

13.2 Principles on the donation and management of blood, blood components and other medical products of human origin

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In focus

The document before the Assembly ([A70/19](#)) sets forth ten ethical principles which should guide the collection, processing and medical use of human derived products. There will be some debate about the values expressed in the principles but the bigger challenge concerns the operationalisation of these principles in terms of institutions, capacity building and regulatory arrangements.

Background

WHA63 (May 2010) adopted resolutions on the availability, safety and quality of blood products ([WHA63.12](#)) and human organ and tissue transplantation ([WHA63.22](#)).

Progress reports on these resolutions were considered by WHA67 in May 2014 and in the Assembly debate ([A67/A/PSR/12](#)) 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](#) was prepared by the Secretariat in response to this request and considered at EB136 (Jan 2015). EB136/32 set out the main policy issues and sketched directions for further development. The debate at EB136 ([10th meeting](#)) focused on a draft decision sponsored by Italy, Lithuania, Malta, Slovenia and Spain and adopted as amended as [EB136\(2\)](#).

The Secretariat's Jan 2015 report ([EB136/32](#)) canvassed a range of issues regarding the collection and use of medical products of human origin including:

- governance for safe donation and use;
- promoting access to life-saving products of human origin in the context of universal health coverage;
- strengthening regulatory oversight including reducing the need for (and inappropriate use of) blood and tissue products;
- a global monitoring system encompassing traceability, surveillance, vigilance, and rapid alert and the reporting and sharing of data on clinical outcomes and adverse events/reactions.

The decision adopted by EB136 ([EB136\(2\)](#)) requested the DG to undertake consultations with a view to developing:

- ethical principles for the donation and management of medical products of human origin;
- good governance mechanisms; and
- common tools to ensure quality, safety and traceability, as well as equitable access and availability.

Pursuant to this request the Secretariat assembled a set of principles and governance models regarding the use of medical products of human origin and undertook an extensive [consultation](#) around those principles and models.

The document now before the Assembly ([A70/19](#)) presents ten principles and some observations about implementation.

An earlier draft ([EB140/18](#)) was considered by EB140 ([PSR9](#)). There was general support for the principles as principles although some concern was expressed regarding paid versus voluntarily donated blood / tissues (Principle 5) and over the balance between transparency and confidentiality (Principle 10).

Several MSs commented on the work remaining to be done in terms of operationalising these principles in terms of institutions, standards, regulation, accountability, etc.

Several delegates from smaller and low and middle income countries emphasised the absolute shortage of medical products of human origin and the need for technology transfer to build capacity as well as the challenge of putting in place appropriate regulatory arrangements.

PHM comment

The report before the WHA70 ([A70/19](#)) is largely focused on ethical principles governing the donation and management of medical products of human origin. These principles are sensible.

However, the report deals with the institutional, technological and regulatory issues at a very general level and stops short of articulating design principles which might guide the establishment of the necessary structures and capabilities.

The report appears to assume that regulatory arrangements will be largely implemented at the national level. However, in view of the globalisation of supply chains, including the illegal trade in organs, a case can be made for enshrining the required design principles in an authoritative international instrument such as a code or a set of regulations.

Beyond the ethical principles which should be expressed in the medical use of products of human origin there is clearly a major capacity building challenge in many low and middle income countries. PHM urges WHO to set targets and appropriate the resources needed to guide and support for such capacity building.

PHM urges the Board to request the Secretariat to further develop this report including attention to design principles to guide implementation including identifying those principles which should be authorised at the global as well as the national level.

Debate

Seventh meeting of Committee A, from 0900 Friday 26 May

Now we are in agenda item 13.2 Principles on the donation and management of blood, blood components and other medical products of human origin, Document [A70/19](#). Health assembly is invited to review.

Lebanon: Support ten guiding principles, especially equity in donation and financial neutrality. In Lebanon, there has been a reorganization of the whole blood transfusion process to establish best practices. Also promotion of voluntary process. Standards of procedure established and incorporated into hospital guidance. Medical devices... Essential for WHO to be actively engaged in developing international guidelines etc. for medical products of human origin.

