How comprehensive should the information published about complications of blood donation be?

Dr. Jose Manuel Cardenas
San Sebastian, Spain
Information to be communicated regarding complications of blood donation

TWO STRIKING EXAMPLES

2005 – Fainting and fatal head injury soon after plasmapheresis procedure

Inaba S. et al Analysis of a questionnaire on adverse reactions to blood donation in Japan. Transf Aph Scie 48(2013) 21-34
Information to be communicated regarding complications of blood donation

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Institutional communications related to severity grade 4 adverse effects on blood donors
Information to be communicated regarding complications of blood donation

Low grade common untoward effects

Fainting
Haematoma
Iron depletion

Other severe complications

Transfusion transmitted infectious disease to blood recipients – perhaps related to a defective selection process
Information to be communicated regarding complications of blood donation

In face of cases with rare but serious adverse complications of blood donation, or common unpleasant adverse effects...

How comprehensive should the information published about complications of blood donation be?
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Blood Establishment’s responsibilities

Objectives of the information to be issued

Methods: Contents and format
Information to be communicated regarding complications of blood donation

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**Risk analysis, preventive and precautionary measures**

A) Local complications
   - Related to vessels
   - Related to pain
   - Other local

B) Generalized complications
   - Vasovagal

C) Apheresis

D) Other

*ISBT Working party on Haemovigilance*
Information to be communicated regarding complications of blood donation

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ISBT Working party on Haemovigilance

Other effects

Iron Depletion
Psychological / Social
   Donor deferral
   Communication of No-OK laboratory results
   BE errors (defective donor data protection)
Information to be communicated regarding complications of blood donation

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ISBT Working party on Haemovigilance
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Vasovagal
  Typology of donors prone to fainting
  Precautionary measures
  Donor advice in the case of fainting
Information to be communicated regarding complications of blood donation

**Risk analysis, preventive and precautionary measures**

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- Typology of donors prone to fainting
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**Apheresis**
- Minimum interval, maximum procedures
- Optimization of devices
Information to be communicated regarding complications of blood donation

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**Iron Depletion**
- Typology of donors prone to get iron complications
- Tests
- Minimum interval, maximum procedures
- Oral iron supplements
Information to be communicated regarding complications of blood donation

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**Risk analysis, preventive and precautionary measures**

Most preventive and precautionary issues are related to good standard practice, improved methods, improved machines, skilled personnel
Information to be communicated regarding complications of blood donation

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Other preventive and precautionary issues depend on donor cooperation.

There are not universal rules regarding risks and preventive measures related to blood donation. Each particular BE should determine its particular situation, mostly based in its own haemovigilance data.
Information to be communicated regarding complications of blood donation

**Risk analysis, preventive and precautionary measures**

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Risk analysis, preventive and precautionary measures

The relationship blood donor – blood bank has evolved over time

- Transfusion Dawn  First WW – Comradery
- Mid – XXth Century  Altruistic, versus paid, versus family
- Seventies  Two quality requirements: 1) altruistic 2) regular
- Nineties  Three Q.R.: 1) altruistic, 2) regular, 3) responsible
Risk analysis, preventive and precautionary measures

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Now we are aware that inter-communication with donors is a critical control point in the BE quality system
Risk analysis, preventive and precautionary measures

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= Donors must be involved in their own selection process
= Donors active response may be important in face of post-donation complications
Information to be communicated regarding complications of blood donation

**Risk analysis, preventive and precautionary measures**

The relationship blood donor – blood bank has evolved over time

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Now we are aware that inter-communication with donors is a critical control point in the BE quality system

- **Donors must be involved in their own selection process**
- **Donors collaborate in the prevention of complications**

**Blood donors should be well informed**
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Blood Establishment’s responsibilities

Objectives of the information to be issued

Methods: Contents and format
Information to be communicated regarding complications of blood donation

Blood Establishment’s responsibilities

**Legal issues**

EU Commission Directive 2004/33/EC establish that BE should provide to donors (among other) the following information:

Reasons why individuals are not to make donations which may be detrimental to their health

*Annex 2 – part A, ítem 4*

Specific information on the nature of the procedures involved in the donation process and their respective associated risks

*Annex 2 – part A, ítem 5*
Blood Establishment’s responsibilities

Social Responsibility

International Standard ISO 26000 provides guidance on social responsibility issues for organizations. Part 4 deals with Principles of Social Responsibility
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TRANSPARENCY. An organization should disclose in a clear, accurate and complete manner... activities for which it is responsible... including the known and likely impacts on the Society

ISO 26000 item 4.3
Blood Establishment’s responsibilities

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**TRANSPARENCY.** An organization should disclose in a clear, accurate and complete manner... activities for which it is responsible... including the known and likely impacts on the Society

*ISO 26000 item 4.3*

**ETHICAL BEHAVIOUR.** Based on the ethics of honesty, equity and integrity... to facilitate the reporting of unethical behaviour without fear of reprisal

*ISO 26000 item 4.4*
Blood Establishment’s responsibilities

Social Responsibility

Social Responsibility bears ethical issues. There are further reasons for an organization to hold S.R. principles.
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Information to be communicated regarding complications of blood donation

