

# Contents

Foreword . . . . .	13
European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) . . . . .	19
Members of the ad hoc group (GTS) . . . . .	27
Recommendation No. R (95) 15. . . . .	31
Good Practice Guidelines . . . . .	36
<b>Chapter 1 General notices</b>	
1.0. Overview . . . . .	115
1.1. Tasks and responsibilities of the GTS . . . . .	115
1.2. Structure and content of the <i>Guide</i> . . . . .	116
1.2.1. Good Practice Guidelines . . . . .	116
1.2.2. Standards . . . . .	117
1.2.3. Monographs . . . . .	118
1.2.4. Appendices . . . . .	118
1.2.5. Abbreviations. . . . .	118
1.2.6. References . . . . .	119
<b>Chapter 2 Donor selection</b>	
2.0. Overview . . . . .	120
2.1. Responsibilities of blood establishments in the selection process . . .	120

2.1.1.	Principle of voluntary non-remunerated donation . . . . .	120
2.1.2.	General requirements . . . . .	121
2.1.3.	Information to be provided to donors . . . . .	121
2.2.	Medical assessment of donors . . . . .	123
2.2.1.	Donor eligibility . . . . .	123
2.2.2.	Donor age. . . . .	124
2.2.3.	Donor haemoglobin . . . . .	125
2.2.4.	Iron stores . . . . .	126
2.2.5.	Questionnaire and interview. . . . .	127
2.3.	Donor deferral . . . . .	127
2.3.1.	General remarks . . . . .	127
2.3.2.	Non-infectious medical conditions . . . . .	128
2.3.3.	Infectious diseases . . . . .	131
2.3.4.	Interventions and treatments. . . . .	141
2.4.	Specific standards for donors of different types of components . . . . .	144
2.4.1.	Whole blood donation . . . . .	144
2.4.2.	Apheresis donation . . . . .	146
2.4.3.	Designated donations . . . . .	152
2.4.4.	Directed donations . . . . .	153
2.5.	Post-donation information . . . . .	153
2.5.0.	Overview . . . . .	153
2.5.1.	Donor instruction . . . . .	153
2.5.2.	Control procedures. . . . .	154

### Chapter 3 **Collection of blood and blood components**

3.0.	Overview . . . . .	155
3.1.	Documentation. . . . .	156
3.1.1.	General requirements . . . . .	156
3.2.	Premises for blood and blood component collection . . . . .	157
3.2.1.	General requirements . . . . .	157
3.3.	Procedures and equipment used during the collection of blood and blood components . . . . .	158
3.3.1.	General requirements . . . . .	158
3.4.	Pre-donation checks . . . . .	159

3.4.1. General requirements . . . . .	.160
3.5. Labelling. . . . .	.160
3.5.1. General requirements . . . . .	.160
3.6. Venepuncture, bleeding and mixing. . . . .	.161
3.6.1. General requirements . . . . .	.162
3.6.2. Venepuncture and mixing of donation during collection . . . . .	.162
3.7. Handling of filled blood bags and samples . . . . .	.164
3.7.1. General requirements . . . . .	.164
3.8. Special requirements for apheresis . . . . .	.165
3.8.1. General requirements . . . . .	.165
3.9. Repository of archive samples . . . . .	.166
3.9.1. General requirements . . . . .	.166
3.10. Management of adverse reactions in donors . . . . .	.166
3.10.1. General requirements . . . . .	.166
3.10.2. Prevention and treatment of adverse reactions in donors . . . . .	.167
3.10.3. Information for a donor with adverse reactions . . . . .	.167

## Chapter 4 **Processing, storage and distribution of blood components**

4.0. Overview . . . . .	.169
4.1. Processing. . . . .	.169
4.1.1. General considerations. . . . .	.169
4.1.2. Choice of bag system . . . . .	.170
4.1.3. Aspects of red cell preservation . . . . .	.172
4.1.4. Centrifugation of whole blood-derived blood components . . . . .	.173
4.1.5. Leucocyte depletion . . . . .	.174
4.1.6. Freezing and thawing of plasma for direct transfusion . . . . .	.175
4.1.7. Cryoprecipitation. . . . .	.176
4.1.8. Open and closed systems and sterile connection devices . . . . .	.176
4.1.9. Component labelling and information. . . . .	.177
4.1.10. Release of blood components. . . . .	.178
4.1.11. Component recall and traceability (see also Chapter 10) . . . . .	.180
4.2. Storage and distribution. . . . .	.181
4.2.1. General requirements . . . . .	.181

