10.6 Blood and other medical products of human origin

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In focus at EB136

In response to proposals from Member States to call for a Health Assembly resolution on self-sufficiency in blood and blood products based on voluntary non-remunerated donations, and the call at the Sixty-seventh World Health Assembly for the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation to be applied to medical products of human origin, the Secretariat has produced this report (EB136/32) *which covers both blood and other medical products of human origin.*

Background

WHA63 (May 2010) had before it Secretariat reports on Availability, safety and quality of blood products (A63/20) and Human organ and tissue transplantation (A63/24). Two corresponding resolutions were adopted: WHA63.12 (page 19) on blood products and WHA63.22 (page 45). Both of these resolutions commissioned progress reports, at least every four years.

Progress reports were submitted to WHA67 in May 2014 in A67/40 and in the Assembly debate (A67/A/PSR/12, page 48) both Spain and Argentina spoke commenting on the broad area of medical products of human origin emphasising the non-commercial nature of the supply systems. Spain welcomed the Secretariat's special initiative on medical products of human origin and asked that it continue to be developed.

EB136/32 has been prepared by the Secretariat in response to this request. EB136/32 sets out the main policy issues and sketches the directions for further development. The EB is requested to advise on further action.

There are two broad policy objectives involved:

- access according to need to blood and tissue products and services; and
- reducing the need for (and inappropriate use of) blood and tissue products.

Access according to need to medical products of human origin involve:

- funded and functional public health systems; health system strengthening,

- technologies for processing (capacity building, technology transfer, institutional development),
- institutional systems for collection, processing, distribution and regulation:
    - health services capacity building: prompt and efficient harvesting, sensitive conversations,
    - capacity building, development cooperation,
- community understanding (importance of donation, willingness to donate without remuneration, advance permission),
- quality and safety of blood and tissue products:
    - national regulatory authorities and institutional systems,
    - international policy frameworks (self sufficiency, guiding principles, regulatory norms, limits on price gouging),
    - international biological standards and reference materials,
    - monitoring, surveillance, responding (national and international; eg policing organ trade, responding to new risks),
- quality and safety regarding the use of blood and tissue products:
    - clinical standards and guidelines,
    - institutional systems for monitoring usage including adverse event monitoring, and
- investing, evaluating, adapting, regulating new technologies.

Reducing the need for medical products of human origin involves:

- injury and NCDs prevention,
- containing overuse and inappropriate use, and
- development and use of alternative products.

PHM Comment

The report before the EB (EB136/32) argues for voluntary, non-remunerated, non-coerced donation of blood and tissues/organs on the basis of the principle of 'human dignity'. In fact the ethical analysis underlying this argument is not well presented. For example, it is not clear why donation of human tissues should be non-coerced in comparison to seat belt laws or drink driving laws.

The Report is confused and confusing regarding incentives for donation. On the one hand it insists (for instance in paras 2, 5 and 7) on 'donation' (free of remuneration, incentive and inducement but potentially including reimbursement for genuine loss of income and out of pocket expenses) but then also discusses 'undue inducement' and 'disproportionate incentives' (para 3), both of which are open to interpretation and exploitation. In paras 3 and 4 there is explicit acceptance of the use of incentives: 'The use of incentives to improve the rate of donation should be avoided when this becomes an undue inducement or coercion' and '… donation incentives should not adversely affect the availability and safety of the final products'. Any material incentive or inducement (other than genuine reimbursement) that causes someone

to do something that they would not otherwise do negates the idea of donation. Further work is needed to develop a more useful and ethical position on the use of medical products of human origin, including for research as well as clinical use.

In para 10 the Report notes the need to ensure evidence based use of medical products of human origin and to avoid inappropriate or overuse. The emerging evidence of widespread inappropriate blood transfusion with considerable morbidity and mortality is of deep concern. (See for instance the worrying video about blood transfusions at: https://www.youtube.com/watch?v=gV4Nmjg29p0 and Goodnough & Murphy in the BMJ in Nov 2014 at http://www.bmj.com/content/349/bmj.g6897). In revising this Report for the Assembly the issue of inappropriate and harmful use of blood products needs to be elaborated much more clearly.