Panama:

- Agrees with the principles of MPHO
- Must be regulated through standard guideline
- Need to ensure that all countries use MPHO come from voluntary donors
- Quality and safety are must

Bahrain: has study the document proposed and the problems; support WHO efforts principles being developed which will protect in term of ethics which is essential; principe is urgent; legal procedure is different for countries; coordinated effort at national level is important; donor protection needed; WHO should continue this effort and if possible more details needed on the the strategies

Malaysia:

- Malaysia has welcomed the principles of MPHO

- Said principle two needs amendments. It is about voluntary donation which should consider socio-economic barriers
- Malaysia would like to participate in amendments. Therefore WHO should proceed for further consultative process and capacity building of member states on managing MPHO

Argentina: recognize the value of the document and guiding principles; protecting the right of donor and receivers; the use of products (organ, tissues) is not adequate in the document, concerns about sales of organs needs attention; preserve restriction with regulatory framework for trafficking of organs and organ transplant tourism; impact of donation is different; this document is insufficient and we need more work on this document

Slovakia

- Set of guiding principles are ambitious
- However, document should include provisions for donor selection
- Principle 2: There is a need to add blood components
- WHO should distinguish between Plasma and Plasma components
- Terminology 'blood products' implies raw materials therefore needs further clarification

Iran: limited medical devices of human source; need for standards to define criteria of screening test to provide product safety; need for clean room; establishment of local protocol to safeguard manu processing; screening test to prevent transmission of disease spread

Indonesia

- Support the principles of MPHO
- Self sufficiency, safety and quality are clearly reflected in the document
- Policies governing the payments need to reconsider:

In most developing countries, the regulatory mechanisms are weak. Many services regarding MPHO are not standardized. Therefore, this target is difficult to achieve

Plasma donation take more time. Therefore providing health insurance, regular health check ups should come together with the principles on MPHO

Compensation to plasma donors in case of any accident should also be considered

Congo: speaks on behalf of 47 African MS; medical product of human origin come from the living and destined for human use; welcome the progress made; we might not guarantee the procedures to do transplant because of technical limitation; need to prevent trafficking of

human organs, taken measures to prevent disease transmission (HIV etc); we have must in measures in places; thank for the 10 principles; recommend the adoption of frame to regulate stewardship; support for MS with limited resources; take note of the framework and effort needs to be undertaken to improve the text

Dominican republic

Dominican republic

- We have developed policies on MPHO
- New therapeutics, vaccines are leading the increased demand on MPHO
- Current guideline is relevant in our country due to ageing population
- We are committed to implement however, ethical principles regarding the non remunerated blood donation needs more carefulness
- We should be able to prevent misuse and abuse of donors of MPHO
- All sectors of population should be involved in the donation
- Context of country should also be considered based on the availability of MPHO
- Lack of coordination among different agencies involving MPHO could be one of the challenges
- MPHO process - collecting, analysis, distributing organizations require coherence

China:the report is good and appreciate; agreed with the content; blood management is important and have a national law; structure is improve and have a blood bank system; improve technical standard and promote rational clinical use; set up legal and policy system for transmission (transfusion) of blood and transplant of organs; have national standard in place; set up entry system for transplantation hospitals; suggest to establish a regulatory authority to track data and global flood of organ; WHO should coordinate the process to cut down trafficking, transplant tourism while ensuring quality

Tunisia

- We support the principles of MPHO
- Any form of payment is prohibited in our country
- Discrimination among donors is also forbidden in our country
- Shortage of MPHO during summer is a issue
- National strategy on the donation of MPHO should be supported by WHO
- Quality management principles need to be developed so that MPHO can be stored safely and used during shortage periods
- Capacity building and trainings to member states on management of MPHO are the key areas to consider

Thailand: appreciate the secretariat contribution; welcomes the regulatory of donor and receiver; demand can not keep up with supply which might lead to organ tourism; governance principle....; (due to distraction, I couldn't follow)

France

- Welcome the principles on MPHO
- Principles are in accordance with France legislation and Convention of human rights. So we agree.