4.2.2.	Equipment . . . . .	183
4.2.3.	Storage of frozen plasma components . . . . .	184
4.2.4.	Storage of platelet components . . . . .	184
4.2.5.	Storage of red cell components . . . . .	185
4.2.6.	Storage of granulocyte preparations . . . . .	185
4.3.	Transportation of blood components . . . . .	186
4.3.1.	General requirements . . . . .	186
4.3.2.	Transport of red cell components . . . . .	187
4.3.3.	Transport of platelet components . . . . .	187
4.3.4.	Transport of frozen plasma components. . . . .	187
4.4.	Additional processes . . . . .	188
4.4.1.	Irradiation of cellular blood components . . . . .	188
4.4.2.	Bacterial safety . . . . .	189
4.4.3.	Prevention of cytomegalovirus transmission . . . . .	190
4.4.4.	Pathogen inactivation technologies . . . . .	191

## Chapter 5 **Blood component monographs**

5.0.	Overview . . . . .	195
Part A.	Whole blood components . . . . .	199
A-1.	Whole blood . . . . .	199
A-2.	Whole blood, Leucocyte-Depleted . . . . .	202
Part B.	Red cell components . . . . .	206
B-1.	Red Cells, Leucocyte-Depleted . . . . .	206
B-2.	Red Cells, Leucocyte-Depleted in Additive Solution . . . . .	207
B-3.	Red Cells . . . . .	209
B-4.	Red Cells, Buffy Coat Removed . . . . .	210
B-5.	Red Cells, in Additive Solution. . . . .	211
B-6.	Red Cells, Buffy Coat Removed, in Additive Solution . . . . .	212
B-7.	Red Cells, Apheresis . . . . .	214
B-8.	Red Cells, Washed . . . . .	215
B-9.	Red Cells, Cryopreserved. . . . .	217
Part C.	Platelet components . . . . .	223
C-1.	Platelets, Recovered, Single Unit, in Plasma . . . . .	223
C-2.	Platelets, Recovered, Pooled, in Plasma . . . . .	227

C-3.	Platelets, Recovered, Pooled, Leucocyte-Depleted, in Plasma . . . . .	.229
C-4.	Platelets, Recovered, Pooled, in Additive Solution and Plasma . . . . .	231
C-5.	Platelets, Recovered, Pooled, Leucocyte-Depleted, in Additive Solution and Plasma . . . . .	.232
C-6.	Platelets, Recovered, Pooled, Pathogen-Reduced . . . . .	.234
C-7.	Platelets, Apheresis . . . . .	.236
C-8.	Platelets, Apheresis, Leucocyte-Depleted . . . . .	.237
C-9.	Platelets, Apheresis, in Additive Solution . . . . .	.239
C-10.	Platelets, Apheresis, Leucocyte-Depleted, in Additive Solution . . . . .	240
C-11.	Platelets, Apheresis, Pathogen-Reduced . . . . .	242
C-12.	Platelets, washed . . . . .	244
C-13.	Platelets, Cryopreserved . . . . .	.245
Part D.	Plasma components . . . . .	.250
D-1.	Plasma, Fresh Frozen . . . . .	.250
D-2.	Plasma, Fresh Frozen, Pathogen-Reduced . . . . .	.254
D-3.	Cryoprecipitate . . . . .	.257
D-4.	Cryoprecipitate, Pathogen-Reduced . . . . .	.259
D-5.	Plasma, Fresh Frozen, Cryoprecipitate-Depleted . . . . .	.262
Part E.	White cell components. . . . .	264
E-1.	Granulocytes, Apheresis . . . . .	264
E-2.	Granulocytes, Pooled. . . . .	.267

