

# AABB, IHN & ISBT Working Group on Haemovigilance 2016 Donor Haemovigilance Case Validation Exercise

## Complications Related to Blood Donation Introduction and Instructions

Dear Colleague,

We are asking you to help validate the harmonized donor haemovigilance definitions that were published by ISBT in December 2014. Your results will be tallied with other transfusion experts from around the world and will be used to validate the definitions. The results will be presented at ISBT in Dubai in September 2016 and will be summarized in a publication; therefore, we are asking all participants to complete and return their answers by July 31<sup>st</sup> to [kland@bloodsystems.org](mailto:kland@bloodsystems.org).

**INSTRUCTIONS:** Using the definitions found in the Standard for Surveillance of Complications Related to Blood Donation (separate document), evaluate the following 30 donor cases, selecting at least one donor adverse event category for each case. Please evaluate the optional categories/attributes where appropriate. Also, please determine the optional grading of complication severity (Mild, Moderate, Severe) and imputability (Definite, Probable, Possible, Unlikely, or Excluded), based on criteria described on page 10 of the Standard definitions document. Two example cases are supplied at the beginning. Use the Answer Scheme form to record your answers. A list of complications with abbreviations is provided at the end of the Answer Scheme.

Thank you for helping us with this valuable project.

Kevin Land MD  
Incoming Chair, ISBT Haemovigilance Working Party

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### Sample Case 1

At the initiation of a whole blood donation the needle was not introduced in the vein at the first attempt, however after more attempts blood was running into the bag, with a normal speed. During the bleeding donor complained of pain in the cubital fossa irradiating down in the forearm and of some tingling in the ulnar fingers. No swelling. Bleeding was stopped, and pressure was put on the venepuncture site.

The next day, at the telephone contact, donor complained still of constant pain in the forearm. It was treated with massage. Two months later, the feeling of pain had changed, and was now only felt, when the arm was moved. Two years after, donor still complains of pain, when the arm or hand is moved. Donor, who is a blood bank technician, has a reduced physical working capacity.

### Sample Case 2

A whole blood donor (hypertensive, controlled with prescribed medication) was shopping in the supermarket after her donation and felt dizzy. She laid down (or collapsed?) next to her supermarket trolley. An ambulance was rung to take her to hospital, despite her assurances that all was well and she just needed to go home and rest. It later appeared from hospital correspondence that she told bystanders that she was fine but just lightheaded. At the emergency unit blood was taken and an ECG made. After observation she was allowed to go home with an early appointment for review of her antihypertensive medication. She reported this to centre staff at her next attendance.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### Complications Related to Blood Donation Cases

#### **Case 1**

Within 24 hours after leaving the bleeding centre, after a normal bleeding without any kind of abnormal symptoms or signs of a complication, with a smooth needle insertion and a normal flow, the donor felt some increasing tingling and prickling sensations in the left arm, which had been used for the phlebotomy. No other abnormal symptoms.

After three weeks, the sense of touch in the left hand was reduced. During the following weeks the symptoms increased and donor had the feeling that the arm was asleep.

Donor was treated with physiotherapy without any convincing effect on the symptoms. Over the next year the symptoms diminished a little but continued to trouble the donor, who complained that they reduced the quality of life.

#### **Case 2**

Donor phoned blood facility late in the afternoon (about 4 hours after uncomplicated donation of whole blood). Since then he had developed swelling and some pain at the venepuncture site. He had initially returned to his work as a supermarket cashier but he had had to stop, and he asked for some advice. Questioned on other symptoms he described some peculiar feelings in the fingers, as if they were filled with sparkling water.

He was advised to rest the arm and to stop work for today. If the swelling increased in size, he should phone again, otherwise he was asked to contact the blood facility again tomorrow. He did not phone and never showed up again.

#### **Case 3**

Just after the bleeding, when donor was sitting on the donor chair, he suddenly fainted, convulsed, and fell to the floor. He continues to lay on his back and when asked about symptoms said he had pain in his head and neck and some tingling in the fingers of both hands. As he could have a fracture of the neck, he was told not to move at all. After transport by ambulance to the nearest hospital he was seen in the emergency department and x-rayed. It was concluded there was no fracture. Donor got some massage of his neck and had no symptoms 1 month after the accident. The donor has no history of seizures.

#### **Case 4**

Double Red Blood Cell (apheresis) donor experiences pain during return with swelling in arm to hand, leakage at puncture site, and tingling in his fingers. Donor also begins experiencing chest pains, mother who was with donor during donation, takes donor to an urgent care clinic after donor is discontinued. Donor is given contact information and notified that collection centre will follow-up.