It is not clear from the current nor previous reports:

- what progress is being made in terms of redressing the current inequities with regard to access to needed medical products of human origin?
- what are the principal barriers to addressing these inequities as fast and efficiently as possible?
- what progress is being made in curbing inappropriate use of medical products of human origin?
- whether all levels of the Secretariat working in the most strategic and coherent ways to overcome the access barriers and to curb inappropriate use?
- if not, what new directions may be required?

The directions suggested under the heading 'The way forward' are quite general. PHM recommends that the Board consider the development of a standardised protocol for health impact assessment regarding both the costs and benefits of the use of medical products of human origin and the costs and benefits of various methods of increasing availability.

PHM urges the Board to request a more comprehensive report regarding availability and use with quantitative indicators reflecting on progress, trends, barriers, and Secretariat activities at all three levels. A health impact protocol as suggested above could provide the basis for comparative indicators.

The availability and use of medical products of human origin is an important issue for health systems around the world. It is not clear that the resources necessary to properly address these issues are currently available to the WHO Secretariat. PHM calls for Real Reform: lift the freeze, reform the regions, hold the MSs accountable.

Report of discussion at EB136

Documents

- EB136/32

- EB136/CONF./3: Principles for global consensus on the donation and management of blood and other medical products of human origin: Draft decision proposed by the delegations of Italy, Lithuania, Malta, Slovenia and Spain

Chair: EB invited to note the report. Resolution proposed too

DRC (& AFRO): in health sector, blood transfer can save many lives. in the region, insufficiency and quality is an issue. not enough control for disease, such as Hepatitis, HIV, creates low availability for safe blood. often not enough resources. 2012, situation in 45 countries. 20 had policies, 12 had legislations. 85% of donors were volunteer. not all countries had systems for blood vigilance. most countries concerned by Ebola have shown the depth of the issue. low capacity of transfusion, low availability in blood banks too. WHO need to work with countries to ensure that blood is pure.

Malaysia: these are scarce resources and will remain limited. root cause that lead to transaction gains in transactions of human parts. WHO guidelines need to be followed. support action in prevention, early diagnosis and intervention to avoid need for these products. need intersector work for awareness. aligns with draft resolution.

Russia: supports draft resolution. thanks secretariat. notes significance of issue of equal access to blood and medical products derived from plasma. important part of national strategies to remedy. problem of possibility to look for financial gains. importance of surveillance. expand exchange of experience. importance to coordinate efforts to encourage donation through media. ensure safety of blood transfusion and donation.

Belgium: follow up is increasingly important in shift from national to international issue. needs to be guided by same ethical consideration everywhere. guiding principles proposed in resolution is needed. agree with report and resolution, would like to be cosponsor.

Lithuania: gives floor to Spain.

Spain: welcomes report, from stand point of use of products. substances contribute to save or improve life. important, essential therapeutic tools. risk from ethics standpoint, and safety of patients, due to transmission of disease. need watch to origine, quality. blood and plasma has been dealt with by WHO through other resolutions, such 72.33. other initiatives at international level, declaration of istanbul, related to vulnerable groups in traffic of organs. Resolution calls for principles and consensus is a strong commitment - good principles. WHO to engage in consultations in relation of use of blood and organs in run up to WHA. proposition of amendments. in context to access to health and UHC, need same language than in ebola resolution, common standards that guarantee, appropriate.

USA: supports principles and sect proposed way forward. sectt to work to strengthen guidelines. encourage systems for safety, availability. appropriate regulatory and monitoring framework for safety, surveillance. USA to share experience with others.

Cuba: transfusion important component of health care, use of blood given by volunteers' importance in ensuring access. done in Cuba since 1960s. ability to reach UN goals. screening is established. blood bank with guidelines for use.Sect. to design guidelines for use, for proposer control.

