice is provided to all donors in written form as per question 4 and also often sent via SMS as part of an appointment reminder.

Staff also ask donors about their hydration preparation as part of the general interview process.

Post-donation:

Following collection all donors are advised by staff to stay in refreshments for 15-20 minutes and have a cool drink and snack before leaving. This is also included in our written information and recommends donors drink 300mL in refreshments. A variety of drinks are currently available across most donation centres including, water, juice, milk drinks, sport drinks, tea and coffee.

Question 8

Pre-donation:

Lifeblood recommends ALL donors having something savoury to eat in the 3 hours before their donation.

This is communicated to donors in written form as per question 4 and also often sent via SMS as part of appointment reminder.

Staff ask donors about their food intake as part of the routine assessment.
Most donor centres have snacks (pretzels and/or biscuits) available for donors pre-donation which are encouraged if the donor has not had something to eat in the last few hours.

Post-donation:

Post-donation we recommend ALL donors remain on site and have a “savoury snack” along with a drink. We provide a variety of snacks including some high salt foods such as pretzels.

Question 9

Yes AMT is encouraged in all whole blood donors. All whole blood donors are provided with an AMT instruction card prior to their donation (attached in Question 4). We encourage this activity at needle in, needle out, before getting up or if they feel dizzy, hot or nauseous.

Question 10

Our procedure is for all donors to remain in the chair for minimum of 5 minutes after the needle is removed and then get up slowly under their own strength.

Donors are advised to stay in refreshments for 15-20 minutes and to have something to eat and drink.

Question 11

Introduction of AMT and pre-donation water loading has been implemented based on both international and local studies. A summary of the results are provided in the images below.
To determine the best way of providing this information to donors, Lifeblood compared three approaches: emailing a link to instructions on our website, emailing a link to a video, and the provision of a small instruction card provided by staff in the donor centre at the time of the donation.

While the video performed well in our preliminary testing, when we conducted a randomised controlled trial, we found that very few donors actually clicked on the link pre-donation. It was much more effective to provide the card in the donor centre, which is the approach that we then implemented.

Evaluation following national implementation
Denmark

Mie Topholm Bruun

Question 1

Yes.

The Danish Society of Clinical Immunology.


Question 2

- reactions with injuries - Yes
- faint reactions - Yes
- pre-faint reactions – Yes
- reactions reported by donors post-donation - Yes
- other – Yes.

We also report all kinds of blood vessel injuries, nerve injuries, apheresis-related complications and other serious complications. Furthermore we grade the complications after severity and imputability.

Danish legislation requires that serious complications are reported to the Competent Authorities (The Danish Patient Safety Authority.)

Question 3

No.

Question 4

No.

- Oral by staff.

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– Prior to first donation, and subsequent ad hoc.
  o description of the donation process - Yes (written information).
  o information about hydration - Yes (written information)
  o information about salt intake - No
  o information about Applied Muscle Tension (AMT) - No

Question 5

17 years.
– No

Question 6

- 60 years old (to be changed to 65 in 2020).
- 69 years old.

Yes. Donors older than 65 years have to answer some supplementary cardiovascular related questions regarding chest pain, swollen legs, dizziness etc. to ensure they are healthy.

Question 7

i.) Yes.
  – Water, juice, soda and drinking chocolate in cups that contains 400 ml.
  – Strongly encouraged.

ii.) Yes
  – Not specified.
  – Strongly encouraged.

Question 8

i.) Yes.
Potato crisps, nuts, fruit and chocolate.

Potato crisps and nuts are chosen because of high content of salt.

Simply available.

ii.) Yes.

Potato chips, nuts, fruit and chocolate.

Potato chips and nuts are chosen because of high content of salt.

Simply available.

Question 9
No.

Question 10
Yes, but only for first time donors.

Repeat donors can leave the donation chair whenever they feel ready for it.

First time donors are encouraged to stay 10 minutes on the donation chair, and afterwards 10 minutes in the refreshment area.

Question 11
No.

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