

Regional Status Report on Blood Safety and Availability

2016



Regional Status Report on Blood Safety and Availability

2016



WHO Library Cataloguing in Publication Data

World Health Organization. Regional Office for the Eastern Mediterranean

The 2016 regional status report on blood safety and availability / World Health Organization. Regional Office for the Eastern Mediterranean

p.

WHO-EM/LAB/392/E

1. Blood Safety 2. Blood Transfusion - statistics & numerical data 3. Blood Donors - statistics & numerical data 4. Annual Reports I. Title II. Regional Office for the Eastern Mediterranean

(NLM Classification: WH 460)

© World Health Organization 2017

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. [Title]. Cairo: WHO Regional Office for the Eastern Mediterranean; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimer. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Contents

Preface	V
Acknowledgements	vii
Introduction	1
Collection of blood and blood components	3
Regional overview of blood collection	3
Collection of blood components through apheresis	4
Types of blood donations	4
Blood donor profile	5
Processing of whole blood donation into components	8
Laboratory screening of blood donations	9
Laboratory screening policy	9
Coverage of laboratory screening of blood donations	10
Prevalence of markers of infection in blood donations	10
Discard of blood	11
Clinical use of blood	12
Transfusion and utilization of blood and blood components	12
Mechanisms to improve and monitor safe and appropriate blood transfusion	12
Haemovigilance	13
Plasma used for fractionation and the provision of plasma-derived medicinal products	14
Organization and management of national blood transfusion services	15
Policy and governance	15
Organization of blood collecting and processing facilities	15
Quality assurance and monitoring	16
Discussion	17
Availability of blood and blood products for transfusion	17
Laboratory screening and testing	18
Clinical use of blood	18
Policy, legislation, regulatory oversight and governance mechanisms	19
Data	20
Limitations	20
Conclusion and the way forward	21

Preface

Universal and timely access to sufficient, secure supplies of blood and blood products and safe transfusion services is an essential part of any strong health system, and is an important component of efforts towards achieving the goal of universal health coverage and sustainable development goals. Blood transfusion is most commonly used in caring for women suffering from bleeding associated with pregnancy and childbirth, children with severe anaemia due to malaria and malnutrition; and victims of trauma, emergencies, disasters and accidents. It is also used to support advanced medical and surgical procedures, including cardiovascular surgery and transplantation in countries with advanced health care systems. Blood and blood products are essential in the treatment of blood and bone marrow disorders as well as immune deficiency conditions.

Significant progress has been made in improving the availability and safety of blood transfusion through the support of the World Health Organization (WHO) as mandated by successive World Health Assembly resolutions, the earliest dating from 1975, and the Regional Committee resolution of 1987. However, significant challenges remain in providing access to sufficient, affordable and sustainable supplies of blood and blood products while ensuring the quality and safety of these products in the presence of known and emerging threats to public health as well as humanitarian emergencies and armed conflicts.

The demand for blood and blood products continues to grow as a result of several factors, including the growth and aging of the population, humanitarian emergencies and armed conflicts, and the availability of and access to increasingly sophisticated medical and surgical procedures.

Ministries of Health are responsible for meeting the increasing clinical needs of patients for safe blood and blood products and for ensuring their quality, safety, availability and equitable distribution through the establishment of an effective national blood supply and transfusion service which is integrated into the national health system.

The WHO Global Database on Blood Safety was established in 1998 to address global and regional concerns about the availability, safety and accessibility of blood for transfusion. The aim is to collect and analyse data from all Member States on blood and blood product safety as the basis for effective action to improve blood transfusion services. The WHO has published several global reports in the past on this topic, the most recent being in 2011. For the first time, a regional status report has been prepared based on the latest Global Database on Blood Safety data for 2013, submitted by the Member States

in the WHO Region for the Eastern Mediterranean, which was complemented by a situation analysis conducted in 2014. The report provides information on the current status of blood transfusion services in the Region.

From the information that Member States have provided to WHO, it is evident that there are gaps in the key elements of national blood systems that will affect the continuity, sufficiency, sustainability and security of national supplies of safe and efficacious blood and blood products to meet the national need. As the world focuses on delivering on universal health coverage, and embarks on achieving the Sustainable Development Goals, no country should be left behind in having sufficient and safe blood supply for its health system. Governments, WHO and international partners need to scale up their efforts in implementing the WHO regional strategic framework for blood safety and availability (2016-2025) and improving the safe and sufficient supply of blood and blood products in the Region.