A few days later, per donor's mother, doing better, testing done with no evidence of a blood clot or compartment syndrome. Donor diagnosed with infiltration by urgent care doctor. Donor advised that donor centre would cover expenses not reimbursed by insurance company.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### **Case 5**

Apheresis donor experienced initial sharp pain during needle withdrawal of an otherwise unremarkable donation. When staff calls the donor the next day, the donor reports that there is a small bruise at the phlebotomy site and some itchiness and a red rash where the armband was wrapped around her arm. Donor also reports some numbness in fingertips. She is advised to see her primary physician who makes a diagnosis and begins treating her.

Two weeks later the staff call the donor back who states that the bruise is fading and the rash is gone-, although she has some residual pain around her haematoma and is being treated by her physician. The pain is gone by 30 days following donation.

### **Case 6**

When the needle was inserted in the left arm donor felt pain and burning around the insertion place. Therefore, the needle was removed immediately and the area was compressed. The donor was then bled in the right arm without problems.

After the donation from the right arm, donor still complained of local pain in the left arm when it was moved. A medical examination revealed no swelling and the radial artery pulse, movements of arm and sensibility of fingers were normal. Donor was advised not to return to work the same day. He was treated with physiotherapy and seen by an Orthopaedic surgeon.

During the following months donor complained of a feeling of scald and severe burning at the insertion area, as if somebody pressed a burning cigarette into it. After 1 year he had still some pain in the elbow region, and cramp in the dorsal part of the hand.

### **Case 7**

Donor had otherwise uneventful whole blood donation. Donor called back a few days later stating that she developed pain and red streak starting at the phlebotomy site that had begun to creep up her bicep. She went to her physician, who diagnosed her with possible staph infection and placed on antibiotics. Over the next week, her symptoms resolved.

### **Case 8**

A woman donating blood felt a severe pain when the needle was taken out, after an uneventful bleeding. The severe pain radiated from the elbow region down into her hand. A few minutes later she had a feeling of constant pain in the arm. The medical doctor on duty could not find any objective symptoms. Donor was asked to return to the collection facility next day.

Next day the donor still complained of pain but had no other symptoms. Ultrasound scanning of the arm did not show anything abnormal. She was followed up as an out patient during the next year in the Department of Rheumatology and treated with physiotherapy. After 1 year, the donor still had pain in the arm.

On the basis of a statement from an Orthopaedic surgeon who had no suggestions for further treatment and did not expect further improvement of her symptoms, she was estimated to have at least a 5% reduction in working capacity or disablement and was given a sum of money as compensation.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### Case 9

A healthy 67 year-old male donated whole blood in his left arm without incident. Within 24 hours he noted left arm pain to the centre staff, who recommended ice packs and massage and told the donor they would call back the next day.

By the next day, the donor had developed left arm edema and neuromuscular dysfunction of the median nerve distribution. He was seen by a surgeon who performed a fasciotomy.

### Case 10

A 78 year old repeat male donor donated two red cell units by apheresis without incident. He subsequently returned home where he maintained his usual routine. He was preparing for bed when his wife reports he started having symptoms of slurred speech and unilateral weakness; she called for assistance and he was transported to the hospital.

### Case 11

A whole blood donor was standing waiting for a cup of coffee to be served after donation and felt light-headed. Staff went to him but were not quick enough to prevent him from falling to the ground. There were convulsive movements of his arms and he passed urine. After several seconds he responded to questions and said he had no pain. The donor was laid on a trolley and encouraged to take sips of water. Soon he felt better and accepted clean clothes. While changing, he felt dizzy again and had to lie down quickly. He drank more. Ten minutes later he tried sitting up again, but again started to sweat and feel dizzy. His mother was called to come and sit with him, and an hour later they were taken home by taxi. The following day, when rung by blood centre staff, he reported that he had had no further problems.

### Case 12

A 56 year old male donor was making his second apheresis donation of plasma. When the return phase started he started to feel itching in his donation arm, and this rapidly spread to his whole body. His eyes also felt itchy. On examination, there was an urticarial rash of all exposed parts of his body and his conjunctivae were red. The collection was immediately stopped without returning his red cells. The donor's blood pressure was not changed from the predonation value. He was kept under observation for an hour, during which time the itching became less and the rash faded gradually. Then he was allowed to go home. He was referred to the local hospital for specialist assessment of possible causes for his reaction.

