



**World Health
Organization**

Good Policy Process for Blood Safety and Availability

AIDE-MÉMOIRE

for National Health Policy Makers

Ensuring the safety and availability of blood and blood products is an essential public health responsibility. Measures to ensure blood safety also play a major role in preventing the transmission of HIV, hepatitis viruses and other bloodborne pathogens in health-care settings.

The safety and availability of blood and blood products continue to be of major concern, particularly in the developing world, where blood shortages and unsafe transfusion contribute significantly to the global burden of disease, especially among women and children, the most vulnerable populations. Through successive World Health Assembly Resolutions, national health authorities have expressed their commitment to ensuring equitable access to safe blood transfusion for patients who depend on it for their survival and well-being. The public health importance of blood safety issues necessitates that each country should establish a sustainable national blood programme with a well-formulated national blood policy and plan, a national blood transfusion service, legislative and regulatory mechanisms, and a structured process for policy making.

National blood policies should address all issues that could affect the quality, safety, availability and accessibility of blood and blood products and should be reviewed regularly, particularly when new issues emerge that have implications for the national blood programme. The adoption of a set of principles that define a good policy process and a structured approach to policy formulation enhances the effectiveness of national decision-making by health policy makers. Since the issues affecting blood safety and availability – and the policy decisions to manage them – have ramifications across national borders, these should be addressed through an international framework of decision-making, with the following considerations:

- Enhanced commitment and support of national policy makers to the principles of good policy process for blood safety and availability
- Structured process of decision-making in accordance with national policies, the level of development of national blood programmes and available resources
- Improved quality of international communication and consultation on blood policy making as an ongoing, dynamic and interactive process.

While many countries may be confronted with similar, often complex, policy decisions, the available policy options, priorities for intervention and the optimal allocation of resources will vary. Good policy process assists national health authorities to address known and emerging threats to blood safety and availability while ensuring the flexibility to address these issues according to varying national contexts, needs and resources. Additionally, a common framework for communicating the basis of national blood policy decisions improves the quality of international dialogue and collaboration on issues of common concern. The integration of scientific, economic, ethical and social considerations into public health policies is fundamental to good policy process.

Surveillance procedures and haemovigilance systems are needed to monitor adverse events and known threats to blood safety and availability and to enable informed policy decisions to be taken in response to new challenges, threats and opportunities. Such policy decisions may include:

- Restructuring of a national blood transfusion service
- Introduction or modification of criteria for donor selection and deferral
- Introduction of a new strategy and/or technology to enhance the safety, quality, supply or use of blood and blood products.



Checklist

Prerequisites

- ☐ Endorsement of government commitment and support
- ☐ National blood programme
- ☐ National blood commission/authority
- ☐ National blood policy and plan
- ☐ Legislative and regulatory frameworks
- ☐ Adequate funding
- ☐ National blood transfusion service with responsibility for the provision of blood and blood products and liaison with clinical services

Principles of good policy process

- ☐ Decisions based on scientific, medical and epidemiological evidence
- ☐ Consideration of economic, ethical and social dimensions
- ☐ Efficiency and cost-effectiveness
- ☐ Partnership and active participation by relevant stakeholders
- ☐ Transparency
- ☐ Effective communication

Structured policy-making process

- ☐ Situation analysis, definition of problem and risk identification
- ☐ Identification of policy alternatives
- ☐ Risk assessment and analysis
- ☐ Identification of preferred policy option and policy formulation
- ☐ Communication of policy decisions and risks
- ☐ Policy implementation
- ☐ Monitoring and evaluation
- ☐ Risk management

Assessing policies

- ☐ Impact on health outcomes
- ☐ Access and fairness of policies
- ☐ Cost and value for money
- ☐ Scientific evidence to back policy
- ☐ Operational capacity of institutions involved
- ☐ Legal issues and international agreements
- ☐ Risks, public health and safety

Key elements

Principles of good policy process

Policy decisions for blood safety and availability should be based on up-to-date scientific, medical and epidemiological evidence, with due consideration of economic, ethical and social factors. Decisions should be made in the interests of public health and promote optimal use of available resources. Desired outcomes and goals should be clearly identified. Authority, responsibility and accountability for the implementation of policy decisions, including structural and functional relationships, should be clearly defined.