Rana Hajjeh

Director, Department of Communicable Disease Prevention and Control World Health Organization Regional Office for the Eastern Mediterranean

Acknowledgements

The Department of Communicable Disease Prevention and Control wishes to express its thanks to the following experts who contributed to the development of this report through data analysis and development of the first draft: Cees Th. Smit Sibinga (IQM Consulting, Netherlands), and Ali Akbar Pourfathollah, Mahtab Maghsudlu, Abdolmajid Cheraghali, Sedigheh Amini, Fariba Seighali, Ardeshir Torab, Azita Chegini, Nasim Hosseini, Ebrahim Koohi and Mehdi Tabrizi (Blood Transfusion Research Centre, High Institute for Research and Education on Transfusion Medicine, WHO Collaborating Centre, Tehran, Islamic Republic of Iran).

The following WHO staff members contributed to the validation of data and the development, editing and production of this report: Yetmgeta Abdella, Humayun Asghar and Rana Hajjeh (WHO Regional Office for the Eastern Mediterranean); and Junping Yu (WHO headquarters).

Special thanks are due to the health ministries and national blood programme/ national blood transfusion services who provided data to the WHO Global Database on Blood Safety. This report would not have been possible without their collaboration and contribution.

Introduction

Significant progress has been made in improving the availability and safety of blood transfusion through World Health Organization (WHO) support, as mandated by successive World Health Assembly resolutions, the earliest dating from 1975 (WHA28.72 Utilization and supply of human blood and blood products¹, WHA58.13 Blood safety: proposal to establish World Blood Donor Day², WHA63.12 Availability, safety and quality of blood products³). In 1987, at its 34th session, the WHO Regional Committee for the Eastern Mediterranean endorsed resolution EM/RC34/R.9 on the development of national blood transfusion services in the countries of the Eastern Mediterranean Region⁴.

However, significant challenges remain in providing access to sufficient, affordable and sustainable supplies of blood and blood products while ensuring the quality and safety of these products in the presence of known and emerging threats to public health. In addition, humanitarian emergencies and armed conflicts in the Region have increased the demand for blood and made delivery of these lifesaving products challenging and complex.

The objective of this report is to provide an overview of the current status of blood supply, safety, sufficiency and usage in the Region. The report is primarily based on data for the year 2013, reported by 15 of the 21 Member States (Afghanistan, Bahrain, Egypt, Islamic Republic of Iran, Jordan, Lebanon, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Tunisia and United Arab Emirates) to the WHO Global Database on Blood Safety. To give a more complete overview of the regional situation, in those cases where 2013 data were not available, data for 2012 from one country (Yemen) and for 2011 from two countries (Iraq and Kuwait) were used. These 18 countries account for a total population of 584 million, representing 95.3% of the population in the Region. The Syrian Arab Republic did not provide data from 2011 to 2013, and Djibouti and Libya did not complete the questionnaire for the most part. These three countries were, therefore, excluded from the report.

The WHO Global Database on Blood Safety was established in 1998 to provide data on the availability, safety and accessibility of blood for transfusion. The main objective of the survey was to collect and analyse data on national blood systems from all countries as the basis for effective action to increase

¹ http://www.who.int/bloodsafety/en/WHA28.72.pdf

² http://apps.who.int/iris/bitstream/10665/20363/1/WHA58_13-en.pdf

³ http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R12-en.pdf

⁴ http://applications.emro.who.int/docs/em_rc34_r9_en.pdf

access to safe blood and blood products and improve transfusion practices. Global Database on Blood Safety data are collected using a standardized tool, then sent to national health authorities for completion. Web-based tools were used for 2011, 2012 and 2013 data collection.

Standardized definitions for the terminology used in the survey questionnaire were prepared to promote consistency of reporting. Where possible, efforts have been made to validate the data reported to WHO. To complement and validate the data, additional information was collected from eight countries (Bahrain, Egypt, Islamic Republic of Iran, Jordan, Oman, Pakistan, Qatar and Tunisia) in 2014 using a structured questionnaire. However, systematic verification has not been performed for all of the data provided by all the countries. In particular, answers to the questions on the existence of policy, programmes or mechanisms could be affected by the way in which the questions asked were interpreted.

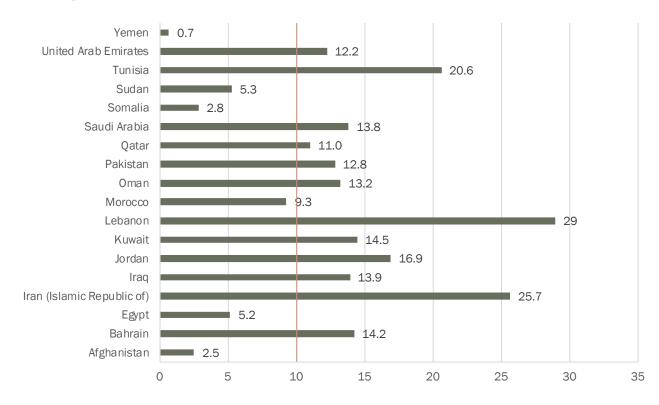
Collection of blood and blood components

REGIONAL OVERVIEW OF BLOOD COLLECTION

It is reported that a total of seven million blood donations were collected in the 18 countries during the reporting period. This accounts for 6% of the global blood supply whereas the Region has 9% of the world's population. However, the percentage of estimated donations covered in this report varies among countries from 25% to 100% as some countries provided only partial data. These donations were collected from all types of blood donors: voluntary non-remunerated, family or replacement, and paid.

