資料３－３

世界保健総会(World Health Assembly)

においてこれまで採択された血液関係の主な決議

１．第28回世界保健総会決議（1975年）（別添１）

WHA28.72　Utilization and supply of human blood and blood products

○　主な加盟国への勧告

「無償の献血に基づく国家血液事業の設置を推進すること。」

『to promote the development of national blood services based on voluntary nonremunerated donation of blood』

２．第58回世界保健総会決議（2005年）（別添２）

WHA58.13　Blood safety: proposal to establish World Blood Donor Day

○　主な加盟国への勧告

「必要に応じ、医療上必要な場合を除き、有償の供血を廃止する法整備を行うこと。また、そのような（有償の供血を実施する）場合は、輸血を受ける患者のインフォームドコンセントを得ること。」

『to introduce legislation, where needed, to eliminate paid blood donation except in limited circumstances of medical necessity and, in such cases, to require informed assent of the transfusion recipient』

３．第63回世界保健総会決議（2010年）（別添３）

WHA63.12　Availability, safety and quality of blood products

○　主な加盟国への勧告

「特別な場合を除き、国内自給を達成することを目的として、資源の入手可能性に基づき、国家的に調整され、効率的に管理された、持続可能な血液および血漿プログラムを実施するためのすべての必要な措置をとること。」

『to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it』

TWENTY-EIGHTH WORLD HEALTH ASSEMBLY, GENEVA, 13–30 MAY 1975
WHA28.72 Utilization and supply of human blood and blood products

The Twenty-eighth World Health Assembly,

Conscious of the increasing use of blood and blood products;

Having considered the information provided by the Director-General on the utilization and supply of human blood and blood products;

Bearing in mind resolution XVIII of the XXII International Conference of the Red Cross;

Noting the extensive and increasing activities of private firms in trying to establish commercial blood collection and plasmapheresis projects in developing countries;

Expressing serious concern that such activities may interfere with efforts to establish efficient national blood transfusion services based on voluntary nonremunerated donations;

Being aware of the higher risk of transmitting diseases when blood products have been obtained from paid rather than from voluntary donors, and of the harmful consequences to the health of donors of too frequent blood donations (one of the causes being remuneration),

1. THANKS the Director-General for the actions taken to study the problems related to commercial plasmapheresis in developing countries;

2. URGES Member States:

   (1) to promote the development of national blood services based on voluntary nonremunerated donation of blood;

   (2) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products;

3. REQUESTS the Director-General:

   (1) to increase assistance to Member States in the development of national blood services based on voluntary donations, when appropriate in collaboration with the League of Red Cross Societies;

   (2) to assist in establishing cooperation between countries to secure adequate supply of blood products based on voluntary donations;

   (3) to further study the practice of commercial plasmapheresis including the health hazards and ethical implications, particularly in developing countries;

   (4) to take steps to develop good manufacturing practices specifically for blood and blood components in order to protect the health of both donors and recipients; and

   (5) to report to the World Health Assembly on developments in these matters.

Handb. Res., Vol. I, 1.5.2.2; 8.2.4 Thirteenth plenary meeting, 29 May 1975
(Committee A, fourth report)

WHA58.13 Blood safety: proposal to establish World Blood Donor Day

The Fifty-eighth World Health Assembly,

Recalling resolution WHA28.72 which urged the development of national blood services based on the voluntary, nonremunerated donation of blood;

Having considered the report on blood safety;[1]

Alarmed by the chronic shortage of safe blood and blood products, particularly in low- and medium-income countries;

Mindful that preventing the transmission of HIV and other bloodborne pathogens through unsafe blood and blood-product transfusions requires the collection of blood only from donors at the lowest risk of carrying such infectious agents;

Recognizing that voluntary, nonremunerated blood donation is the cornerstone of a safe and adequate national blood supply that meets the transfusion requirements of all patients;

Noting the positive responses to World Blood Donor Day, 14 June 2004, for the promotion of voluntary, nonremunerated blood donation,

1. AGREES to the establishment of an annual World Blood Donor Day, to be celebrated on 14 June each year;

2. RECOMMENDS that this blood donor day should be an integral part of the national blood-donor recruitment programme;

3. URGES Member States:

(1) to promote and support the annual celebration of World Blood Donor Day;

(2) to establish or strengthen systems for the recruitment and retention of voluntary, nonremunerated blood donors and the implementation of stringent criteria for donor selection;

(3) to introduce legislation, where needed, to eliminate paid blood donation except in limited circumstances of medical necessity and, in such cases, to require informed assent of the transfusion recipient;

(4) to provide adequate financing for high-quality blood donation services and for extension of such services to meet the needs of the patients;

(5) to promote multisectoral collaboration between government ministries, blood transfusion services, professional bodies, nongovernmental organizations, civil society and the media in the promotion of voluntary, nonremunerated blood donation;

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[1] Document A58/38.

