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BLOOD SAFETY: A STRATEGY FOR THE AFRICAN REGION

Report of the Regional Director

EXECUTIVE SUMMARY

1. Blood safety is still a major concern of countries in the African Region in view of the high prevalence of HIV/AIDS and other transfusion-transmissible infections.
2. In 1994, the forty-fourth session of the WHO Regional Committee for Africa, by its resolution AFR/RC44/R12, invited Member States to take urgent measures to formulate and implement a policy on blood transfusion safety, mobilize resources for developing the infrastructure of the blood transfusion services of central and district hospitals and set the objectives for the transfusion, in hospital settings, of blood uninfected by HIV.
3. Today, very few countries have acquired the structures and resources needed to promote the development of blood transfusion services.
4. The present strategy aims to propose concrete actions and a framework that will help the countries to have reliable and sustainable transfusion facilities.
5. The success of this strategy will depend primarily on the mobilization of adequate financial and material resources and the preparation and implementation of a realistic plan, based on an objective analysis of the situation prevailing in each country.
6. The priority interventions are the formulation and implementation of national blood transfusion policies, quality assurance, mobilization of funds and development of human resources.
7. The Regional Committee is invited to examine this strategy, enrich it, adopt it and give guidance for its implementation.

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INTRODUCTION

1. Transfusion therapy is a form of treatment based on the use of blood and blood products of humans. Although this therapy helps to save human lives in some circumstances, blood can nonetheless be a dreadful vector of some infectious and parasitic diseases or can trigger serious and, sometimes, fatal reactions of rejection if the rules governing its prescription and use are not properly followed.
2. The safety of blood and blood products is of serious concern to the countries, all officials in charge of blood transfusion services and the clinicians who prescribe blood. This concern is even greater in the African Region where there is a heavy burden of HIV/AIDS, a high prevalence of other transfusion-transmissible infections and a high frequency of malaria anaemia, deficiency anaemia and severe haemorrhages which, sometimes, require massive transfusion.
3. The safety of blood transfusion depends on three main factors:
 - (a) the availability of blood, which is contingent upon the adequacy of storage facilities and the existence of a sound policy of recruitment and retention of voluntary and benevolent donors;
 - (b) the innocuity of blood, taking into account all the immuno-haematological and serological aspects;
 - (c) the judicious use of blood transfusion as a mode of treatment, which requires smooth collaboration between blood transfusion centres and clinicians as well as adherence to the rules of prescription.
4. In May 1975, the Twenty-eighth World Health Assembly, by its resolution WHA28.72, called on Member States to promote national blood transfusion services, based on voluntary and benevolent donations, and to promulgate laws to govern their operation. In spite of that recommendation, very few African countries have a reliable and well-organized transfusion system, today.
5. In 1994, the Regional Committee for Africa, in its resolution AFR/RC44/R12, noted with great concern that only 10 out of the 46 Member States of the African Region could guarantee the safety of blood transfusion in health care settings and, consequently, urged Member States to take urgent steps to enact blood safety policies and mobilize resources for the development of the infrastructure of blood services in central and district hospitals.
6. Twenty-six years after the World Health Assembly resolution and seven years after the Regional Committee resolution, there is still a lot to be done to improve the safety of blood transfusion in countries in the Region. The present strategy therefore proposes interventions and a framework that will enable Member States to improve blood transfusion safety.

SITUATION ANALYSIS AND JUSTIFICATION

Situation analysis

7. Of the 46 Member States in the African Region, only 30% have drawn up their national blood transfusion policy. Even so, the recommendations of the policy are not always implemented, with the result that coordination has been lacking at field level. This has led to non-standardization of practices, and, indeed, to exposure of patients to complications that are sometimes fatal, and exposure of health personnel to avoidable risks of contamination.
8. Less than 15% of countries in the Region have implemented effective strategies for the recruitment of regular and benevolent blood donors. About 40% of the blood collected is from family replacement donors even though it is firmly established that the prevalence of transfusion-transmissible infections among that category of donors is higher than among regular and benevolent donors.

9. It is estimated that over 25% of the units of blood transfused in Africa, today, are not tested for HIV, and that 5% to 10% of cases of HIV infection in Africa are transmitted via blood. Furthermore, less than 50% of the units of blood are actually tested for hepatitis B in most of the countries while barely 19% of the countries test blood units for hepatitis C. This situation exposes transfused patients to the risk of infection by the viruses that cause hepatitis or liver cancer.¹

10. Inadequate supply of reagents still poses a major obstacle to the determination of the serological status of donated blood. Red tape in centralized systems, coupled with inadequate funding, often creates stockouts. Lack of national reagent procurement strategies and of reference centres that can validate the testing of blood for transfusion-transmissible infections has led to the introduction, on national markets, of products whose quality is, sometimes, dubious.

