

# The Dublin Consensus Statement 2011 on vital issues relating to the collection and provision of blood components and plasma-derived medicinal products

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Following a conference in Dublin in 2010, a consensus statement was published in this journal (1). In January 2011, a follow-up conference was convened in Dublin under the auspices of the plasma users coalition (PLUS) to further consider the statement produced in Dublin in 2010. The goal was to negotiate a revised set of principles which could be potentially accepted by most stakeholders including global patient, donors, manufacturing and provider organisations. PLUS was eager to continue the constructive dialogue that commenced between key stakeholders in 2010.

PLUS represents the concerted views of seven patient organisations, whose members are dependent on products manufactured from plasma. The goal of PLUS in this work is to help encourage the production of a sufficient supply of safe and effective plasma-derived medicinal products (PDMPs) to meet the global needs of patients. By recognising that the collection systems for blood components and PDMPs are interrelated in a number of countries, this meeting considered the collection of both blood and plasma and the manufacture of PDMPs from both the industry and not for profit sectors, and the views of national blood authorities, patient and donor organisations.

The meeting was attended by the following persons representing organisations as follows:

PLUS members: Brian O'Mahony (Convenor) -European Haemophilia Consortium (EHC) and Irish Haemophilia Society, David Watters-IPOPI, Larry Warren, Johan Prevot-IPOPI, Uwe Schlenkrich-EHC, David Page-WFH,

Other participants: Mark Skinner-A-PLUS and World Federation of Hemophilia(WFH), Charles Waller and Albert Farrugia - Plasma Proteins Therapeutics Association, Bob Perry and Theo Evers- International Plasma Fractionation Association (IPFA), Roger Dodd-International Society of Blood Transfusion, Niels Mikkelsen-International Federation of Blood Donor Organizations (IFBDO), Jim MacPherson-America's Blood Centers, Alison Turner-National Blood Authority Australia, Patrick Robert-Marketing Research Bureau Cees van der Poel EDQM, Paul Strengers -ISBT/ Sanquin, Gilles Follae-European Blood Alliance (EBA).

A number of other organisations were invited to send representatives, including WHO, Thalassaemia International Federation and the International Federation of Red Cross and Red Crescent Societies but were unable to attend because of other commitments.

The statement produced in 2010 had been fully endorsed by 22 patient organisations and was endorsed with qualification by a number of other key stakeholder organisations. The most consistent qualification raised by organisations related to the previous clause 2.11 which was interpreted by some as providing endorsement for paid donations. Organisations that operate within a framework that only supports unpaid donors were therefore unwilling to fully endorse the 2010 statement. Not unexpectedly, this issue occupied a significant amount of time at the 2011 meeting. The final wording agreed recognises that different organisations will operate within different policy and regulatory frameworks, but acknowledges that both systems are needed at the current time. Encouragingly, there has emerged an improved understanding and dialogue between paid and non paid system advocates of the need for both

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systems to work together in the interests of patients and safe and ethical production.

The following Dublin Consensus 2011 statement was agreed by all the participants present as being suitable for submission to their respective organisations for their consideration and possible endorsement.

The scope of those endorsing the 2011 statement has significantly broadened beyond the 22 patient organisations that endorsed the 2010 statement and now includes 29 patient organisations and many of the major global blood sector organisations representing blood donors, European and USA alliances of blood operators and not-for-profit plasma fractionators.

As of 6 June 2011, the Dublin Consensus Statement 2011 has been fully endorsed by the following organisations:

PLUS\*

A PLUS (American Plasma users coalition)<sup>§</sup>

Network of Rare Blood Disorder Organisations (Canada)<sup>†</sup>

International Federation of Blood Donor Organizations (IFBDO)

European Blood Alliance (EBA)

International Plasma Fractionation Association (IPFA)

America's Blood Centres

Alliance of Blood Operators (USA)

The statement is supported in principle with qualification by the following:

International Society of Blood Transfusion (ISBT) and

Plasma Protein Therapeutics Association (PPTA)

The ISBT intend to have the statement considered by their ethics committee prior to making a decision on full endorsement. They wish to clarify whether the activities of commercial plasma collectors are covered by the ISBT Code of ethics. The qualifications expressed by the PPTA relate to section 3, and the statement that the coexistence of two independent collection systems could create a risk of shortage in supply. They are also of the view that there is no justification for a difference in wording between sections 3.1 and 3.2 as they believe that both sectors should be equally committed to respect the roles of the other sector. Both ISBT and PPTA welcome the 2011 statement as a significant improvement on the 2010 statement.