**Chapter 6 Component monographs for intrauterine, neonatal and infant use**

6.0.	Overview . . . . .	.271
Part A.	Component monographs used for intrauterine transfusion . . . . .	.276
A-1.	Red Cells, Leucocyte-Depletedfor Intrauterine Transfusion . . . . .	.276
A-2.	Platelets, Leucocyte-Depletedfor Intrauterine Transfusion . . . . .	.278
Part B.	Component monographs used for neonatal exchange transfusion	280
B-1.	Whole Blood, Leucocyte-Depletedfor Exchange Transfusion . . . . .	280
B-2.	Whole Blood, Leucocyte-Depleted, Plasma Reduced for Exchange Transfusion. . . . .	.282
B-3.	Red Cells, Leucocyte-Depleted, suspended in Fresh Frozen Plasma, for Exchange Transfusion . . . . .	284

Part C. Component (small volume) monographs for neonatal and infant transfusion . . . . .	286
C-1. Red Cells for Neonatal and Infant Small-Volume Transfusion. . . . .	286

## Chapter 7 **Pre-deposit autologous donation**

7.0. Overview . . . . .	289
7.1. Selection of patients for PAD and blood collection . . . . .	290
7.1.1. Role of the physician in charge of the patient . . . . .	290
7.1.2. Role of the blood establishment physician . . . . .	290
7.1.3. Contraindications and deferral criteria for PAD. . . . .	291
7.1.4. Blood collection . . . . .	292
7.1.5. PAD in children . . . . .	293
7.2. Testing, processing, storage and distribution of PAD blood components . . . . .	293
7.2.1. Blood group testing and screening for infectious disease . . . . .	293
7.2.2. Processing . . . . .	293
7.2.3. Labelling . . . . .	294
7.2.4. Storage and handling. . . . .	294
7.3. Record keeping . . . . .	295
7.4. Audit. . . . .	295

## Chapter 8 **Immunohaematology**

8.0. Overview . . . . .	296
8.1. Requirements for samples. . . . .	297
8.1.1. Identity of donors and donations. . . . .	297
8.1.2. Identity of patients . . . . .	297
8.1.3. Sample handling, retention and storage . . . . .	297
8.2. Selection and validation of reagents and methods . . . . .	298
8.2.1. General requirements . . . . .	298
8.3. Quality control and quality assurance. . . . .	299
8.3.1. Quality control . . . . .	299
8.3.2. Internal quality control. . . . .	299
8.3.3. External quality assurance (proficiency testing). . . . .	300
8.4. Blood group testing . . . . .	300

8.4.1. General requirements . . . . .	300
8.4.2. Blood group testing of blood donors and donations . . . . .	301
8.4.3. Blood group testing of patients . . . . .	303
8.5. Pre-transfusion testing . . . . .	304
8.5.1. General requirements . . . . .	304
8.5.2. Type and screen procedure . . . . .	305
8.5.3. Electronic release . . . . .	306
8.5.4. Selection of red cells . . . . .	306
8.5.5. Additional considerations . . . . .	307

## Chapter 9 **Screening for markers of transfusion-transmissible infection**

9.0. Overview . . . . .	308
9.1. Selection and validation of infectious marker tests . . . . .	309
9.1.1. General requirements . . . . .	309
9.2. Requirements for samples . . . . .	311
9.2.1. Identity of donors and donations . . . . .	311
9.2.2. Sample handling, retention and storage . . . . .	311
9.3. Quality control and quality assurance . . . . .	312
9.3.1. Quality control . . . . .	312
9.4. Confirmatory testing, donor notification and lookback . . . . .	313
9.4.1. General requirements . . . . .	313
9.5. Classification of TTI testing . . . . .	314
9.5.1. Mandatory testing requirements . . . . .	314
9.5.2. Nucleic acid amplification techniques (NAT) . . . . .	315
9.5.3. Additional screening . . . . .	316
9.5.4. Selective screening . . . . .	318

## Chapter 10 **Haemovigilance**

10.0. Overview . . . . .	323
10.1. Pre-requisites for implementation of a haemovigilance system . . . . .	324
10.1.1. Traceability of blood components . . . . .	324
10.1.2. Confidentiality of haemovigilance data . . . . .	326

