Safety of Labile Blood Products

by **Alex Aquilina** *MD DCP (Lond.)*
Responsible Person/Medical Director
National Blood Transfusion Services
St Luke's Square, G'Mangia

The safety of blood depends on a number of processes, procedures, people and premises. The integration of all these factors within a total quality system is critical to ensure a safe and sustainable blood supply. Quality is defined as 'the degree to which a set of characteristics fulfills requirements'. In a blood transfusion service, the primary goal of quality is 'transfusion of a safe unit of blood'. The National Blood Transfusion service is committed to this goal. The main factors influencing infectious complications are discussed

Key words: safe and sustainable blood supply, transfusion, infectious complications.

The practice of blood transfusion is very old and transfusion of blood was considered a method of restoring a person believed to be dying by pouring blood from another person into his veins. The main problems encountered then were clotting of blood and serious adverse reactions.

Today blood transfusion therapy is scientific and successful. The practice of blood transfusion since its adventurous beginnings has improved dramatically. The decision to transfuse must be based on clinical judgement weighing the therapeutic benefits to potential risks. The possibility of transmitting one or more viruses to the recipient continues to be one of the major risks in transfusion medicine.

The prevention of infectious complications of blood transfusion involves multiple factors:

1. Reliance on voluntary non-remunerated donors, donor education and selection by medical criteria. Blood from remunerated donors poses a higher risk of infection .[1,2] The final quality of blood components starts with the selection of donors and blood collection. Donors should be carefully selected according to national regulations. In selecting individuals for blood donation the main purpose is to determine whether the person is in good health, in order to protect the donor against damage to his/her own health, and to protect the recipient against transmission of diseases or drugs which could be detrimental to the patient. To obtain relevant information about the donor's medical history and general health, it is recommended that a pre-printed questionnaire be completed. The premises for blood donation should be clean, well ventilated and with a secure water supply. Facilities should be available for a confidential interview with a donor. All the processes of blood donation such as preparation of puncture site, proper handling of containers, labelling etc. should be standardised.

2. Donation testing for infectious markers using increasingly sensitive screening and confirmation tests. Tests currently used in all countries of the Council of Europe detect HIV I/II antibodies, HCV antibodies, HBs Antigen and with few exceptions *Treponema pallidum* antibodies. In certain countries additional tests for hepatitis B Core antibodies, ALT, and HTLV I / II antibodies are also performed. Only validated tests that have been licensed or authorised by the responsible Health Authorities are applied. Some of these tests are specific to an infection, others are only indicative. With the current generation of anti HIV I / II test kits the average window period is approximately 22 days. There is evidence that HIV I Antigen screening reduces the window period by approx. six days. On these premises the FDA issued recommendations for blood and plasma donation screening with HIV I p24 antigen detection and a confirmatory p24 neutralisation assay. Nucleic Acid amplification tests are able to detect viral or other microbial nucleic acid in biological material even when this is negative by 'traditional' detection techniques. Detection of HIV RNA by PCR shortens the HIV window period by approximately five days more than the p24 Ag testing. HCV RNA could be detected in plasma on average 10-12 days after infection.[3] The HBV DNA could not be detected until 20-30 days after infection.[4]

The hepatitis A-E agents belong to five different virus families. hepatitis A and E are mainly transmitted via the faecal-oral route. The hepatitis B, C and D (delta) as well as GBV – C/V agents are predominantly transmitted parentally.[5,6]

In the early 90's, clusters of HAV infection were seen in Haemophiliacs in four European countries. So far there is no conclusive evidence that HGV causes hepatitis or any other disease. Possibly it is an innocent bystander in diseases caused by other agents. Detection of HGV relies on the demonstration of HGV specific RNA.

Iatrogenic transmission of CJD has been documented for recipients of Human Pituitary derived hormones and dura mater transplants. Furthermore it was also reported in corneal transplants. All lookbacks in recipients of blood from donors who developed CJD were negative.

Surrogate tests: ALT elevation precedes anti HCV seroconversion by about 4 weeks. In a small minority, hepatitis B and C patients may remain seronegative. An acute hepatitis A may be identified. Anti HBc may also pick up seronegative hepatitis B donors. Several reports have shown that hepatitis B Virus infection may be transmitted to recipients from donors with Anti HBc as the only serological marker of hepatitis B infection.[7-9]

Other viruses of potential significance include Parvovirus B19, HTLV I / II and CMV.

In screening for infectious markers there must be special emphasis on training of staff, maintenance and calibration of equipment, and good documentation of all the steps involved. Where the donor is found to have a repeat reactive result on a first sample, a further sample should be tested to confirm these results and to confirm the identity of the donor.

The specific approach to quality of screening must rely on:

a. Internal day-to-day quality control;
b. External Quality checks;
c. Occasional internal exercises;
d. External proficiency exercises.

3. Removal of cell associated micro organisms by leucocyte filtration. Leucocytes are vectors and reservoirs for many infectious agents including CMV and HIV. They may also harbour bacteria such as *Yersinia enterocolitica*. Leucocyte depleted blood is an acceptable alternative to CMV negative blood for the prevention of CMV transmission. Differentiated B-lymphocytes appear to be responsible for transferring Transmissible Spongiform Encephalopathies to the brain, and these cells may be a vector of infection. Universal leucodepletion is today practiced in an increasing number of countries.