11. The cold chain is an essential link in any blood transfusion system. In the African Region, the irregular supply of electricity, lack of equipment suited to field conditions or the absence of an effective equipment maintenance programme adversely affect the storage of reagents and blood products. In some Member States, this situation hampers the establishment of functional blood transfusion services at all levels of the health pyramid and, more particularly, in district hospitals.

12. The shortage of qualified staff in the African Region puts a major limitation on health services in general and blood transfusion services in particular. In addition, lack of career prospects for the staff of blood transfusion centres often leads to staff demotivation and consequent departure for other areas deemed to be more rewarding and more fulfilling. This instability of the staff of transfusion services is prejudicial to the development of the skills needed to establish sustainable and reliable blood transfusion services.

13. In most cases, blood transfusion services are administratively answerable to, and physically located within, hospital laboratories. They, therefore, have no fixed staff or specific budgets of their own, a situation which adversely affects their smooth functioning. The fact that transfusion services are not hierarchically structured is yet another impediment to their effective supervision and the quality of the services they provide.

14. Very few countries have built quality assurance programmes into their blood transfusion services or into the facilities serving such a purpose. Consequently, the blood products made available to prescribing physicians do not always meet the required safety standards. Although in January 2000, WHO started a project on the provision of quality management training for blood transfusion centres, the lessons learnt from the project have yet to be translated into deeds.

¹-Report of the intercountry workshop of Directors of national blood transfusion centres of the Francophone and Lusophone countries, Abidjan, 13-17 December 1999:

-Report of the intercountry workshop of Directors of national blood transfusion centres of the Anglophone countries, Harare, 2-5 May 2000.

-WHO Global Database on Blood Safety, 1999.

-Country reports presented at the above workshops, 1999 and 2000.

-Situation of blood safety in Africa, WHO/AFRO and UNAIDS/ICT, 1997.

15. Few African countries have assigned a budget line to activities related to blood transfusion safety. Since blood transfusion is often not an independent entity on its own, its funding in many countries is assured by bilateral or multilateral cooperation agencies. Given the lack of national blood transfusion policies in most of the countries, the cooperation agencies limit their funding to only the procurement of reagents. Unfortunately, the countries are unable to purchase the reagents for themselves after the cooperation programme is ended.

16. Bilateral and multilateral cooperation has played, and continues to play, an important role in the development of blood transfusion systems in Africa and, more particularly, in the prevention of HIV transmission by blood. However, since there is no national coordination, each donor agency pursues its own blood transfusion policy within the geographical area specifically assigned to it. The result is that, within a given country, the blood transfusion policy may vary from province to province or from region to region.

17. In 1999, the annual blood needs of countries in the Region were estimated at 12 million units, but blood collection in that year totaled just 30% of that quantity, thus leaving a substantial deficit.

18. Very few countries in Africa have laid down stringent rules to govern the use of blood and blood products. In most cases, transfusion involves whole blood, and some of the accidents that occur in the process are due to either inadequate staff training or non-adherence to the rules of sound professional practice and ethics. Although the techniques of autotransfusion have undisputed advantages in regard to safety, they are not practised on a widespread scale.

Justification

19. Despite the recommendation of the World Health Assembly in 1975, and of the Regional Committee in 1994, a situation analysis clearly shows that the blood transfusion systems of countries in the Region are still fraught with weaknesses.

20. WHO has made blood transfusion safety one of its priorities since the year 2000 when the main theme of World Health Day was blood safety. Furthermore, the year 2000 saw the birth of many initiatives aimed at mobilizing energies to promote the safety of blood and blood products. These initiatives include the WHO quality management training project.

21. In the year 2000, WHO classified all countries of the world according to the level of safety of their blood transfusion services. More than 85% of countries in the African Region were thus classified among the countries in which blood transfusion is least safe.

22. In the implementation of the present strategy by the countries, blood transfusion should be made a health priority and the related services must be reorganized so that blood transfusion safety in the Region can be improved.

THE REGIONAL STRATEGY

Aim

23. The aim of the regional strategy is to improve blood transfusion safety and bridge the gap between blood needs and blood availability in health services.

Objectives

24. The main objectives are:

- (a) to assist the countries to set up an effective system of recruitment of low-risk, voluntary and regular donors;
- (b) to improve the safety of blood and blood products by implementing quality assurance programmes and mapping out effective strategies for the screening of blood for all transfusion-transmissible infections;
- (c) to promote the judicious use of blood and blood products by clinicians.

