Establishing External Quality

Assessment Programmes for

Screening of Donated Blood

for Transfusion-Transmissible

Infections

Implementation Guide



Establishing External Quality

Assessment Programmes for

Screening of Donated Blood

for Transfusion-Transmissible

Infections

Implementation Guide



WHO Library Cataloguing-in-Publication Data

Establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections: implementation guide.

1.Blood Transfusion - adverse effects. 2.Blood Transfusion - standards. 3.Disease Transmission, Infectious - prevention and control. 4.Donor Selection. I.World Health Organization.

ISBN 978 92 4 151583 2

(NLM classification: WB 356)

This publication was originally published under ISBN 978 92 4 151043 1

© World Health Organization 2016

All rights reserved. Publications of the World Health Organization are available on the WHO website (http://www. who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; email: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications –whether for sale or for non-commercial distribution– should be addressed to WHO Press through the WHO website (http://www.who.int/about/licensing/ copyright_form/index.html).

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 and dashed 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.

Printed in France.

Contents

ACKNOWLEDGEMENTS

ABBREVIATIONS

INTRODUCTION				
1	EXT	ERNAL QUALITY ASSESSMENT	3	
	1.1	EQA as part of a quality system in the screening of donated blood for TTI	3	
	1.2	Assessment	4	
	1.3	External quality assessment	5	
	1.4	Objectives and benefits of EQA	5	
	1.5	EQA programmes	6	
2	EST/	ABLISHING EQA PROGRAMMES FOR TTI SCREENING	8	
	2.1	Organizing institution	8	
	2.2	Advisory committee	10	
	2.3	Technical and administrative support	11	
	2.4	Information management system	12	
	2.5	Finances	13	
	2.6	Quality system of the EQA programme	14	
	2.7	Participating laboratories	15	
	2.8	Pilot study	16	
	2.9	Practical steps in establishing an EQA programme	16	
3	PAR	TICIPATING LABORATORIES	18	
	3.1	EQA programme information manual	18	
	3.2	Rules of participation	19	
	3.3	Registration	20	

4.	PRAC	TICAL CONSIDERATIONS IN ESTABLISHING AN	
	EQA	PROGRAMME	22
	4.1	Scope	22
	4.2	EQA programme exercise format	22
	4.3	EQA programme objectives	23
	4.4	Sources of exercise material	23
	4.5	Establishing a sample bank	24
	4.6	Processing candidate exercise material	25
	4.7	Exercise documentation	29
	4.8	Logistics	31
5.		INING AND OPERATING AN EQA PROGRAMME FOR TTI	
	TEST		32
	5.1	Developing an annual EQA programme plan	32
	5.2	Developing the plan for a specific EQA exercise	33
	5.3	C C	33
	5.4	Preparation of exercise materials	34
	5.5	Dispensing exercise material	34
	5.6	Verifying homogeneity and stability	35
	5.7	Verifying stability	36
	5.8	Packing and dispatch	37
	5.9	Collection of and deadline for EQA results	37
		Collation of EQA results	38
		Analysing EQA results	38
		Statistical analysis of EQA exercise results	39
		Preparation of EQA reports	40
		Preliminary report	40
		Final report	40
	5.16	Certificates of participation	41
6.		ITORING LABORATORY PERFORMANCE, FEEDBACK	40
		EDUCATION	42
	6.1	Setting standards of acceptable performance	42
	6.2	Numerical scoring systems for performance monitoring	43
	6.3	Follow-up of unsatisfactory performance	43
	6.4	Self-assessment	44
	6.5	Education	44

7. MONITORING AND EVALUATING AN EQA PROGRAMME	46
7.1 Indicators	46
7.2 Impact	47
7.3 Annual report	47
GLOSSARY	48
ANNEXES	51
1. Preliminary questionnaire for potential participating	
laboratories	52
2. EQA registration form	54
3. Exercise instruction sheet	55
4. Exercise results form	56
5. Protocol for homogeneity testing of exercise material	59
6. Protocol for stability testing of exercise material	61
7. Record of exercise distributions and returned results	63
8. Exercise analysis and report	64
9. Numerical scoring systems	68

Acknowledgements

The Blood Transfusion Safety Programme in the WHO Department of Service Delivery and Safety wishes to express its thanks to the experts in external quality assessment screening for transfusion-transmitted infections who contributed to the development of these guidelines.

Authors

Ms Susan Best and colleagues

National Serology Reference Laboratory Melbourne, Australia

The authors also acknowledge the following individuals who prepared the WHO publication *External quality assessment of transfusion laboratory practice: guidelines on establishing an EQA scheme in blood group serology* (WHO/ EHT/04.09), to which the present publication is a companion.

Editorial team and contributors

Dr Wilai Chalermchan, Senior Laboratory Advisor (contractor), Thailand MOPH – U.S. CDC Collaboration (TUC)

Dr Marcia Mitiko Otani, Chefe Depto Controle de Qualidade Serologia, Fundação Pró-Sangue Hemocentro de São Paulo, Brazil

Dr Neelam Dhingra, Coordinator, Patient Safety and Quality Improvement, Service Delivery and Safety, WHO

Critical readers

Dr Alan Kitchen, Head of National Transfusion Microbiology Reference Laboratory, NHS Blood and Transplant, United Kingdom

Dr Jane Carter, Amref Health Africa, Wilson Airport, Langata Road, Nairobi, Kenya

Ms Jenny White, Deputy Scheme Manager, NEQAS for Blood Transfusion Laboratory Practice Watford, United Kingdom

Mr Robin Knight, Red Cell Immunohematology Service Development Manager, National Blood Service, North London Blood Centre, United Kingdom

Dr Noryati Abu Amin, Medical Officer, Blood & Transfusion Safety, Service Organization and Clinical Interventions Unit, Service Delivery and Safety Department, WHO

Mr Junping Yu, Technical Officer, Blood & Transfusion Safety, Service Organization and Clinical Interventions Unit, Service Delivery and Safety Department, WHO

Dr Vengetassen (Ravi) Reddy, Chief Operations Officer, South African National Blood Service

Dr Vivienne James, Northern Sydney Central Coast Health, Australia

Dr Xun Wang, Head of Transfusion-Transmitted Disease Laboratory, Shanghai Blood Centre, China **Dr Panadda Silva**, Director/Expert at Department of Medical Sciences, Ministry of Health, Thailand

The publication was coordinated by Dr Noryati Abu Amin and Mr Junping Yu. Overall guidance was provided by the Coordinator, Patient Safety and Quality Improvement Unit, Dr Neelam Dhingra and the Coordinator of Service Organization and Clinical Interventions Unit, Dr Hernan Montenegro.

Development of this publication was supported by Cooperative Agreement Number GH001180 from the United States Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official view of CDC.

预览已结束,完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5 27145