SAFE BLOOD AND BLOOD PRODUCTS

Manual on the management, maintenance and use of blood cold chain equipment

World Health Organization
Geneva

SAFE BLOOD
AND BLOOD
PRODUCTS

Manual on the management, maintenance and use of blood cold chain equipment

World Health Organization
Geneva

WHO Library Cataloguing-in-Publication Data

World Health Organization.
Manual on the management, maintenance and use of blood cold chain equipment.

At head of title : Safe blood and blood products.

1.Blood preservation - instrumentation 2.Blood preservation - methods 3.Plasma 4.Blood platelets
5.Refrigeration - methods 6.Equipment and supplies - standards 7.Guidelines 8.Manuals I.Title

ISBN 92 4 154673 5 (NLM classification: WH 460)

Acknowledgements

The Department of Essential Health Technologies acknowledges the continued support of the Government of Luxembourg towards the WHO Blood Cold Chain Project. The publication was produced by Mr David Mvere, WHO Consultant and Dr Elizabeth Vinelli, National Blood Council, Tegucigalpa, Honduras. Edited by Ms Kay Bond, EHT/WHO. The contribution of the following persons is particularly acknowledged:

Mrs Beryl Armstrong, South African National Blood Service, Pinetown, South Africa
Dr Neelam Dhingra, World Health Organization Headquarters, Geneva, Switzerland
Dr Jean Emmanuel, National Blood Transfusion Service, Malawi
Ms Jan Fordham, World Health Organization Headquarters, Geneva, Switzerland

Reviewers included:

Dr Noryati Abu Amin, World Health Organization Headquarters, Geneva, Switzerland
Dr Rama Bhasin, All India Institute of Medical Sciences, New Delhi, India
Professor Kamel Boukef, National Blood Transfusion Centre, Tunis, Tunisia
Dr Jose Cruz, World Health Organization Regional Office for the Americas/Pan American Health Organization, Washington, D.C., United States of America
Dr Graham Harrison, World Health Organization Regional Office for the Western Pacific, Manila, Philippines
Mrs Shân Lloyd, World Health Organization Headquarters, Geneva, Switzerland
Dr Nishi Madan, University College of Medical Sciences, New Delhi, India
Dr Ana del Pozo, Argentine Association of Hemotherapy and Immunohematology, Buenos Aires, Argentina

Photographs by Sail Vega unless specified
Designed by minimum graphics
Printed in India

Contents

Preface vii

Useful abbreviations ix

Glossary x

1 Introduction 1

1.1 Blood: the raw material 1

1.2 Links in the cold chain 1

1.3 Target audience for this Manual 2

1.4 Using the Manual 3

1.5 Limitations of this Manual 3

2 Storage and transportation of blood and blood components 5

2.1 Safe storage of blood 5

2.1.1 Whole blood 5

2.1.2 Fresh frozen plasma 6

2.1.3 Cryoprecipitate 6

2.1.4 Platelet concentrates 7

2.1.5 Plasma derivatives 8

2.1.6 Cold chain samples and reagents 9

2.2 Packing and transportation of blood and blood components 9

2.2.1 Transportation of whole blood from the collection site to the laboratory 9

2.2.2 Transportation of blood components from one blood bank to another 11

2.2.3 Issuing blood components to clinical areas 12

3 Blood storage equipment: Refrigerators, plasma freezers and platelet agitators 15

3.1 Technical terms for specifications of blood cold chain equipment 15

3.2 Design features common to refrigerators and freezers 17

3.2.1 The cabinet 17

3.3 Ideal design features specific to blood bank refrigerators 19

3.4 Ideal design features specific to plasma (and cryoprecipitate) freezers 21
3.5 Walk-in cold rooms and freezer rooms 21
3.6 Platelet agitators 22
3.7 The cooling mechanism and its maintenance (the refrigeration cycle) 23
3.7.1 Refrigerant gas 24
3.7.2 The compressor 24
3.7.3 The condenser 24
3.7.4 The evaporator 24
3.7.5 The thermostat 25
3.8 Ensuring electrical safety of the equipment 25
3.9 Care of refrigeration equipment 25
4 Other blood cold chain devices 27
4.1 Plasma thawing equipment 27
4.2 Equipment for the transportation of blood 28
4.2.1 Technical terms used 28
4.2.2 Blood transport boxes 28
4.2.3 Ice packs, cooling plates and cooling pouches 30
4.3 Temperature monitoring devices 30
4.3.1 Portable thermometers 31
4.3.2 Temperature recorders/thermographs 31
4.4 Manual recording of temperatures 33
4.5 Alarm systems 34
4.6 Blood warmers 35
4.7 Essential accessories for all refrigeration equipment 35
4.7.1 Voltage regulators (stabilisers) 35
4.7.2 Stand-by generators 35
5 Installing blood refrigerators and plasma freezers 38
5.1 Action on reception of equipment 38
5.2 Siting of refrigerators and plasma freezers 39
5.2.1 Heat and light 39
5.2.2 Air circulation 40
5.2.3 Levelling 40
5.3 Door seals 40
5.4 Cleaning 41
5.5 Energy supply 41
5.6 Starting the equipment 41
5.7 Verifying installations and operational performance 44