There were wide variations in annual blood donation rates among countries (Fig. 1), ranging from 0.7 per 1000 population in Yemen to 29.0 per 1000 population in Lebanon. Six countries reported collecting less than 10 whole blood donations per 1000 population per year in 2013.

Fig. 1. Whole blood donations per 1000 population in countries of the Eastern Mediterranean Region



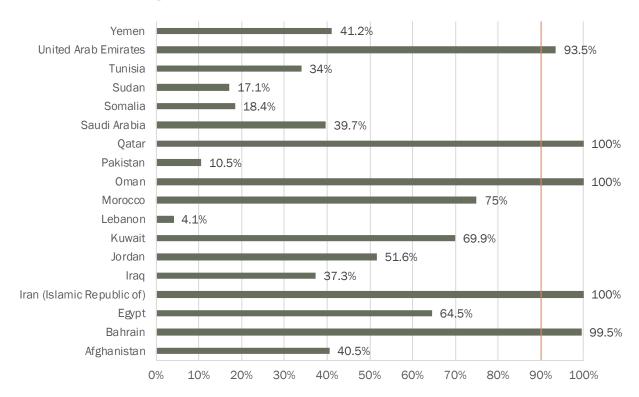
COLLECTION OF BLOOD COMPONENTS VIA APHERESIS

Fourteen of the 18 responding countries reported collecting blood both as whole blood and through apheresis procedures. Of the total donations reported in 2013, less than 1% were collected by apheresis.

TYPES OF BLOOD DONATIONS

Information on types of blood donation was provided by all countries that reported. Overall, of the total 7.1 million whole blood donations, 3.6 million (50.5%) were reported as voluntary non-remunerated donations, 3.5 million (49.4%) as family or replacement donations, and 4297 (0.1%) as paid blood donations. Fig. 2 shows the proportion of voluntary non-remunerated donations (both whole blood and apheresis donations) by country. Five countries collected more than 90% of their blood supply from voluntary non-remunerated donation and in four countries the rate was actually more than 99%. Nine countries remained greatly dependent on family/replacement and paid blood donors, with these donations accounting for more than 50% of their blood supplies in 2013.

Fig. 2. Proportion of voluntary non-remunerated blood donations in countries of the Eastern Mediterranean Region



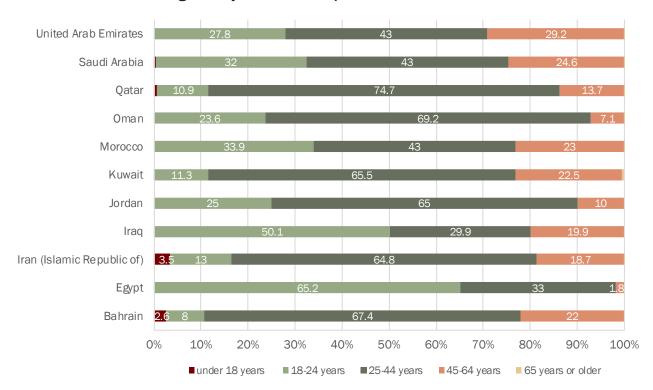
Of a total of 36 731 apheresis donations, 46% were from voluntary non-remunerated donors, 33% from family or replacement donors, and 21% from paid donors. In addition, 15 965 donations collected through the apheresis procedure were reported as apheresis platelet units; the type of donor is unknown.

BLOOD DONOR PROFILE

Sex and age profile

Of 12 countries reporting on the sex profile of blood donors, nine reported that less than 10% of donations were from female donors; the other three countries (Egypt, Morocco and Tunisia) reported 54%, 40% and 35% respectively. The age profile of blood donors was analysed for only 11 countries owing to incomplete data (Fig. 3).

Fig. 3. Age profile of blood donations collected from donors in countries of the Eastern Mediterranean Region (n = 11) (donations from those aged under 18 years for Kuwait, Qatar and Saudi Arabia were 0.1%, 0.7% and 0.3% respectively; in Kuwait 0.6% of donations came from those aged 65 years and older)



Repeat and first-time donors

A total of 11 countries reported data on the number of voluntary non-remunerated whole-blood donations given by first-time and repeat donors. Overall, the percentage of whole blood donations given by repeat voluntary non-remunerated donors ranged widely, from 1% in Egypt to 96% in Kuwait (Fig. 4). The overall proportion of first-time donations in the Region is 34.7%.