4. All aspects of blood safety depend on strict adherence to good manufacturing procedures. All procedures must be well documented. The final point should be a comprehensive audit of all the procedures involved including a 'Haemovigilance' system. Haemovigilance is defined as a system of surveillance, ranging from the collection of blood products to the follow up of recipients, to gather and assess incidents resulting from the transfusion of labile blood products. The aim of such a system is to prevent the recurrence of incidents by identifying their cause.[10,11]

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Abdominal Wall Hernias: Imaging with Spiral CT

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Complications of Hernias:

The most common complications of abdominal wall hernias are bowel obstruction secondary to the hernia, incarceration (Figure 4), and strangulation. These complications can often be detected at clinical evaluation. Presenting symptoms may include abdominal pain, vomiting, and distention. Physical examination may reveal a firm, tender abdominal wall mass. Abdominal distention, dehydration, or peritoneal signs eventually become manifest.

After adhesions, abdominal wall hernias are the second leading cause of small bowel obstruction (10%–15% of cases). Colonic obstruction caused by abdominal wall hernia is uncommon.

Most cases of bowel obstruction secondary to abdominal wall hernia occur after incarceration and strangulation. In these cases, bowel obstruction occurs with the transition point at the level of the hernia. Key CT findings include *(a)* dilated bowel proximal to the hernia and *(b)* normal-caliber, reduced-caliber, or collapsed bowel distal to the obstruction. Other findings may include tapering of the afferent and efferent limbs at the hernia defect, dilatation of the herniated bowel loops, and faecalization of small bowel contents proximal to the obstruction. Findings of strangulation may also be observed.

Incarceration refers to an irreducible hernia and is diagnosed clinically when a hernia cannot be reduced or pushed back manually. The diagnosis of incarceration cannot be made with imaging alone but can be suggested when herniation occurs through a small defect and the hernia sac has a narrow neck (Figure 7).

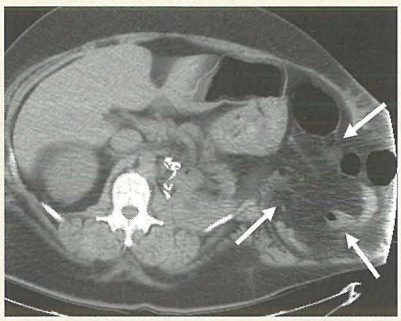

Figure 6: *Diffuse lumbar hernia (arrows) in a 58-year-old man after left nephrectomy for renal cell carcinoma. Note the extensive herniation of the mesentery and bowel loops through the wall defect*

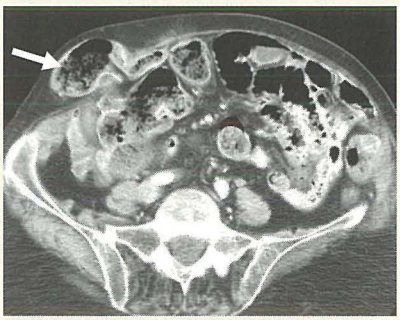

Figure 7: *Incarcerated incisional hernia in a 78-year-old man. Herniation of stool-filled, thin-walled colon (arrow) is seen through a narrow abdominal wall defect. The patient was asymptomatic but presented with acute abdomen 1 month later. The sac of the hernia eventually contained extraluminal fluid and obstructed colon*

Impending strangulation of these hernias should be suspected when there is free fluid within the hernia sac, bowel wall thickening, or luminal dilatation (Figure 7). Strangulation refers to ischemia caused by a compromised blood supply. It usually occurs when the hernia defect obstructs the afferent and efferent bowel loops, creating a closed loop within the herniated bowel.

Surgical Repair

Several different surgical procedures are used to repair abdominal wall hernias, ranging from open or laparoscopic suture repair to the use of mesh. To date, tension-free mesh repair has been accepted as the standard surgical technique for the majority of abdominal wall hernias, regardless of defect size, and is most commonly used.

Occasionally tissue expanders may be required to help stretch the abdominal wall to avoid tension. Complications after surgical hernia repair may occur in up to 50% of cases, depending on surgical technique and the status of the hernia sac vasculature. Approximately one-half of these complications may require surgical reintervention. Complications include hernia recurrence, fluid collections, infections, small intestinal obstruction due to adhesions and mesh-related problems (such as mesh shrinkage due to fibrosis).

Dr Pierre Vassallo can be reached at the Medical Imaging Centre on 21 491 200 or by email on pvassallo@mic.com.mt

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5. Quality Systems – the development and continuous improvement of the blood transfusion service is based on Total Quality Implementation. This involves quality management, quality planning, quality assurance and quality control. The EU Directive 2002/98/EC sets the legal framework for quality in blood establishments.[12] Article 2 of Directive 2005/62/EC sets out the Quality system standards and specifications, which are elaborated in the relevant annex with the same directive.[13]

Conclusion

The provision of a safe and sustainable blood supply reflects the mission statement of the National Blood Transfusion Service. Obviously blood is not 100% safe though all the necessary measures have been implemented. Like any pharmaceutical agent that can potentially have harmful effects (though life saving) it should be used appropriately. Just as there are quality systems in the collection, processing, screening and distribution of blood, quality systems to improve the clinical use of blood should be developed.

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