Iraq: necessary for management of blood and component of human origin; need to fight inappropriate action; need to manage blood transmission; need for blood bank for healthy and safe component; transport process should be efficient; request strategy focus on result; need improve lab for quality and safety of blood products to better response in crisis; need support to boost capacity (hospital and staff); underscore to improve the quality of services and provide support to migrants and refugees

Russian Federation

- Principles need to be coordinated with criminal law of the countries
- It is important to bring the principles of MPHO into national regulation
- Implants, bio-cells which are certified and various types of reproductive cells should also be included as MPHO

Vietnam: from 1990 voluntary donation initiated; since 2016 voluntary donation is 98%; the government have fund transfusion center and expect to expand in years; according to experience for developing countries lack resources and financial it is difficult to have robust system; have legislation on voluntary contribution; ensure quality and safety of products; WHO network and donors to support, monitor and help establish facilities and management center for blood in remote areas

Germany:

- Different types of MPHO should be distinguished
- Organ transplantation issues should also be considered because sometimes there are also cases of human trafficking for organs

India: demand is growing; implement the WHO strategy; undertaken measures voluntary organ transplant; need for guidelines; welcome the approach; comments: flood from poor to rich is ..., universal access to blood and blood component needed; prevent the flood of blood and components from poor to rich nations

Pakistan

- Appreciated the principles of MPHO
- They have proceeded to consultation with subject experts

Colombia: need for ethical framework in line with international approach to protect human right; regulation and legislation to prevent legislation and trafficking; guarantee transparency, equity (regulate procedure for products of human origin); we need to prevent criminal activities; no financial profit and economic losses should be made from this; concerns of payment for biological materials

Maldives:

- Shortage of MPHO is an issue due to its voluntary nature. Maldives has nationally coordinated MPHO related system and it is integrated with NHP
- Strengthening of technical capacity on laboratory services and research require support
- WHO should strengthen regulation on MPHO to prevent its mis-use
- Good governance should be promoted
- Sharing of best practices and establishment of guidelines for organ transplantation need to be considered by WHO

Ecuador: thanks for the report; need for national priorities based on ethical principles and governance; need better surveillance services; UHC is important; voluntary donation is need for quality and prevention of exploitation; raise awareness on donation; underscore the importance of health system effectiveness and efficiency; prohibit the payments for blood donation with increased risks; work on the terminology use; applied ethical practices for safety and quality and principles

Liberia

- On behalf of AFRO region, we support the principles on MPHO.
- Ethical issues are clearly described in the principles.

Kenya: aligns with COngo; have the request of the secretariat; committed to the implementation of framework; have health bill to ensures the implementation of framework

USA

- USA encouraged WHO to assist the MS to develop regulatory frameworks to implement the principles of MPHO and its surveillance and monitor

Afghanistan: has drafted regulation to address this issue, needs technical support from WHO

Australia

Recommended to ensure the ethical practices during procurement of MPHO and strengthen local governance system

Sri Lanka: endorse the report; as a middle income countries we have challenges and the government have take efforts to provide best blood product and components to its citizens; need technical and medical device to fully screen blood product for related infections

Bangladesh

- Committed to ensure the quality of MPHO
- Bangladesh has endorsed safe blood transfusion law and rules
- Seeks support on technical and financial aspects from WHO to manufacture MPHO

No further speakers on the list, now the floor is open to observers

IFRC: congratulates MS and WHO on the donation and management of blood product; this is an issue of high importance and pledge full support; voluntary donation is a platform for safe and effective supply; work with WHO to develop the global framework which is implemented by many nations; advocate for global commitment to support government everywhere to provide the services needed in these countries

Now the floor is open to NSA

Chair:

- Notes the comments on sharing on knowledge in the area of MPHO
- Many interventions covering broader scope of MPHO are considered
- Different types of cells, bio-cells to include in MPHO are also considered
- Secretariat decided to finalize the MPHO with further consultation with interested member states

The committee is invited to note the report; agenda is closed

Action

Report noted