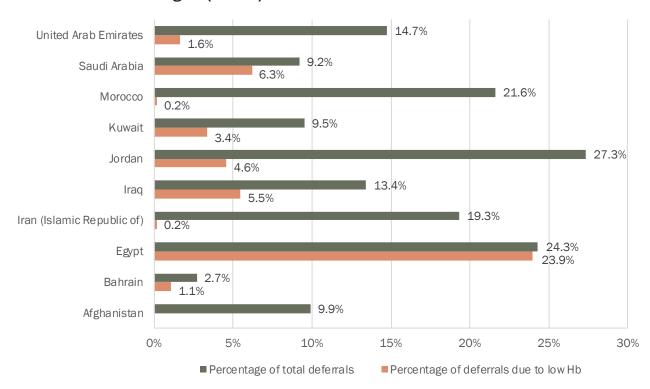
United Arab Emirates Somalia Saudi Arabia 0 man Morocco Kuwait Jordan Iraq Iran (Islamic Republic of) Egypt Bahrain 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ■ % first-time donations ■% repeat donations

Fig. 4. Distribution of first-time and repeat voluntary non-remunerated whole blood donations in countries of the Eastern Mediterranean Region (n = 10)

Donor deferral

Data on deferral from blood donation were provided by 11 countries. The total deferral rates (percentage of deferrals among all blood donor presentations) varied among countries, from 3% to 18%. Fig. 5 shows the total deferral rate and the rate of deferral due to low haemoglobin in 10 countries of the Region. Reasons for the variations include absence of donor selection criteria, lack of appropriate donor selection procedures and differences in donor registration practices. It is important to note, however, that there may be underreporting of the total number of deferrals or deferrals due to specific reasons. Collection of data on the number of deferrals from blood donation and the underlying reasons should be encouraged as it is useful for countries in monitoring the implementation of their donor selection guidelines and in identifying needs for improving donor education.

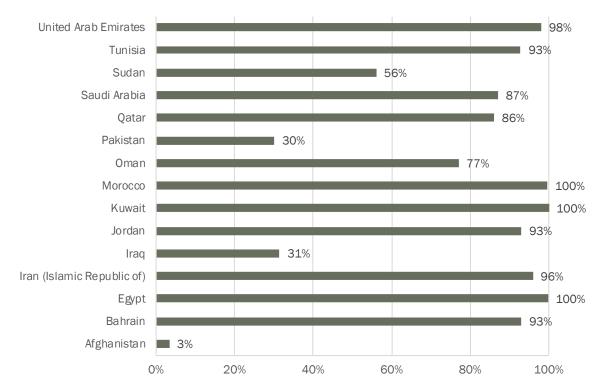
Fig. 5. Total deferral and deferral due to low haemoglobin (Hb) rates in countries of the Eastern Mediterranean Region (n = 10)



Processing of whole blood donations into blood components

According to data reported by 16 countries, 65% of whole blood donations collected in the Region were processed into components. The proportion varies widely, from 3% in Afghanistan to 100% in Morocco, Kuwait and Egypt (Fig. 6). Nine countries processed 90–100% of blood donations into components. Data from the WHO Global Database on Blood Safety show that there are great country-level variations in the degree of processing of whole blood donations into different components among the countries in the Region: on average, 0.4 units of platelets and 0.5 units of fresh frozen plasma are produced per collection.

Fig. 6. Proportion of whole blood donations processed in countries of the Eastern Mediterranean Region (n = 16)



Laboratory screening of blood donations

LABORATORY SCREENING POLICY

All the responding countries reported having a policy of screening of all blood donations for human immunodeficiency virus, hepatitis B virus, hepatitis C virus (HIV, HBV, HCV) and syphilis. All 18 countries perform confirmatory tests on all units that are reactive for HIV, HBV and HCV. Confirmatory testing on all or part of syphilis reactive blood units is done in 13 countries.

The following subsections analyse the data on laboratory screening policy according to the screening component.

HIV-1/2

Two countries reported testing for HIV-1/2 antibodies (Ab), while 11 countries reported testing for HIV-1/2 antibodies and antigens (Ab+Ag). Five countries reported testing HIV RNA using nucleic acid amplification testing in addition to Ab testing (two countries) or Ab+Ag serological testing (three countries).

Hepatitis B virus

Six countries reported having a policy of testing all blood donations for hepatitis B surface antigen (HBsAg). Seven countries reported having a policy of testing all blood donations for anti-HBc in addition to testing for HBsAg. Five countries reported using nucleic acid amplification testing for HBV in addition to HBsAg + anti-HBC serological testing.

Hepatitis C virus

Ten countries reported having a policy of serological testing of all donated blood for HCV antibodies, and three countries for testing for HCV Ab+Ag. Five countries reported testing using nucleic acid amplification in addition to HCV antibodies (four countries) and HCV Ab+Ag (one country).

Syphilis

All countries have a policy of performing syphilis testing for all donations.