Measures to ensure the safety, availability and accessibility of blood transfusion should be given a high priority within the health care system given the importance of preventing the transmission of HIV, hepatitis and other

bloodborne pathogens and the cross-cutting role of blood transfusion in underpinning programmes of major public health importance, including maternal and child health, medical and surgical procedures, and in emergency and disaster situations.

The establishment and endorsement of a good policy-making process is based on the following principles:

- Evidence-based: maximization of health outcomes when decision-making is based on robust evidence
- Efficiency and cost-effectiveness: prioritization of resource allocation in the context of overall public health and the prudent use of human, technical and financial resources

- Participation and partnership: involvement of relevant stakeholders in the policy process, under the umbrella of the national blood commission/authority, to ensure the legitimacy and effectiveness of policy; stakeholders include ministry of health, national blood transfusion service, regulatory agency, experts in blood transfusion, clinicians, blood donor organizations, nongovernmental organizations, patient associations and the media
- Transparency: clear and open policy process to help ensure the legitimacy and effectiveness of blood policy
- Proactive communication: to ensure public awareness of the needs, benefits and risks associated with blood policy issues.

Key questions for policy makers and stakeholders

Policy making should be a structured, stepwise, cyclical process. Policy makers and stakeholders should address the following questions:

- What is the problem to be solved?
- What is the proposed intervention?
- What are the known and likely positive and negative effects of the intervention?
- Do the positive effects outweigh the negative effects?
- What is the cost of the proposed intervention?
- What is required to make the intervention work?
- How can equity and sustainability be assured?
- What options are lost if the intervention is adopted?
- How often and by what criteria will the intervention be reviewed?

Situation analysis and problem definition

Objective situation analysis is required at regular intervals. This should include:

- Definition of the problem and its causes
- Review of existing policy to identify limitations
- Assessment of strengths, weaknesses, opportunities and threats
- Review of scientific and medical evidence and epidemiological data
- Identification of actual and potential risks.

Assessment of potential interventions

The identification and assessment of potential interventions should include:

- Commitment to ethical principles, including accountability and transparency
- Access to relevant information by relevant stakeholders and their inputs into the identification and review of policy alternatives
- Formal analysis of policy options, including:
 - Risk assessment, analysis and risk-benefit ratio
 - Cost-effectiveness and cost-benefit analysis
 - Feasibility: technical, administrative and political
 - Education and training requirements
 - Sustainability
 - Timeliness of options
- Evaluation of strategies to avoid or reduce risks.

Preferred policy option and policy formulation

The selection of the preferred policy option and policy formulation should be based on the formal analysis of alternative interventions as well as consideration of social and political factors, including the likely effects on public confidence.

Communication

The effective communication of the decision requires a systemic strategy that cuts through the entire policy process. In order to retain public confidence, a clear statement is required of the scientific, economic, social and political rationale for the decision and the benefits and risks associated with the policy.

The opportunities and actions required by different stakeholders should be highlighted.

Policy implementation

Policy implementation should use appropriate mechanisms to ensure maximum compliance with the policy. Government may choose to collaborate with, or entrust policy implementation entirely to, partners in civil society and the private sector.

Assessing policies

A policy can be systematically assessed using a range of methods to determine its impact, value and feasibility. The following issues could be used in assessing policies on blood safety and availability:

- Impact on health outcomes and public health: assessing improvements in the quality, safety and availability of blood and blood products
- Access and fairness: assessing the effects on access to safe blood and blood products and the impact on individuals and groups (e.g. region, gender, ethnic, socioeconomic)
- Cost and value for money: assessing cost-effectiveness and correlation with impact
- Scientific evidence: assessing if credible scientific evidence supports the policy
- Operational capacity: assessing the operational capacity of the institutions involved and their compatibility with the requirements of the new policy
- Legal issues and international agreements: e.g. on the movement of blood and blood products across borders
- Risk, public health and safety: assessing implications for the public, including vulnerable groups and the environment, in relation to the provision and use of blood and blood products, infection control in health-care settings and management of biohazardous clinical waste.