### Case 13

During whole blood donation donor complained of local pain around the inserted needle. As an increasing swelling was also seen, the phlebotomy was immediately stopped, the needle was taken out. The arm was elevated, and pressure was put on the area where the needle had been inserted. In spite of these precautions a huge but very superficial haematoma developed. Donor had only a little pain around the swelling. No nerve symptoms or paraesthesiae.

During the following days donor was seen each day by an Orthopaedic Surgeon and observed for possible complications like compartment syndrome and nerve injuries. However, the haematoma disappeared during the following weeks without any further symptoms.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### **Case 14**

Donor called donor centre staff 4 days after donation to advise of a red middle finger. This was the finger use for haematocrit check. Donor went to primary care physician and was diagnosed with cellulitis and treated with antibiotics.

Two weeks later, the donor calls back and states that she has had to go back to the doctor and had an abscess lanced on her middle finger.

### **Case 15**

A plasma donation was completed in 45 mins although there were flow problems and repeated alarms from the machine and he had to squeeze a ball during most of the collection. The donor left the centre after quickly taking a cold drink. In the car park he felt light-headed and sensibly sat down on the ground next to his car. Another donor saw him, told him to put his head down between his knees and used his cell phone to call centre staff. The donor was helped onto a trolley and taken back indoors. Initially he looked pale and sweaty and complained of nausea. After lying down for a while this passed. He drank more water and after eating a little the donor left with his partner, who had been called to accompany him home.

### **Case 16**

On his way out of the donor centre after an uncomplicated blood donation, donor stumbled on the staircase, fell down and got a fracture of the antebrachial bones. Donor had no symptoms of a vasovagal reaction.

Donor was referred by the physician on duty to the emergency department, where the fracture was treated. After 6 months, donor had no more symptoms.

### **Case 17**

A 49 year-old female donated a unit of whole blood in the right arm without incident. Immediately after donation she complained of tenderness in the antecubital area near the phlebotomy site. During a routine followup call by the centre staff, the donor reported an area of blue-black discoloration of the skin extending to the axilla.

Four weeks later she sought medical attention for an "egg-sized" lump at the venepuncture site. The surgeon noted a 4.0 cm diameter pulsatile mass over the right brachial artery at the level of the antecubital fossa. She has decreased sensation of her right 1<sup>st</sup> through 4<sup>th</sup> fingers. She underwent successful surgical repair of her lesion.

### **Case 18**

During a whole blood collection, the donor looks pale and starts to feel sick. The collection is stopped, staff applies pressure to the venepuncture site and the chair is placed in the 'feet raised' position. With a cold wet towel on his forehead the donor feels better and the nausea passes.

The donor is allowed to leave, having received appropriate advice, after a further period of observation. No further contact.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### Case 19

A 45-year-old female donor was making her first plasma donation. During the first return phase she noticed a strange taste in her mouth but did not mention this to staff. The second time when she received her red cells back the taste was more pronounced and she felt tingling in her fingers; staff reduced the speed of return and the symptoms became less. However during the next return phase the tingling came back, she felt light-headed and her fingers went into spasm. At this, the staff stopped the procedure.

### Case 20

On inspection of the arm after whole blood donation, and just before leaving the donor centre, the bleeding resumes and there is a tender swelling in the antecubital fossa. Pressure is applied for ten minutes. There is no further bleeding so a pressure bandage is applied and the donor goes home with advice.

The following day the donor came back to the donor centre, now with considerable bluish swelling in the antecubital fossa and around the elbow, pain on flexing the arm and a slight tingling feeling in the fingers. There is no muscle weakness or loss of sensation. The donor is referred to the local hospital for neurological review. The arm is treated by advice for elevation and massage, and symptoms subside gradually over a period of three weeks.

### Case 21

An 85-year-old male long-term donor with a history of prior heart problems left collection centre after unremarkable whole blood donation. Following donation, the donor had stayed in the canteen area for 15 minutes where he had eaten several salty snacks and drank water and fruit juice.

An hour later, the donor calls back stating he was feeling lightheaded. He was advised to put his feet up and perform muscle-tensing exercises. Over the next 5-10 minutes, while still being on the phone with centre staff, the donor began complaining of sweating and pain in chest radiating down donation arm. Staff called emergency medical services and the donor was admitted to the hospital for three days.

After the donor was discharged from the hospital, he calls back the centre stating that all cardiac tests came back negative and he was feeling fine. He thanked the staff for their concern about his health and for calling 911.

### Case 22

When the needle was inserted, donor felt a severe pain in the arm, irradiating down in the forearm and tingling in the fingers. The bleeding procedure was stopped immediately.