Human T-lymphotropic virus

Four countries (Kuwait, Qatar, Saudi Arabia and United Arab Emirates) reported having a policy of testing all blood donations for human T-lymphotropic virus (HTLV-I/II) antibody. The Islamic Republic of Iran reported implementing selective testing for new donors or donors who have not been tested before.

Malaria

Six countries (Bahrain, Kuwait, Pakistan, Qatar, Saudi Arabia and the United Arab Emirates) test all or part of donations for malaria.

COVERAGE OF LABORATORY SCREENING OF BLOOD DONATIONS

One country reported not being able to test 100% of the blood collected for one or more of the four transfusion-transmissible infections – HIV, HBV, HCV and syphilis – as required by the national testing policy. One country reported not being able to test all donations for HIV; another reported not being able to test all donations for HCV and a third reported not being able to test all donations for syphilis

PREVALENCE OF MARKERS OF INFECTION IN BLOOD DONATIONS

The prevalence of infection among blood donations or the proportion of blood donations with a positive result is directly related to the safety of the blood supply because this has an impact on the residual risk of blood products used for patient care and also on the risk due to errors in blood quarantine and release (even though test-positive donations are discarded). The prevalence of an infection in blood donations is dependent on the prevalence of the infection in the population from which donors are selected and on the effectiveness of donor motivation, mobilization and selection processes. Table 1 shows the proportion of donations with reactive results in screening tests for HIV, HBV, HCV and syphilis from 16 countries.

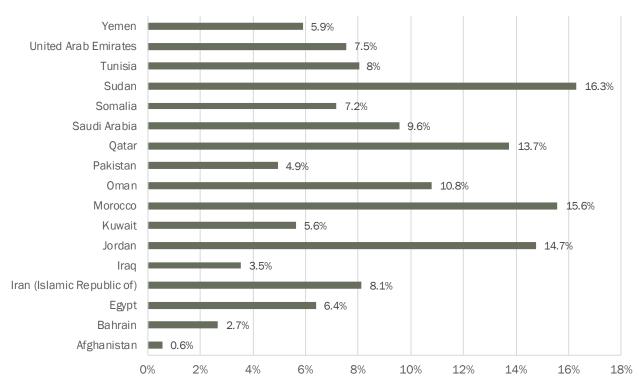
Table 1. Proportion of blood donations with reactive results on screening tests from 16 reporting countries in the Eastern Mediterranean Region

Infection	Reactive donations			
markers	No.	% (range)		
HIV	3 455	0.05 (0.00-1.00)		
HBV	77 842	1.10 (0.06–5.00)		
HCV	84 188	1.19 (0.05–3.35)		
Syphilis	26 545	0.38 (0.07–5.00)		

Discard of blood

Information on discarded blood donations was provided by 17 countries. Overall, 7.1% of total donations (whole blood/red blood cells) was discarded in 2013. Fig. 7 shows the proportion of blood units discarded for 17 countries in the Region. Reactivity for markers of transfusion-transmissible infections (51.5%) was the main reason for discard, followed by outdated stock (26.5%), incomplete collection (10.7%) and problems with processing (9.8%). Storage problems and transportation problems accounted for only 1.0% and 0.4% of discards respectively.

Fig. 7. Proportion of blood units discarded in countries of the Eastern Mediterranean Region (n = 17)



Clinical use of blood

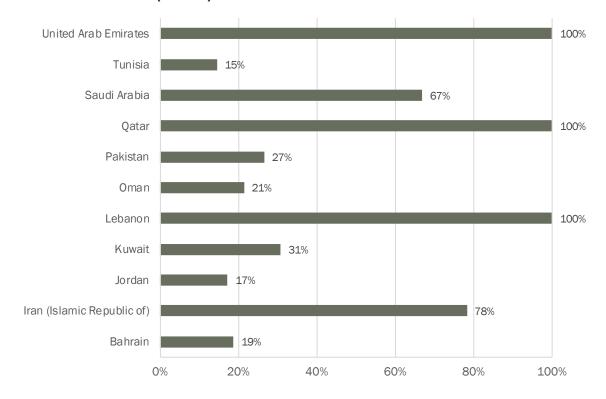
TRANSFUSION AND UTILIZATION OF BLOOD AND BLOOD COMPONENTS

Complete and accurate data on clinical transfusions and utilization of blood and blood products are limited. However, information collected from some countries suggests that transfusions are often given unnecessarily, with a preference for transfusing whole blood rather than blood products. National guidelines on the clinical use of blood are available in 13 countries, however, the guidelines are often not adhered to by clinicians or may not be effectively distributed and updated. Quality systems and management for the clinical transfusion process are not well developed in many countries.