10.1.3. Co-operation between blood establishments, hospital blood banks and clinical departments . . . . .	326
10.2. Types of adverse reactions and adverse events collected in a haemovigilance system. . . . .	327
10.2.1. Adverse reactions in recipients . . . . .	327
10.2.2. Adverse reactions in donors . . . . .	328
10.2.3. Adverse events . . . . .	328
10.3. Device defects. . . . .	330
10.3.1. Reporting requirements . . . . .	330
10.4. Post-transfusion infection reported to the blood establishment . . .	330
10.4.1. General requirements . . . . .	330
10.4.2. Tracing of recipients of potentially infectious blood donations (look-back) . . . . .	332
10.5. Post-donation information . . . . .	332
10.6. Reporting haemovigilance data . . . . .	332
10.6.1. Standardisation of reporting . . . . .	332
10.6.2. Minimum information to be captured in the initial incident report at hospital level . . . . .	332
10.6.3. Component information . . . . .	333
10.6.4. Information about severity. . . . .	333
10.6.5. Information about imputability . . . . .	333

## Chapter 11 **Elements for a quality system on the clinical use of blood**

11.0. Overview . . . . .	335
11.1. Key measures for the safety of transfusion . . . . .	335
11.2. Decision to transfuse. . . . .	337
11.2.1. Documentation of the indication for transfusion . . . . .	337
11.2.2. Patient blood management. . . . .	339
11.2.3. Alternatives to the transfusion of allogeneous blood components . .	339
11.3. Completion of the transfusion request form, identification of patient and blood sampling . . . . .	342
11.3.1. General considerations. . . . .	342



---

11.4. Correct identification of the patient and obtaining a pre-transfusion sample . . . . .	343
11.4.1. Collection of samples. . . . .	343
11.4.2. Minimum requirements for identification . . . . .	343
11.5. Testing within the laboratory . . . . .	344
11.6. Selection and issue of appropriate blood components. . . . .	344
11.6.1. Minimum requirements . . . . .	344
11.7. Handling and storage of blood components in hospital clinical areas	345
11.7.1. Minimum requirements for systems and documentation . . . . .	345
11.7.2. Storage of blood components in hospital clinical areas . . . . .	345
11.8. Administration of blood components . . . . .	346
11.8.1. General considerations. . . . .	346
11.8.2. Administration of blood components . . . . .	347
11.9. Special precautions. . . . .	347
11.9.1. Warming of blood . . . . .	347
11.9.2. Addition of medicinal products or infusion . . . . .	348
11.10. Transfusion monitoring . . . . .	348
11.10.1. Observation of the patient . . . . .	348
11.10.2. Documentation. . . . .	348
11.11. Management and reporting of transfusion reactions . . . . .	349
11.12. Traceability and haemovigilance . . . . .	351
11.12.1. General considerations. . . . .	351
11.13. Hospital transfusion committees . . . . .	351
Appendix 1. Key criteria for donor eligibility . . . . .	353
Appendix 2. Tables for calculation of blood volumes or collection volumes. . . . .	371
Appendix 3. Data processing systems . . . . .	389
Functional testing of components. . . . .	392
Data migration. . . . .	392
Environmental testing . . . . .	392

Change control . . . . .	.393
Maintenance of the system . . . . .	.393
Quality assurance . . . . .	.394
General requirements. . . . .	.396
Signature manifestations . . . . .	.396
Signature/record linking . . . . .	.396
Controls for identification codes/passwords/biometrics . . . . .	.396
<b>Appendix 4. Statistical Process Control.</b> . . . . .	<b>.399</b>
Introduction . . . . .	400
Implementation of SPC. . . . .	400
Strategy for statistical sampling . . . . .	400
Tolerance of failure. . . . .	.401
Confidence level . . . . .	.401
Frequency of control sampling. . . . .	.401
Example 1. Use of control charts . . . . .	403
Example 2. Method of scan statistics. . . . .	407
Example 3. Statistical process control for dichotomous outcomes: an approach based upon hypergeometric/binomial distributions. . . . .	411
<b>Appendix 5. Health economics in blood transfusion . . . . .</b>	<b>.421</b>
Overview . . . . .	.422
Investing in quality . . . . .	.422
Costing analysis . . . . .	.423
Modelling cost-effectiveness analysis in transfusion . . . . .	.423
Economic aspects of the clinical use of blood . . . . .	424
Abbreviations. . . . .	.425
References . . . . .	.431