Donor had still some symptoms, when he left the bleeding facility; however they disappeared after 1 week.

### Case 23

Despite multiple attempts, phlebotomy staff are unable to initiate flow of blood and donor is released with an unsuccessful draw. The donor calls centre staff the day following donation, stating that he has developed bruising and pain "deep" in arm from elbow to arm pit.

Donor was advised to see personal physician, who diagnosed puncture through vein into underlying tendon. Donor was treated for pain management, given a sling, and told to rest arm for two weeks. Donor went back to work two days later on light duty. Donor's symptoms resolved fully within three weeks and was able to return to full work duty.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### Case 24

A donor was seated in the refreshment area drinking a cup of coffee after donation when others noticed that she had turned pale. Staff were called and as they arrived the donor slumped to the ground. She did not answer staff initially when spoken to but soon afterwards responded normally. She was pale but said she had no pain anywhere and was not feeling nauseated. After resting on a bed and drinking as recommended by staff she was able to sit again without recurrence. She left the donor centre with a friend and reported no further problems when phoned by staff the next day.

### Case 25

A donor donates without incident. The following day the donor rings the blood centre to tell them that four hours after donation the donor attends the accident and emergency department of the local hospital because the arm has re-bled (he saw blood coming through his clothes, so he pressed on the site through the clothes and his girlfriend drove him to the hospital). The bleeding stopped with further pressure and a haematoma is also apparent. Donor is advised not to work for three days.

Over the next two weeks there are two further telephone contacts. There has been no further bleeding. Two weeks after donation there is no haematoma and no more discomfort or inconvenience. The blood centre offers reimbursement for the cost of cleaning his clothes and any loss of salary which may result.

### Case 26

Three days after successful whole blood donation, a 17 year old female on oral contraceptive pills contacted the blood center complaining of progressive pain and swelling in her arm and a small hematoma at the site of venepuncture. She denied redness, fever or warmth of her skin. She was seen in an urgent care center and was referred to a hospital where an ultrasound confirmed the presence of clot in her proximal brachial vein extending to her basilic vein. She was treated with warfarin and taken off her OCP with complete resolution.

### Case 27

The day after whole blood donation (no problems noted on paper or computer dossier) the donor contacts the donor centre by telephone because of considerable pain and some swelling in the elbow region.

Donor is requested to attend the blood centre. Donor has a haematoma, slight tingling in the fingers, and is reluctant to use the arm. No clear muscle weakness or loss of sensation.

Donor is advised to rest and elevate the arm, and gently massage the fingers. Symptoms persist the next day. Donor is referred to hospital for surgical opinion. No compartment syndrome diagnosed. Pain when arm or hand is moved and some muscle weakness persist after disappearance of haematoma, despite physiotherapy, and are still present 1 year after donation.

# AABB, IHN & ISBT Working Group on Haemovigilance

## 2016 Donor Haemovigilance Case Validation Exercise

### **Case 28**

A 23 year-old right-handed male donated blood; the phlebotomist noted fast, bright red blood flow and pressure was applied for 10 minutes followed by ice for 15 minutes. The donor called back a two days later and reported a 7cm by 5cm bruise located in the venepuncture area. he refrained from lifting weights but continued to play soccer.

Two weeks after donation he noticed a “thrill” in the left antecubital fossa and went to his doctor. Physical exam demonstrated a “thrill and bruit” with distended median antecubital, cephalic and basilic veins. No pulsatile mass was noted. Doppler studies demonstrated continuity between the L brachial artery to median antecubital vein. He underwent successful surgical repair of his lesion.

### **Case 29**

A nurse from the emergency room called the bleeding facility and reported that a donor (Ms. X) had been involved in a car accident and had a fracture of the left femur.

Another donor, who was a passenger in the car, told that Ms. X, after driving for about 5 minutes had started to smoke a cigarette. A few minutes later the car swerved to the other side of the road, and was hit by another car. Ms. X had been conscious when ambulance staff lifted her out of the car. The passenger had never lost consciousness and had no injuries.

The donor had fully recovered when she was contacted by the bleeding facility 6 months after the accident.

### **Case 30**

During a whole blood collection, the donor assistant notices that the bag is filling very quickly and the blood is light red in colour. Suspecting arterial puncture, the physician on duty is called. The collection is completed immediately, the needle is removed and 10 minutes’ direct pressure is applied. A firm bandage is put on and after a further period of observation the donor is allowed to leave, with advice and an arrangement that the donor will be rung up the following day. The following day the donor is contacted as arranged. He has removed the bandage by then and there is not even any bruising visible.