MECHANISMS TO IMPROVE AND MONITOR SAFE AND APPROPRIATE BLOOD TRANSFUSION

Hospital transfusion committees are key institutional mechanisms for improving clinical transfusion. Although 11 countries reported having established hospital transfusion committees in hospitals prescribing and performing blood transfusion (Fig. 8), only 5 countries conducted clinical audits – the Islamic Republic of Iran, Lebanon, Pakistan, Saudi Arabia and the United Arab Emirates.

Fig. 8. Proportion of hospitals in countries of the Eastern Mediterranean Region which have a transfusion committee (n = 11)



HAEMOVIGILANCE

An important component of a blood safety system is the establishment of haemovigilance, which includes efforts to monitor and evaluate adverse events associated with the blood supply and transfusion service, and to use the findings to improve blood safety and transfusion outcomes. Nine countries reported having a national haemovigilance system.

Plasma used for fractionation and the provision of plasmaderived medicinal products

Two countries (Islamic Republic of Iran and Tunisia) reported various arrangements for utilizing plasma collected within the country for (contract) fractionation. A total of 245 381 litres of plasma was sent for fractionation by the blood services of these two countries in 2013, with 50% coming from recovered plasma. Most countries import plasma-derived medicinal products from international sources to meet the needs of patients. Patients with bleeding disorders and immune deficiencies still have very limited access to life-saving products, whether plasma-derived or derived from whole blood such as cryoprecipitate and hyperimmune plasma. There are about 27 000 patients with bleeding disorders (haemophilia A and B and von Willebrand Disease) in the Region, accounting for 9% of the reported global disease burden for haemophilia⁵.

Tunisia started contract fractionation as early as 1995 (largely albumin and immunoglobulins) and the Islamic Republic of Iran in 2004, and there has also been a recent development in Morocco. Contract fractionation has not only improved the Iranian national blood system and increased the availability of plasma-derived medicinal products, but also provides substantial savings on the national health resource. Another initiative worth mentioning is the Arab Project for Plasma Derivatives, which was adopted by the Arab Health Ministers in March 2011 under the auspices of the Arab Authority for Blood Transfusion Services.

⁵ Report on the annual global survey 2014. Montreal: World Federation of Hemophilia; 2015 http://www1.wfh.org/publications/files/pdf-1627.pdf.

Organization and management of national blood transfusion services

POLICY AND GOVERNANCE

Of the 18 countries that responded, 14 (78%) have a national blood policy, 13 (72%) have a national strategic plan and 12 (67%) have constituted a national advisory committee (or equivalent) for blood transfusion services. Where there are national advisory bodies established, they are not empowered to take key technical decisions. A regulatory mechanism for the registration, licensing, operation and inspection of the blood transfusion service exists in nine countries (50%), and nine (50%) have legislation that covers the safety and quality of blood and blood products.

Financing of blood transfusion services is often given low priority and many countries report a lack of adequate, sustainable and specific funding by governments. A dedicated budget for national blood donor services and national blood services is only provided in eight countries. Nine countries reported receiving extra budgetary funding from bilateral or multilateral cooperation agencies and development partners. Only seven countries have put in place a cost recovery system through health insurance schemes or direct payments such as user fees to improve available funding.

ORGANIZATION OF BLOOD COLLECTING AND PROCESSING FACILITIES

The countries of the Region are at varying stages of development with respect to their blood transfusion services. While some have established well funded and well developed services, in many countries services are still developing and fragmented, with challenges including coordination and collaboration among different stakeholders. There are 1240 blood banks in the Region, of which 264 (21%) are stand-alone and 976 (79%) are hospital-based.

In 16 countries, there is a specific unit or department within the health ministry which is responsible for the blood supply and blood transfusion service. However, only a few of these have autonomous or semi-autonomous structures. Blood transfusion services are often placed under other departments, e.g. laboratory, hospital, patient safety, etc. In countries with private sector blood

banks, operations are usually not coordinated with, or do not come under, the national blood programme, and they are mostly unregulated.

In many countries there is a centralized system for evaluation and validation of test kits and reagents. Stock management, as an integral part of the quality system and its management, is ineffective, inadequate or even absent. Five (28%) countries report interruptions in the regular supply of test kits, reagents and consumables, often due to insufficient budgetary allocation or to trade embargo. Interruptions of this kind are major obstacles for the collection, screening and processing of blood donations.

Strategic partnerships and collaborations with blood donor organizations and patient associations, academic and research institutions, scientific and professional societies and industry are not strong. In addition, linkages with other health programmes such as those for maternal and child health, HIV/AIDS and hepatitis, infection control, patient safety and waste management need further development. There are also efforts to coordinate and centralize the evaluation and validation of test kits and reagents as well as the procurement and distribution of blood bank equipment and supplies. However, an efficient procurement and supply chain system that ensures the continuity of supplies in all blood centres and hospital blood banks is lacking in many countries. A cohesive system for standardized data collection, management and reporting is also lacking in most countries.

