Medicine Papers, 2016, 2 (4): 53–58

Clinical and management considerations on Donor Deferral

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Summary

The haemotransfusion and haemovigilance systems are regulated by specific national laws. For the purpose of analysing haemovigilance data, donors are classified as "first time donor" and "regular donor". Most of Italian and European donating centers follow the method of the "first time donor". However, many donating centers, in occasion of the first contact with the newcomer, would rather stop to the phase that we could define as clinical information: in this case, we talk about "aspirant donor", who waits for a call in order to become a "candidate" and the method used is that of the so-called "first donor deferral". In the following work, clinical and management considerations on "donor deferral" are provided.

Key Words

Blood; first time donor; regular donor; Donor Deferal; examination; PCR; microbial diversity.

Received 10.06.2016; accepted 02.10.2016; printed 30.11.2016

Introduction

According to all those who work in the transfusion system, the large-scale homogeneity of the procedures to be followed is considered a "value". Infact, the blood, as well as any other drug, must have the same quality requirements wherever it is born.

This is why there is a great number of laws that historically have regulated the system both at national and European level, describing step by step its criteria and methods, in order to make them binding. In laws related to blood transfusions currently in force in Italy (Italian Ministerial Decree of 3 March 2005) we always talk about "candidate donor", namely "*a person who reports to a blood collection unit or a donating center and wishes to donate blood or blood components*", without any reference to the fact it was the "first time" or not.

For the purpose of analysing haemovigilance data, donors are classified as:

- first time donor: someone who has never donated blood or plasma in the donating centers; it includes both first time deferred donors (people who volunteer to donate and are preliminarily subjected to an anamnestic, clinical and diagnostic evaluation intended to determine their donor eligibility) and first time non-deferred donors;
- regular donor: someone who routinely donates blood/plasma (i.e. within the last 2 years) in the same donating center.

Table 1 shows the levels of severity and imputability of serious adverse reactions in recipients adopted in accordance with the European Directive 2005/61/EC.

Discussion and Conclusions

Taking into account these premises, most of Italian and European donating centers follow the method of the "first time donor".

However, many donating centers, in occasion of the first contact with the newcomer, they would rather stop to the phase that we could define as information (collection of the informed approval, history and medical examination, blood test for analytical evaluation), postponing the donation to another moment. Therefore, in this case, we talk about "aspirant donor", who waits for a call in order

LEVEL	DESCRIPTION
SEVERITY	
0	No symptoms
1	Mild symptoms (no therapeutic intervention)
2	Symptoms requiring therapeutic intervention
3	Severe symptoms requiring resuscitation procedures
4	Death
IMPUTABILITY	
N.A. - Non assessable	When there are insufficient data to evaluate the imputability.
0 - Excluded/unlikely	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to alternative causes.
1 - Possible	When the evidence is not such as to allow the attribution of the adverse event either to the blood/blood component or to alternative causes.
2 - Probable	When the available evidence is clearly in favour of attributing the adverse event to the blood or blood component.
3 - Certain	When there is conclusive evidence beyond reasonable doubt that the adverse reaction can be attributed to the blood or blood component.

Figure 2. Microarray test on meat samples. The spots indicate the hybridization signals and the report show the quantitative index that reveal the relative abundance of each specie-specific DNA target.

to become a “candidate” and the method used is that of the so-called “first donor deferral”. (Sicily, Marche, Emilia Romagna, Holland, Denmark, part of Germany).

In Sicily it has been enshrined even with Regional Law, the Decree of 4 April 2006 (“Piano operativo per l'implementazione dei livelli di sicurezza trasfusionale nell'ambito della Regione siciliana” - “Operation Plan for the implementation of transfusion safety levels in Sicilian Region”) requiring that: “*the doctor who is responsible for the collect of units of blood and/or blood components is not allowed to take a blood sample form the citizen volunteering (candidate donor) for donation for the first time without preliminary evaluations having been carried out on him*…”

What donor deferral means: it’s a new way of donating blood for the first time, with the aim of making donors more informed and increasing the safety of collected blood.

The very first time or after a two-years gap after the last donation donor was devoted to a path which provides a double contact with the transfusion service.

During the first meeting, tests establishing blood components safety will be run and they will be completed at the time of donation, during the second contact.

Donor deferral represents a new way to become donors; infact the donor before donating obtain all the information on blood sample techniques, side effects, risk of transmission of infectious diseases with transfusion, risk behaviors for transmission of these infections. The donor follows a training and information path in order to obtain the awareness of a gift that must be safe both for recipients and donors.

These candidate donors are subjected by the transfusion medicine doctor to a clinical-anamnestic evaluation and then to a venous blood sampling in order to confirm their donor eligibility. Then the candidate donor will be able to donate within a timeframe established by the transfusion medicine doctor.

Donor deferral is divided into two steps with the

first considered as pre-qualification and the second as donation.

The tests run during the first step are defined as "pre-qualification tests" and consists in:

a) serological screening (anti HIV, anti HCV, HBsAG, Lues)

b) clinical chemistry profile (ALT, ferritin blood test)

c) complete Blood count

If the tests of the aspirant donor are normal, he or she will receive the results of the tests during the second step, so during the donation. If the tests of the aspirant donor are positive, so if he or she is not eligible to donate, he or she will be included in the haemovigilance protocols (will be immediately reconvened by the transfusion service) for control and confirmation tests.

The reasons given by those who use the method of the "first donor deferral" are basically:

a) higher donor loyalty;

b) the possibility to fight the "occasional blood donor", which is usually aimed at the achievement of a specific and temporary objective (a relative's or a friend's need etc…), whose aim would be undermined by the postponement;

c) an increased awareness due to the period of reflection that, by encouraging the self-exclusions, would result in an increased safety and reduction of losses of transfusion units caused by serological positivity.

With the first donor deferral, the regular and informed donor path starts concretely and give to the donor a central role in terms of increased health protection of the donor himself and the recipient too, all thanks to:

- Appropriate information
- education
- Promotion of healthy lifestyles
- Higher frequency of health checks
- Better monitoring also during identification and pre- and post-donation tests
- Doctor-donor higher confidentiality
- Responsible self-exclusion
- Haemovigilance
- Individuation of any "pre-pathological" state and donor health status monitoring with preventive measures
- Better planning
- Start of new types of donation
- Increase in associative sense of belonging
- Positive social enhancement on other people with whom the donor interacts.

These reasons are in contrast with the ones of those following the alternative method of the "first time donor":

a) the deferral would discourage the new donors, with the result that a large part of them would not recur a second time for blood sampling;

b) the decline of the "occasional blood donor" in favor of the "regular" one represents a cultural objective that must be achieved over time. Reaching it directly through the imposition of a procedure would be inappropriate and probably dangerous for the balance of the system;

c) the deferral could attract "aspirant donors" who actually want to verify for free, regularly and "without exposing themselves", the result of risk behaviors (denied intentionally during the first step);

d) additional costs.

The reasons of both have in common the total lack of documented evidences.

Since the promulgation of the Sicilian disposal has put this issue on the agenda of the Italian transfusion system, it's time to look for these evidences.

A list of papers and documents consulted in the study about Donor Deferal is listed in the following references.

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