(6) to ensure the proper use of blood transfusion in clinical practice so as to avoid abuse of blood transfusion, which may result in a shortage of blood and hence stimulate the need for paid blood donation;

(7) to support the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems through, in particular:

(a) government commitment and support for a national blood programme with quality-management systems, by means of a legal framework, a national blood-safety policy and plan, and adequate resources

(b) organization, management and infrastructure to permit a sustainable blood transfusion service

(c) equitable access to blood and blood products

(d) voluntary, nonremunerated blood donors from low-risk populations

(e) appropriate testing and processing of all donated blood and blood products

(f) appropriate clinical use of blood and blood products;

(8) to establish a quality process for policy- and decision-making for blood safety and availability based on ethical considerations, transparency, assessment of national needs, scientific evidence, and risk/benefit analysis;

(9) to share information nationally and internationally in order to make clear the scientific, economic and social basis of national policy decisions related to blood safety and availability;

(10) to strengthen partnerships at all levels in order to accomplish these recommended actions;

4. CALLS UPON international organizations and bodies concerned with global blood safety to collaborate in promoting and supporting World Blood Donor Day;

5. INVITES donor agencies to provide adequate funding for initiatives to promote voluntary, nonremunerated blood donation;

6. REQUESTS the Director-General:

(1) to work with other organizations of the United Nations system, multilateral and bilateral agencies, and nongovernmental organizations to promote World Blood Donor Day;

(2) to work with concerned organizations to provide support to Member States in strengthening their capacity to screen all donated blood against major infectious diseases in order to ensure that all blood collected and transfused is safe.

(Eighth plenary meeting, 23 May 2005 –
Committee B, first report)

126th Session EB126.R14

Agenda item 4.16 22 January 2010

Availability, safety and quality of blood products[1]

The Executive Board,

Having considered the report on availability, safety and quality of blood products,[2]

RECOMMENDS to the Sixty-third World Health Assembly the adoption of the following resolution:

The Sixty-third World Health Assembly,

Recalling resolution WHA58.13 on blood safety: proposal to establish World Blood Donor Day and preceding related resolutions since resolution WHA28.72 on utilization and supply of human blood and blood products, which urged Member States to promote the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems and to enact effective legislation governing the operation of blood services;

Recognizing that achieving self-sufficiency, unless special circumstances preclude it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population;

Conscious that plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines[3] and of the need to facilitate access to these products by developing countries;

Concerned by the unequal access globally to blood products, particularly plasma-derived medicinal products, leaving many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment;

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[1] The term Blood products is defined by the WHO Expert Committee on Biological Standardization as follows:

"Blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products".

[2] Document EB126/19.

[3] The WHO Model List of Essential Medicines identifies individual medicines that together could provide safe and effective treatment for most communicable and noncommunicable diseases. This List includes plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide (http://www.who.int/medicines/publications/essentialmedicines/en/index.html).

Aware that a major factor limiting the global availability of plasma-derived medicinal products is an inadequate supply of plasma meeting internationally recognized standards for fractionation;

Bearing in mind that treatment using labile blood components is gradually being included in medical practice in developing countries and that thereby increased quantities of recovered plasma should become available for fractionation into plasma-derived medicinal products to meet their needs;

Concerned that in developing countries, blood components separation technology and fractionation capacity are lacking, and because of insufficient regulatory controls and failure to implement appropriate practices in blood establishments, plasma from developing countries is often unacceptable for contract fractionation, with considerable wastage of plasma as a result;

Convinced that assuring the suitability of plasma for fractionation requires the establishment of a nationally coordinated and sustainable plasma programme within a properly organized, legally established and regulated national blood programme;

Recognizing that the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs;

Convinced that fractionation should be set up as close to the source as possible, and that, where national plasma fractionation capacities are lacking, there should be an option for supply of fractionation capacity in other countries, it should be ensured that the supply of plasma derived medicinal products can be made available to meet local needs in the country of the plasma supplier;

Recognizing that access to information about strategies to ensure supplies of blood products sufficient to meet demand, effective mechanisms of regulatory oversight, technologies to ensure the quality and safety of blood products, guidelines on the appropriate clinical use of blood products and the risks of transfusion have become more and more necessary;