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Public image of Blood Donation is vulnerable. In general it holds a favourable image in public opinion and media, something that may change overnight in face of a real or perceived scandal
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- And S.R. is also worth in terms of public image

Public image of Blood Donation is vulnerable. In general it holds a favourable image in public opinion and media, something that may change overnight in face of a real or perceived scandal

It is essential to preserve the image in order to not endanger the blood donation network and the blood service. S.R. methods are useful tools for this to be true
Information to be communicated regarding complications of blood donation

**Blood Establishment’s responsibilities**

**Good standard practice**

Donors must be involved in their own selection as suitable donors

- Should be well informed about the blood donation process, including reasons not to donate in case of risk for themselves or for the recipient

The particular response of a blood donor in case of a delayed reaction may be crucial

- Donors should leave the blood donation site, well informed regarding how to act if he or she feels sick

This information should be provided in a timely manner, by means of a friendly interview and supported by brochures, posters, or other printed material
Information to be communicated regarding complications of blood donation

Blood Establishment’s responsibilities

LEGAL RULES

SOCIAL RESPONSIBILITY RULES

GOOD STANDARD PRACTICE RULES
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Blood Establishment’s responsibilities

Objectives of the information to be issued

Methods: Contents and format
Objectives of the information to be issued

Once reviewed the risks related to blood donation and the BE responsibilities, it should be made clear: which are the objectives of the information to be communicated?
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First of all, to follow standard haemovigilance methods:

- To provide evidence about real facts
- To evaluate them
- To identify improving measures
INFORMATION OBJECTIVES (cont)

To make the public opinion aware of the necessity of blood donors
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To make the public opinion aware of the necessity of blood donors

To inform actual blood donors about the donating process, its risks, post-donation information, and how to act in case of untoward effects
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To inform actual blood donors about the donating process, its risks, post-donation information, and how to act in case of untoward effects

Do not alarm unnecessarily: Blood donation is a safe process, complications are rare and preventable
Information to be communicated regarding complications of blood donation

INFORMATION OBJECTIVES (cont)

To make the public opinion aware of the necessity of blood donors

To inform actual blood donors about the donating process, its risks, post-donation information, and how to act in case of untoward effects

Do not alarm unnecessarily: Blood donation is a safe process, complications are rare and preventable

To present an attractive image of blood donation, friendly, transparent and reliable, even if negative effects have occurred
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Blood Establishment’s responsibilities

Objectives of the information to be issued

Methods: Contents and format
Information to be communicated regarding complications of blood donation

**Methods: Contents and format**

As explained above the public information related to complications of blood donation should be complete.
Information to be communicated regarding complications of blood donation

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As explained above the public information related to complications of blood donation should be complete. It should not be ignored that adverse effects always have alarming negative connotations
Methods: Contents and format

As explained above the public information related to complications of blood donation should be complete. It should not be ignored that adverse effects always have alarming negative connotations.

Transparency does not mean to present raw facts. Simple raw information may be misleading. Severe adverse effects, errors, should not be hidden. Transparency means that data are presented with all the circumstances and coupled with the corrective and preventive measures adopted in each particular case.
Methods: Contents and format (cont.)

The language has to be carefully chosen. Clear, not confusing, not giving room to speculate.
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The more severe the facts are, the higher in the top management must be the reporter.
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At the time of reporting you should bear in mind who will read the report: public opinion, journalists, politicians… However, the most important receiver of the message certainly is the regular donor.
Methods: Contents and format (cont.)

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At the time of reporting you should bear in mind who will read the report: public opinion, journalists, politicians… However the most important receiver of the message certainly is the regular donor.

Remember: the blood donor trusts you. You are in debt with her or him.
Information to be communicated regarding complications of blood donation

Risk analysis, preventive and precautionary measures

Blood Establishment’s responsibilities

Objectives of the information to be issued

Methods: Contents and format

CONCLUSIONS
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Information to be communicated regarding complications of blood donation

How comprehensive should the information published about complications of blood donation be?

1) Haemovigilance data, risk analysis, and preventive measures adopted are altogether the source of information to be transmitted. Blood donors should be well informed.
Information to be communicated regarding complications of blood donation

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1) Haemovigilance data, risk analysis, and preventative measures adopted are altogether the source of information to be transmitted. Blood donors should be well informed.

2) BE responsibilities regarding information encompass legal rules, social responsibility rules, and good standard practice rules.
Information to be communicated regarding complications of blood donation

How comprehensive should the information published about complications of blood donation be?
(cont.)

3) At the time of giving information make yourself clear (explicit) which are the objectives you are looking for
Information to be communicated regarding complications of blood donation

How comprehensive should the information published about complications of blood donation be?
(cont.)

3) At the time of giving information make yourself clear (explicit) which are the objectives you are looking for

4) Language must be clear, complete, not giving room to speculations, bearing in mind the blood donor as the most important receiver of the message. Blood donation is a safe process with very rare complications, preventable in most cases.
THANK YOU!