The discussions in Dublin raised a number of issues that were of concern to both operators and patient groups alike. One key concern related to the need to facilitate the collection and use of plasma that is not needed for component production. In some cases, this plasma is not able to be used as it cannot be collected and transported under the appropriate quality conditions to a fractionation facility, and frequently, national regulations do not allow the processing of imported plasma. While there is unanimous support for regulation supporting safe manufacture, there was agreement that there needs to be further discussions as to

whether regulation can better support an increased global supply of safe PDMPs.

The meeting was also supportive of the need for more comprehensive, accurate and timely data on all aspects of blood components and PDMPs. This data will be important to allow for appropriate planning and evidence-based decision-making.

The issues that delegates had differing views on included the value and practicality of self-sufficiency and the potential impact on supply because of the presence of two independent collection systems, one for blood and one for plasma, in a country. Further discussions on this issue would be enhanced by evidence of performance when both systems coexist.

All delegates accepted the need for a co-operative and respectful coexistence between the two systems

The 2011 meeting was an important facilitator of improving dialogue that will promote a co-operative approach to the development of ethical and safe systems of blood and plasma collection and provide the best quality of care for both donors and patients.

PLUS has agreed to support a further conference in 2012 to encourage more detailed discussion on the issues of concern to the patient community and to bring people together to discuss possible solutions in a spirit of co-operation.

\*PLUS members comprise the International Patients Organisation for Primary Immunodeficiency (IPOPI), the World Federation of Hemophilia (WFH), the European Haemophilia Consortium (EHC), Alfa Europe, Idiopathic Thrombocytopenic Purpura Support Organisation (ITP), Hereditary Angiodema International (HAEI) and Guillain-Barre Syndrome Foundation International (GBS/CIDP).

<sup>§</sup>American Plasma Users coalition is comprised of the following organisations -Alpha 1 Association, Alpha 1 Foundation, GBS/CIDP Foundation International, Committee of Ten Thousand, Hemophilia Federation of America, Immune Deficiency Foundation, Jeffrey Modell Foundation, National Hemophilia Foundation, Platelet Disorder Support Association, Patient Services Incorporated.

<sup>†</sup>Network of Rare Blood Disorder Organisations, Canada - Answering TTP (Thrombotic Thrombocytopenic Purpura), Aplastic Anaemia and Myelodysplasia Association of Canada (AAMAC), Canadian Association of Paroxysmal Nocturnal Hemoglobinuria (PNH), Canadian Hemophilia Society (CHS), Canadian Hereditary Angioedema Network (CHAEN), Canadian Immunodeficiencies Patient Organization (CIPO), Canadian Organization for Rare Disorders (CORD), Canadian Association for Porphyria (CAP), Quebec Sickle Cell Anemia Association (QSA), Sickle Cell Association of Ontario (SCAO), Sickle Cell Disease Parents' Support Group of Ottawa (SCDPSC), Thalassemia Foundation of Canada (TCF).

# Dublin Consensus Statement 2011

*Principles to apply to the collection and provision of blood components and plasma-derived medicinal products*

## Introduction

The two major priorities for the global community in providing patients with adequate and safe blood components and plasma-derived medicinal products (PDMPs) are to:

- Provide and maintain safe, sustainable and sufficient blood components in all countries through the development of national blood transfusion systems based on voluntary non-remunerated donors.
- Provide an adequate supply of PDMPs from recovered and source plasma to meet patient needs on a global level.

The following principles apply to:

- Blood establishments whose principal objective is the collection of blood for the production of blood components for transfusion purposes and, in some cases, plasma for further fractionation, and
- The plasma industry which collects plasma exclusively for subsequent fractionation into PDMPs.

PDMPs made from both non-remunerated and remunerated donations are currently essential to meet global health needs.

The donation of blood or plasma and its transformation into products that save and enhance the lives of patients are invaluable contributions to modern healthcare.

Respect for individuals, maintaining the health of blood and plasma donors and providing safe blood and PDMPs for patients are of utmost importance.

Countries and regions are entitled to have policies and practices on blood and plasma, which reflect their political, cultural, ethical and economic contexts.

Blood establishments and the plasma industry must operate within stringent national, regional and international regulatory regimes that support the safe and effective collection and provision of blood components and PDMPs.

The principles outlined below provide the foundation on which blood establishments and the plasma industry should build their operations.

## Principles

### 1. Patients

The absolute focus of the blood establishments and the plasma industry in health care must be the patient.

- 1.1 Meeting the health needs of patients through a sufficient supply of safe and effective blood components

and PDMPs is the principal goal of blood establishments and the plasma industry. An insufficient supply is a major safety risk to patients.