Bearing in mind that voluntary and non-remunerated blood donations can contribute to high safety standards for blood and blood components and being aware that the safety of blood products depends on testing of all donated blood for transfusion-transmissible infections, and correct labelling, storage and transportation of blood products;

Bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimize the patient's own blood volume, to minimize the patient's blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following the WHO's guide for optimal clinical use (three pillars of patient blood management);

Recognizing that excessive and unnecessary use of transfusions, and plasma derived medicinal products, unsafe transfusion practices and errors (particularly at the patient's bedside) seriously compromise patient safety;

Concerned that unsafe and/or poor-quality blood products can render patients vulnerable to avoidable risk if the blood programmes are not subject to the level of control now exercised by experienced national or regional regulatory authorities;

Alarmed that patients in developing countries continue to be exposed to the risk of preventable transfusion-transmitted infections by bloodborne pathogens such as hepatitis B virus, hepatitis C virus and HIV;

Noting the increasing movement across boundaries of blood products and blood safety related in vitro diagnostic devices, together with their rapid development and introduction into health-care systems of both developed and developing countries;

Recognizing the value of international biological reference materials (WHO International Standards) for the quality control of blood products and related in vitro diagnostic devices for detection of known and emerging bloodborne pathogens;

Convinced that traceability of all stages of the preparation of blood products, from the donor to the recipient and vice versa, is essential to identify risks, particularly the transmission of pathogens and transfusion reactions, and to monitor the efficacy of corrective measures aiming to minimize such risks;

Convinced that good practices need to be implemented for recruiting voluntary, non-remunerated healthy blood and plasma donors from low-risk donor populations, and testing of all donated blood for transfusion-transmissible pathogens, and that the whole chain of processes in the production of blood products, i.e. correct processing, labelling, storage and transportation needs to be covered by relevant, reliable quality assurance systems;

Recognizing that stringent regulatory control is vital in assuring the quality and safety of blood products, as well as of related in vitro diagnostic devices, and that special effort is needed to strengthen globally the technical capacity of regulatory authorities to assure the appropriate control worldwide;

Recalling previous resolutions of the Health Assembly mentioning the vital need to strengthen blood establishments and ensure the quality, safety and efficacy of blood products.

1. URGES Member States:[1]

(1) to take all the necessary steps to establish, implement and support nationally coordinated, efficiently managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it;

(2) to take all the necessary steps to update their national legislation on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products and operation of regulatory authorities to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards;

[1] And regional economic integration organizations, where applicable.

(3) to establish quality systems, for the processing of whole blood and blood components, good manufacturing practices for the production of plasma-derived medicinal products and appropriate regulatory control;

(4) to build human resource capacity through the provision of initial and continuing training of staff to ensure quality of blood services and blood products;

(5) to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices;

(6) to establish or strengthen systems for the safe and rational use of blood products and to provide training for all staff involved in clinical transfusion, to implement potential solutions in order to minimize transfusion errors and promote patient safety, to promote the availability of transfusion alternatives including, where appropriate, autologous transfusion and patient blood management;

(7) to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma-derived medicinal products, including transmissions of pathogens.

2. REQUESTS the Director-General:

(1) to guide Member States to meet internationally recognized standards in updating their legislation, national standards and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

(2) to advise and build capacity in Member States on leadership and management of blood supply systems in order to strengthen national coordinated and sustainable blood and plasma programmes by sharing best practices about the best organizational structure for blood supply systems in order to increase efficiency and minimize error;

(3) to extend the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and fostering the creation of regional collaborative and regulatory networks where necessary and appropriate;

(4) , to ensure sustainable development and provision of international biological reference materials (WHO International Standards) for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to international biological reference materials and to the scientific information obtained in their validation in order to assure the appropriate use of these materials;

(6) to develop, provide and disseminate guidance and technical support to strengthen national coordinated blood and plasma programmes and introduction of blood component separation and plasma fractionation technology, to meet local needs, and promote effective regulatory oversight of blood services and implementation of good

manufacturing practices in plasma-fractionation programmes, under the responsibility of regulatory authorities;

(7) to provide guidance, training and support to Member States on safe and rational use of blood products to support the introduction of transfusion alternatives including, where appropriate, autologous transfusion, safe transfusion practices and patient blood management;

(8) to encourage research into new technologies for producing safe and effective blood substitutes;

(9) to inform regularly, at least every four years, the Health Assembly, through the Executive Board, on actions taken by Member States and other partners.

Twelfth meeting, 22 January 2010
EB126/SR/12

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