QUALITY ASSURANCE AND MONITORING

Quality management programmes have been initiated in the blood transfusion systems in many countries but have not been subsequently followed up. A total of 15 countries reported having national standards for the collection, testing, processing, storage and distribution of blood and blood products. There are challenges in the development of complete and accurate records and systems for controlling documents. Eleven countries reported a system of regular inspection and licensing of the blood transfusion services by the national regulatory agency or another entity. A total of 13 countries reported having a national external quality assessment scheme for laboratory screening for transfusion-transmissible infections. Eleven countries reported having a national external quality assessment scheme for blood group serology and compatibility testing and six countries reported that their national blood transfusion services were accredited.

A total of 15 countries reported having a programme of continuing education for personnel involved in blood transfusion and five countries reported having educational programmes that offered a nationally recognized university degree or diploma in blood transfusion medicine or science.

Discussion

AVAILABILITY OF BLOOD AND BLOOD PRODUCTS FOR TRANSFUSION

There are currently no global or regional standards for the estimation of national requirements for blood and blood products. The need for blood and blood products is dynamic and is dependent on a number of factors related to health service coverage, the level of development and sophistication of the health care system, and hospital blood usage. Nevertheless, the whole blood donation rate per 1000 population can be considered a general indicator of the availability of blood for transfusion in a country, and an indicator of comparability for countries at similar levels of economic and social development. Although there has been a general increase in blood collections in the Region, the current levels in six countries remain too low to cover the blood requirements of their health care systems. Strategies to improve blood collection in these countries need to be developed or strengthened and implemented effectively.

Regular voluntary non-remunerated blood donation is a key component for any successful blood programme. This ensures adequacy and sustainable availability of quality blood and blood products. However, nine countries remained largely dependent on family/replacement and paid blood donors, with these donations accounting for more than 50% of their blood supplies in 2013. Greater efforts and investment are required to increase the collection of voluntary non-remunerated blood donations so as to reduce the reliance on family/replacement and paid donors for the national blood supply.

Donor retention is important in further improving the safety and quality of the blood supply. The proportion of repeat voluntary non-remunerated blood donation is 65.3%. This will keep the prevalence of transfusion-transmissible infections among blood donors at much lower levels than in the general population. However, some countries in the Region have very high proportion of first-time donations. Donor retention strategies need to be emphasized in all the countries to achieve the same level of safety.

Treatment using labile blood products is gradually being expanded in medical practice in the Region, and increased quantities of recovered plasma will become available for fractionation into plasma-derived medicinal products to meet the need. It is important for the countries involved to develop appropriate standards for donor motivation, selection, and care and retention, and to put in place appropriate blood product separation technology and fractionation

capacity, quality systems, and good manufacturing practices to improve the quality of plasma for fractionation. They also need to explore the development of alternative mechanisms for contract fractionation of recovered plasma in this developmental and transitional period.

LABORATORY SCREENING AND TESTING

Obtaining data on testing of donor blood is critical in getting a regional picture of the blood safety situation from the testing point of view. This report indicates that there are some countries in the Region that are as yet unable to test all donations for one or more of the markers of transfusion-transmissible infections among their donor populations. This seriously compromises the safety of the blood supply in these countries, and requires urgent action by national authorities to avert the risk to the blood supply.

CLINICAL USE OF BLOOD

Appropriate clinical use of blood is an important aspect of blood safety. It reduces unnecessary exposure of patients to allogeneic blood, along with its attendant risks, while ensuring judicious utilization of a scarce resource. Evidence-based transfusion guidelines and transfusion audits are useful tools in the education of those ordering blood products, potentially resulting in the reduction of inappropriate use of these products. Five countries reported not having national guidelines.

Structures such as hospital transfusion committees can provide leadership within a hospital for optimizing the use of blood. Although 11 countries reported the existence of hospital transfusion committees, this does not indicate whether they were effectively implemented. The proportion of transfusion-performing hospitals which had (or participated in) hospital transfusion committees and which performed clinical audits was low in the Region. More effort and investment is required for countries to develop and implement evidence-based policies and guidelines; educate and train health workers working in blood transfusion and focusing on patient blood management; and implement an effective system for monitoring the clinical use of blood and blood products and transfusion practices.

In addition, obtaining accurate data on the clinical use of blood and blood products is challenging owing to the wide diversity of institutions and hospital settings that perform transfusion and the highly variable policies and procedures for documentation and recording of transfusion.

POLICY, LEGISLATION, REGULATORY OVERSIGHT AND GOVERNANCE MECHANISMS

The provision of safe and adequate blood is a government responsibility and should be an integral part of each country's national overarching health care policy and health care infrastructure. The WHO recommends that every country should put in place policies, systems and structures to ensure the safety, quality, accessibility, affordability and timely availability of blood and blood products to meet the needs of all patients who require transfusion. The WHO also recommends that the policy be supported by appropriate legislation to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products.