Australia: supports voluntary non remunerated donation. availability and access is important. importance of regulation, to avoid misuse. aim of self sufficiency. quality can lead to waste, will collaborate in setting up quality control. notes changes proposed by spain and supports them.

China: agree with Spain amendments. China collection and supply, regulation, other systems, quite complete. many volunteers, for organ donation too. allocation system runs smoothly. under WHO guidelines, specific guideline on blood and organs. promote donation. ai to equal access to donations. need to combat trafficking and transplant tourism. support for new technologies and advance monitoring means. allow to increase surveillance and availability.

Argentina: supports spain amendments. para 5 agree that should be mentioned stems cells and justify use. happy that organisation focuses on code and would like a defined framework. process should be progressive.

Iran: robusts ethical rules for donation. suggestions. art 9 technological complexity and question of resources - plasma fractionation. suggest regional center. para 10, expertise be shared.

Panama: fundamental principles are set in documents. need more procedures to guarantee not only access, but also safety and quality. handling had great impacts. strengthen volunteer donation, to cover more disease and avoid disease too. blood is critical when dealing with acute and chronic conditions. need to avoid sale and trafficking of products. require monitoring to make possible to integrate better management. support amendments by spain.

Japan: there is global consensus. comparing organs transplantation and other tissues not adequate. fundamental differences. has to be taken into account when principles are frame. Scet should collaborate to deal with specific issues of different products.

Albania: concerns on compliance to guidelines, especially in conflict areas. procedures also require technical support, legal advice and coordination. could pool funds for regional centers of reference and excellence. support draft decision on consensus.

Croatia gives floor to Slovakia.

Slovakia: consider initiative as important for self sufficiency. important issue for all regions. recognises voluntary and unpaid character of donation. in EU, slovakia has attain high level in this issue. blood or plasma is not a product. can't be bought or sold. main issue is existence of human being at origin of this product. monetary incentives and unawareness puts donors at risk. room for improving. support proposal in draft decision for consultation. consultation will lead to better definition of terms, blood, blood product and blood components and medical components of human origin.

Brasil: key area that requires investment for equal access, on voluntary based without remuneration. strengthening of health system, training of professionals, data, surveillance are key. support draft, would like to co sponsor.

Switzerland: medical products of human origin are diverse, some already covered. para 16, issue of grouping of these is problem.

Mexico: para 16, 17 proposal of global framework based on consultation. need of world wide principles on use of stem cells and bone marrow. use of local sources important, due to local cultures. need to set standards on use of plasma, instruction on unjustified transfusions.

Argentina: would like to cosponsor with additions from Spain.

Thailand: supports the report and draft decisions. concerns on the issue of blood. supports direction of quality, safety, availability. concerns on human rights and dignity of donors and recipients. management of products is where these principles have to be taken care of. issue of human rights and dignity not been adequately addressed in report and decision. management effectiveness needs to be strengthened. shortages and complications due to poor management and monitoring systems.

France: endorse principles, dignity, availability, safety and governance. particularly important of voluntary unpaid donation. cosponsor. thanking secr, delegations that had drafted the document. Endorse principles. Respect with human dignity, good governance. Committed to voluntary donation. Want to cosponsor the draft resolution. Towards Global consensus. Garantee for quality, safety and availability

Holy See: guidelines on principles of dignity and solidarity. issue of trafficking and transplant tourism. properly regulated and monitored donation after death. respect for life of donors must prevail. has to be done after true deaths. maintains that procedures that tends to commercialise human organs is morally unacceptable. proposes additional principles to be included in report: 1. free and full consent of donor. 2. proportionality of risk for donor. 3. respect for human life from conception to real death.

NGOs

- International Council for Commonality in Blood Banking Automation Inc. (ICCBBA)
- International Pharmaceutical Students´ Federation (IPSF)

ADG:

Chair: EB takes note of Report. Decision EB136(2) adopted as amended. Item closed.