

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

**Dr. Jose Manuel Cardenas  
San Sebastian, Spain**

## TWO STRIKING EXAMPLES

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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**

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**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?**

**Risk analysis, preventive and precautionary measures**

**Blood Establishment's responsibilities**

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**Methods: Contents and format**

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### A) Local complications

Related to vessels

Related to pain

Other local

### B) Generalized complications

Vasovagal

### C) Apheresis

### D) Other

*ISBT Working party on Haemovigilance*

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Donor deferral

Communication of No-OK laboratory results

BE errors (defective donor data protection)

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Typology of donors prone to fainting

Precautionary measures

Donor advice in the case of fainting

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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 – XX<sup>th</sup> Century Altruistic, versus paid, versus family
- = Seventies Two quality requirements: 1) altruistic 2) regular
- = Nineties Three Q.R.: 1) altruistic, 2) regular, 3) responsible

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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

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

**Blood donors should be well informed**

**Risk analysis, preventive and precautionary measures**

**Blood Establishment's responsibilities**

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**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*

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**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*

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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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**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**

**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**

## Blood Establishment's responsibilities

**LEGAL RULES**

**SOCIAL RESPONSIBILITY RULES**

**GOOD STANDARD PRACTICE RULES**

**Risk analysis, preventive and precautionary measures**

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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)**

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**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**

**Risk analysis, preventive and precautionary measures**

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**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.**

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However the most important receiver of the message certainly is the regular donor**

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**Remember: the blood donor trusts you. You are in debt with her or him**

**Risk analysis, preventive and precautionary measures**

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**CONCLUSIONS**

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**2) BE responsibilities regarding information encompass legal rules, social responsibility rules, and good standard practice rules**

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

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

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**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!**