A high proportion of countries in the Region reported having national blood policies and strategic plans. This reflects the commitment of national governments to improve blood safety and adequacy of supply. About half the countries reported having legislation to support their policies. However, blood policies and plans need to be implemented for a blood service to realize tangible outcomes. Supportive systems such as a functioning national committee or its equivalent are needed to ensure the effective implementation of a national blood policy and strategic plan.

Similarly, a high proportion of countries in the Region has national standards for the collection, testing, processing, storage and distribution of blood and blood products. However, many reported having no mechanisms for quality oversight and monitoring, nor any programmes to enforce the implementation of standards and sustain the functionality of the quality systems. There is an urgent need to establish sustainable quality systems and strengthen the capacity for regulation and quality oversight in many countries.

Governments should ensure that adequate, sustainable financing for the national blood programme is integrated within the financial structure of national health care systems through mechanisms such as specific budget allocation, cost recovery and health insurance, or a combination of these. Inadequate financing of blood services impedes efforts to improve blood safety. Investment in blood services in many countries in the Region is often too low to achieve sufficient and safe blood supplies.

DATA

A data collection and reporting system is an important element of a well managed, nationally coordinated, blood transfusion programme. Adequate national data on blood availability and safety allow countries to set priorities and to further strengthen the national blood system. There is a need to establish surveillance systems on the incidence and prevalence of HIV, HBV, HCV and other infections in blood donors, and maintain vigilance on the transfusion outcomes of recipients, including post-transfusion risk of infection.

Information on clinical transfusion forms the basis for the monitoring of clinical transfusion practice and provides critical performance measures to influence desirable changes in the prescribing and administration of blood and to reduce variations in transfusion practice. Countries providing partial data should consider instituting standardized systems for data collection and management at national level. There is a need for national blood transfusion services to provide greater structure and support for the information management system, and for hospitals to establish mechanisms for improving data collection, donor tracking, traceability and overall haemovigilance.

LIMITATIONS

While great effort has been undertaken to obtain accurate data from countries, the data submitted by national health authorities have not been independently verified. Data accuracy therefore depends on the data collection systems in the countries, and this report can only reflect the information provided by WHO Member States. While many countries report comprehensive national data on blood availability and safety, others provide limited information on the activities of a subset of blood centres in the country. For instance, Egypt reported collections only from the national blood transfusion service, which accounts for only 33% of the estimated national collection. Incomplete data and variation in the interpretation of some indicators affected the analysis of some of the information received from countries.

Conclusion and the way forward

The WHO survey continued to show significant variations in the availability, safety and use of blood and blood products among countries of the Region. Blood transfusion safety is still a concern in some countries, where the prevalence of transfusion-transmissible infections among blood donors is high but quality and coverage of blood screening is inadequate. Furthermore, some countries still lack enough regular voluntary unpaid blood donors, with low donation rates accompanied by high rates of discard. A blood system that gives patients access to safe blood and blood products in sufficient quantity is a key component of an effective health system. More effort is, therefore, still required to strengthen national blood systems so as to ensure sufficient and safe blood supplies in the Region.

The WHO developed a regional strategic framework to address the challenges identified in the situation analysis and to guide countries over the 10-year period 2016–2025 in developing and strengthening national systems⁶. This will ensure the continuity, sufficiency, affordability, sustainability and security of national supplies of safe and efficacious blood and blood products to meet the needs of patient populations. It will also play an important role in supporting the implementation of WHO resolutions and Executive Board decisions on the safety, quality and availability of blood; on guiding principles on human cell, tissue and organ transplantation; on principles for global consensus on the donation and management of blood, blood products and medical products of human origin; on hepatitis; on sickle-cell anaemia; and on thalassemia and other haemoglobinopathies.

The implementation of the strategic framework at country level is a collective endeavour that will require concerted and coordinated actions by all stakeholders, national and international, under the leadership of the ministries of health. These actions should be adapted to, and aligned with, the specific context, political and socioeconomic environment, available resources and capacities, and overarching health and development strategies, laws and regulations in each country.

Strategic framework for blood safety and availability 2016-2025 http://applications.emro. who.int/dsaf/EMROPub_2017_EN_19608.pdf?ua=1

Countries should carry out a review of their blood transfusion services regularly and develop their own strategic and operational plans, guided by the strategic framework, to address country-specific needs in accordance with their existing resources.

The monitoring of the strategic framework should be undertaken annually by each country to enable necessary adjustments to be made in a timely manner. Data on blood safety and availability indicators will be collated annually for the WHO Global Database on Blood Safety, and each country will, in addition, define monitoring indicators based on its specific situation that will be used to assess its individual progress.

The WHO will continue to provide support to Member States at regional and country level in their efforts to improve their blood transfusion services in a cross-cutting and comprehensive manner.