Targets

25. By the end of 2012:

- (a) all the Member States will have carried out a situation analysis of blood transfusion safety;
- (b) at least 75% of the countries will have drawn up, adopted or implemented their national blood transfusion policy;
- (c) one hundred per cent of the blood units transfused will be screened, beforehand, for HIV and other transfusion-transmissible infections;
- (d) at least 80% of blood donors in all countries of the Region will be voluntary and regular donors.

Guiding principles

26. The principles that will guide the implementation of the strategy will be the following:

- (a) formulation, adoption and implementation of national blood transfusion policies;
- (b) establishment of universally applicable norms for avoiding discrimination in the distribution and use of blood products;
- (c) creation of an enabling environment for the development of effective, reliable and sustainable blood transfusion services at all levels, especially in the districts.

Priority interventions

27. The first intervention will consist in carrying out a situation analysis of blood transfusion safety in all countries in the Region in order that the prevailing problems and needs can be well identified. The information thus gathered will help improve the planning of future activities.

28. The second intervention will involve drawing up and/or implementing national blood transfusion policies and action plans whose main thrusts will be: the formulation of a strategy for the recruitment and retention of regular and benevolent donors; the definition of norms to be followed in the screening and processing of blood donations; the development of guidelines for the prescription of blood and blood products; review of ethical and regulatory issues; financing and cost recovery.

29. The third intervention will involve addressing the special challenge faced by countries with high HIV prevalence, in terms of attracting and retaining a pool of low-risk blood donors.

30. The Member States must assess their staffing needs, judiciously select persons to be trained and create an environment conducive to the advancement of the staff of blood transfusion services and, thereby, dissuade them from deserting, or resigning from, their posts.

31. In addition, each country must pursue a true policy of education, sensitization and retention of low-risk donors.

32. Health authorities must ensure that safety standards are met in the screening of blood for transfusion-transmissible infections, in the context of clearly established national blood transfusion policies.

33. Participation in the WHO project on the training of staff of blood transfusion centres in quality management techniques and procedures will be the bedrock of future actions and should foster concrete action at field level.

34. Blood transfusion research which generates information indispensable for the planning of activities, must be encouraged and supported by the countries. There is need for research into the optimal use of blood products, including HIV-positive blood.

35. Particular attention must be given to the training of blood prescribers and care providers. Guidelines for the prescription and use of blood and blood products, including for research on the technique of auto-transfusion must be produced and made available to them. In each health facility, a committee must be set up to enforce the rules of good practice and thereby foster judicious use of blood.

Implementation framework

Role of Member States

36. As proof of their commitment, Member States must include blood transfusion safety in the priorities of their health programmes, assign a budget specifically to it and draw up programmes and plans of action for its development. That will lead to a more rational and more proactive approach to the resolution of blood transfusion problems.

37. The ministry of public health will, as a matter of duty, prepare texts on the organization of blood transfusion services, propose a plan of action, implement the national policy and coordinate this activity nationwide. Furthermore, it will play a normative role, ensure adherence to the set rules in the private and public sectors and undertake the development of human resources. In addition, it will collaborate with all national and international structures that are in a position to promote blood transfusion safety.

Role of partners

38. In the context of the national blood transfusion policy, and under the coordination of the ministry of public health, the various bilateral and multilateral international cooperation agencies as well as non-governmental organizations will be called upon to provide technical and financial support for the implementation of strategies leading to effective and reliable blood transfusion services.

Role of WHO

39. WHO will play a vital role in ensuring the success of this strategy by supporting the countries to formulate and implement national blood transfusion policies; establish a consultation framework for all stakeholders in the area of blood transfusion safety; design and provide to the Member States the tools needed to assess the blood transfusion situation and; determine the blood transfusion profile of each country. In collaboration with the other partners, WHO, will produce procedures handbooks and guidelines and provide technical or financial support for staff training. Furthermore, WHO, in collaboration with Member States, will develop a database on blood safety and make it available to them.

Monitoring and evaluation

40. It will be important to establish a mechanism for the monitoring and evaluation of this strategy. The monitoring should be undertaken, each year, in the countries to enable the necessary adjustments to be made on time. At the regional level, a mid-term review will be conducted after five years of implementation of the strategy and progress reports submitted to the Regional Committee every two years.

41. WHO will develop evaluation indicators and each country will, based on its specific situation, define monitoring indicators that will be used to assess its own progress.

CONCLUSION

42. Today, at the dawn of the 21st century, blood transfusion safety poses a real challenge to the African continent. The present strategy, mapped out as a consequence, examines the weaknesses of the blood transfusion system in Africa and proposes a framework and actions to expand the pool of low-risk blood donors, ensure adequate screening of blood for transfusion-transmissible infections and promote research as well as the judicious use of blood in order to foster progress.

43. The Regional Committee is invited to examine this strategy, make the necessary amendments for its improvement, adopt it and give guidance for its implementation.