6 Organizing the blood cold chain **46**
6.1 The structure of a national blood transfusion service 46
6.2 Activities of the blood bank 47
6.3. Critical stages in the movement of blood from collection to transfusion 48
6.3.1 Packing procedures for transportation 49
6.3.2 Receipt and handling on incoming, unprocessed blood and plasma derivatives 50
6.3.3 Receipt and handling of processed blood and blood components 51
6.3.4 Quarantine policies and procedures 51
6.3.5 Labelling of products 52
6.3.6 Method of storage of blood components in available stock 52
6.3.7 Release of whole blood/red cells for use from available stock 53
6.3.8 Procedures for thawing and releasing frozen plasma and cryoprecipitate 53
6.3.9 Procedures for the release of platelet concentrates 53
6.3.10 Discarded blood products and their safe disposal 54
6.4 Monitoring the blood inventory 55
6.4.1 Theoretical count 55
6.4.2 Physical count 56
6.4.3 Daily blood bank report 56
6.4.4 Unused blood components 56
6.5 Model list of essential blood cold chain equipment 59
6.6 Ensuring the blood cold chain during the issuing of blood 60
6.7 Withdrawal of blood from the blood bank, transfusion service or a satellite refrigerator 61
7 Preventive maintenance, care and repair of equipment **63**
7.1 Organizing an equipment maintenance programme 63
7.2 Basic care and preventive maintenance of blood cold chain equipment and accessories 67
7.2.1 Blood bank refrigerators and freezers 67
7.2.2 Blood transport boxes 70
7.2.3 Platelet agitators 70
7.2.4 Plasma thawers 70
7.2.5 Stand-by generators 70
7.2.6 Basic preventive maintenance and repair tool kit 71
7.2.7 Calibration of cold chain devices and equipment 72
7.3 Disposal or decommissioning of cold chain equipment 72
8 Monitoring and evaluating the blood cold chain **74**
8.1 Definition of terms 74
8.2 Planning for monitoring and evaluation 75
8.3 Quality indicators for evaluation 75

8.4 Records 76
8.5 Reports 76
8.5.1 Blood cold chain performance report 77
8.5.2 Blood cold chain care and preventive maintenance log and repair record 77
8.6 Analysis and interpretation of data 78
8.7 Using the findings from the monitoring and evaluation exercise 78
9 Guidelines for the development of a training programme 80
9.1 Objectives 80
9.2 Key points in the training programme 80
9.3 Preparing a training programme 80
9.4 Developing a training guide 81
References 84
Annex 1. The use of CFC in blood cold equipment 85
Annex 2. WHO Minimum performance specifications for blood cold chain equipment 87
Annex 3. Basic operational framework for the blood cold chain 92

Preface

The critical contribution that effective management and use of medical equipment brings to health service delivery is only recently gaining recognition. Managing medical equipment has often been misunderstood as the mere procurement of accessible products within a given budget. However, this narrow perspective has proven neither effective, nor cost-effective in the running of health services. The World Health Organization (WHO) promotes the adoption in countries of a comprehensive life cycle approach that falls largely into the following stages: (i) planning and decision-making (e.g. policy, needs assessment and budgeting); (ii) acquisition (including selection, procurement and donation guidelines); (iii) installation (inspection, testing, acceptance, inventories and documentation); (iv) monitoring of performance and use, including preventive maintenance, care and repair; and (v) decommissioning.

The first two stages have been covered extensively in the publication *The Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories*.[1] In that Guide, WHO provided blood bank managers, procurement agencies and manufacturers with a description of, and minimum performance specifications for all the essential equipment needed for the efficient storage and transportation of blood and blood components. WHO plans to update this Guide in line with the improved pre-qualification process for immunization cold chain equipment.[2]

This new, complementary publication concentrates on the later stages of the life span. Detailed explanations, illustrations and standard operating procedures provide hospital administrators, managers, technicians and all users of blood cold chain equipment with information on how to receive, install, operate, maintain and monitor the equipment. Inspired by