- *'One size doesn't fit all'.*
  - Minimum safety of blood and blood components should be set but the best means to achieve that might differ from country to country.
  - Geographical differences in epidemiology of infectious diseases are very significant4, while deferral criteria outlined in Directive 2004/33/EC do not vary accordingly.
  - Within supposedly homogeneous risk groups, the actual risk level varies widely, while the approach to managing these risks is the same.
  - Several improved techniques of processing of blood components (including pathogen inactivation), which significantly reduce the risk of transmission of pathogens by blood products, are not properly reflected in the risk assessment process.

- *Inflexibility.*

The Directive is rather inflexible regarding donor eligibility criteria. However, since its adoption, several risks of acquiring a transfusion-transmissible infection have evolved, either to a lower or higher level, for example:

  - Endoscopy (lower risk), tattoo and body piercing (lower risk), major surgery (lower risk), travellers' borne infectious diseases (higher risk);

- *Inconsistency.*

In absolute measures comparable risks at times lead to highly variable deferral periods (see also Table 1 in Annex).

  - For transfusion-transmittable infections, the length of the window period of donor screening tests should logically determine the deferral period, but in many situations this is not the case.
  - Deferrals related to the use of medicinal products often lack the support of toxicological/pharmacological/pharmacokinetic reasoning;
  - Risks related to both donor safety and possibly transmissible diseases, such as pre-malignancies or prion diseases show widely varying deferral periods.

Proposed solutions

The revision exercise should not only integrate medical and technical progress acquired in the last decade but go further, enabling the blood transfusion community to deal with future changes or emerging threats to blood safety without the need to revise European law.

- The acceptable risk to donors should be further defined and communicated to donors
- The acceptable risks to patients should be further defined and elaborated, eg by setting standards of acceptability [allowable/confidence range for predictive values] in identifying the true risk to an individual combined with morbidity or mortality

[4] European Centre for Disease Prevention and Control. Annual epidemiological report 2014 - sexually transmitted infections, including HIV and blood-borne viruses. Stockholm: ECDC; 2015.