- 1.2 Patients are entitled to expect that all stakeholders will support their need for access to safe and effective products.
- 1.3 Patients whose continued health is dependent on the use of blood components or PDMPs have a right, through their representative organisations, to be consulted on any issue which may have an impact on the safety, efficacy or supply of the treatment they receive. Health Authorities should ensure that robust mechanisms are in place to ensure that this happens.
- 1.4 Blood establishments and the plasma industry must ensure that their actions do not compromise the health status of those who receive blood components or PDMPs.
- 1.5 Blood establishments and the plasma industry should take all reasonable steps to eliminate the possibility of adverse reactions and events including transmission of pathogens. Benefits and risks vary from product to product, and each product should be assessed individually.

### 2. Donors

- 2.1 Blood establishments and the plasma industry must respect the intrinsic dignity of all people involved in the blood and plasma donation process.
- 2.2 Blood establishments and the plasma industry and society in general should highly value all those who donate blood or plasma for the benefit of patients and recognise that donors perform a good deed and treat donors with respect.
- 2.3 There is a limit to the capacity of blood establishments and the plasma industry to ensure the safety of blood and PDMPs through testing and processing alone. It is therefore important that measures to defer donors are based on a precautionary approach and underpinned by evidence-based assessment where feasible. Deferral policies should be explained clearly to donors.
- 2.4 All people may offer blood or plasma to the community, and their generosity is highly valued. However, blood establishments and the plasma industry have an obligation to only accept blood or plasma where the donor selection criteria are met.

- 2.5 All donors must be provided with clear and accessible information prior to their donation, which should include information on:
- the potential risks to them of donating blood or plasma,
  - the intended use of their donation,
  - who might benefit from their donation, including the health benefits for patients, benefits to the blood establishment, the plasma industry and to any other party that facilitates the donation.
- 2.6 All donations should be voluntary.
- 2.7 All donors must give their free and informed consent prior to the donation.
- 2.8 Donor identity and their personal and medical information will be kept private and confidential in accordance with relevant guidelines and legislation.
- 2.9 Donors should not be exploited by any individual or organisation. Measures and initiatives taken to encourage blood, and plasma donations should not overwhelm the capacity of the donor to make an informed decision about whether to donate.
- 2.10 Blood establishments and the plasma industry owe a professional duty to act in the best interests of those that donate and receive blood and PDMPs.
- 2.11 The health of the donor should not be compromised by their donation.

### 3. Co-operation

Currently, two main systems exist for people who donate

- non-remunerated donations according to current definitions and
- remunerated donations

The production of blood components and of PDMPs involve different manufacturing pathways, have access to different risk mitigation measures, and the products are used to treat different diseases. There is concern that the presence of two independent collection systems, one for blood and one for plasma, in the same region or country, could create a risk of shortage in supply. Co-operation between blood establishments and the plasma industry is important to ensure that the best community outcomes are achieved including sufficiency of supply for patients.

- 3.1 Activities undertaken to support plasma collection should not compromise the ability of a nation or a region to collect adequate supplies of blood components to meet clinical needs.

- 3.2 Similarly, activities undertaken to provide adequate supplies of blood components should take into account the ability of those who collect plasma for fractionation to meet the requirements of patients who rely on these therapies.
- 3.3 Organisations involved in blood and plasma collection should co-operate with the goal of ensuring the health of the donor and potential blood component and PDMP recipients.
- 3.4 The manufacture of blood components and PDMPs to treat patients with very rare diseases should be welcomed and actively supported by all those that operate in blood establishments and the plasma industry.
- 3.5 All stakeholders in blood establishments and the plasma industry have the right to hold and express opinions and should treat each other with mutual respect.

### 4. Global utilisation of donated blood and plasma

The products of blood establishments and the plasma industry are sometimes not needed to meet the blood and plasma product needs in that particular region. This is because a number of different products can be produced from a single blood or plasma donation. Many regions lack the capacity to collect and produce all the blood products they need, so they are reliant on blood or plasma donated in another region. Donors expect their blood or plasma to be used to benefit patients who need blood and PDMPs.

- 4.1 The needs of patients should determine the optimal collection of blood and plasma.
- 4.2 Blood establishments and the plasma industry have an obligation to donors to make their best endeavours to use that blood or plasma for the purposes for which it was donated.
- 4.3 Having satisfied the principal purpose for its collection, blood components, plasma and plasma intermediates not required for that purpose should be made available to meet the health needs of others and contribute to global health outcomes where feasible. Feasibility includes whether the costs of provision are able to be met and whether the regulatory regime and health care systems in both regions support availability.
- 4.4 Regulation of the collection and use of plasma for manufacture should be based on appropriate risk management principles. Regulation should facilitate global movement of plasma, intermediates and PDMPs when safe and appropriate to do so.

### References

- 1 O'Mahony B, Turner A: The Dublin Consensus Statement on vital issues relating to the collection of blood and plasma and

the manufacture of plasma products. *Vox Sang*, 2010; **98** (3p2), 447–450, Article first published online: 11 FEB 2010, DOI: 10.1111/j.1423-0410.2010.01310.x.