



GDBS

Global Database on Blood Safety



Report 2001–2002

Needs and challenges

The need for a safe and adequate blood supply is universal. In countries with developed health care systems, blood and blood products are primarily used to support advanced medical and surgical procedures, trauma care and the treatment of patients with conditions such as haematological disorders and leukaemia. The pattern of blood usage is different in countries where diagnostic facilities and treatment options are more limited, with a greater proportion of transfusions being prescribed for the treatment of complications during pregnancy and childbirth, severe childhood anaemia and trauma. In developing countries, maternal conditions are the third leading cause of deaths among women between 15 and 44 years (1). Obstetric haemorrhage is responsible for 25% of these deaths (2). Malaria, a major cause of life-threatening anaemia, is one of the main causes of mortality among children aged 0–4 with 8% of all deaths in that age-group (3). Globally, road traffic injuries are the second leading cause of death for both sexes aged 5–29 (4). The transfusion of blood is frequently central to the management of all these conditions.

Whatever the transfusion requirements of its patient population, every country has the same need to ensure:

- Availability of adequate supplies of blood and blood products and their accessibility to all patients requiring transfusion
- Safety of blood and blood products
- Safe and appropriate clinical use of blood and blood products.

The capacity of countries to respond effectively to these challenges tends to mirror the level of development of their health care systems. In high-income countries with well-structured health systems and blood transfusion services (BTSs), access to safe blood for all patients requiring transfusion is generally assured. In middle- and low-income countries, sophisticated health care provision may be available in capital cities and other major urban centres, but the majority of the population, particularly those in rural areas, often have access only to more limited health services. Transfusion is an essential component of treatment for many patients, but equitable access to safe blood is still not guaranteed. Blood component production is not widely practised in developing countries, resulting in inadequate provision of life-saving support for patients requiring blood component therapy.

The safety of blood and blood products remains a continuing cause for concern, particularly in developing countries. The transfusion of a unit of blood infected with HIV, hepatitis B (HBV), hepatitis C (HCV), syphilis, malaria or Chagas disease carries a high risk of transmission of infection to the recipient. Every new infection can, in turn, contribute to a widening pool of infection in the general population.

Recognition of the high risk of transmission of HIV through unsafe blood transfusions led to the introduction of blood safety interventions in the mid-1980s, with a particular focus on the testing of donated blood for HIV. Testing is essential but the first and most important line of defence is the collection of blood from the safest possible donors. Voluntary non-remunerated blood donors who give blood regularly are the lowest-risk donors because they are motivated solely by altruism and have no reason to conceal any reason why their blood may be unsafe.

Data on blood utilization are limited, but studies suggest that transfusions are often given unnecessarily when simpler, less expensive treatments can provide equal or greater benefit. Not only is this wasteful of a scarce resource, it also exposes patients unnecessarily to the risk of serious adverse transfusion reactions or transfusion-transmitted infections.

Strategy for blood safety

The WHO Blood Transfusion Safety unit has developed the following integrated strategy for the safety of blood transfusion which is described in the WHO Aide-Mémoire: *Blood Safety*. This strategy is recommended to national blood programmes.

Organization and management

The establishment of a well-organized, nationally coordinated blood transfusion service, integrated into the health care system, that can provide adequate and timely supplies of safe blood to meet the transfusion needs of the patient population. This requires firm government commitment and support, a specific and adequate budget for the BTS and the implementation of a national blood policy and plan supported by a legislative and regulatory framework.

Quality systems

The implementation of a quality system in the BTS covering all aspects of its activities, including organizational management, the development and implementation of quality standards, an effective documentation system, training of all staff and regular quality assessment.

Blood donors

The collection of blood only from voluntary non-remunerated blood donors from low-risk populations. This requires the establishment of an effective blood donor programme for the education, motivation and recruitment of voluntary blood donors, the use of stringent criteria for assessing the suitability of donors, safe blood collection procedures and high quality donor care to promote donor retention.

Testing

Quality-assured testing of all donated blood for transfusion-transmissible infections (TTIs), including HIV, HBV, HCV, syphilis and other infectious markers, where relevant, such as Chagas disease. WHO also recommends appropriate, accurate and controlled procedures for blood group serology and compatibility testing.

Appropriate clinical use of blood

A reduction in unnecessary transfusions through the use of blood only to treat conditions that might otherwise result in death or significant morbidity and that cannot be prevented or managed effectively by other means. WHO also promotes the use of appropriate blood component therapy and the safe administration of blood and blood products to minimize the risks associated with transfusion.

The elements of this strategy provide a framework for the collection of national data for the Global Database on Blood Safety.

Global Database on Blood Safety

In response to the need to address global concerns on blood safety and monitor the implementation of its strategy, WHO has established the Global Database on Blood Safety (GDBS), a mechanism for the collection of data from all its Member States. The objectives of the GDBS are to:

- Obtain the best available information on blood transfusion services in each Member State
- Assess the global situation on blood safety
- Monitor trends and progress
- Identify problems and needs in order to provide appropriate technical assistance
- Identify priority countries for support.

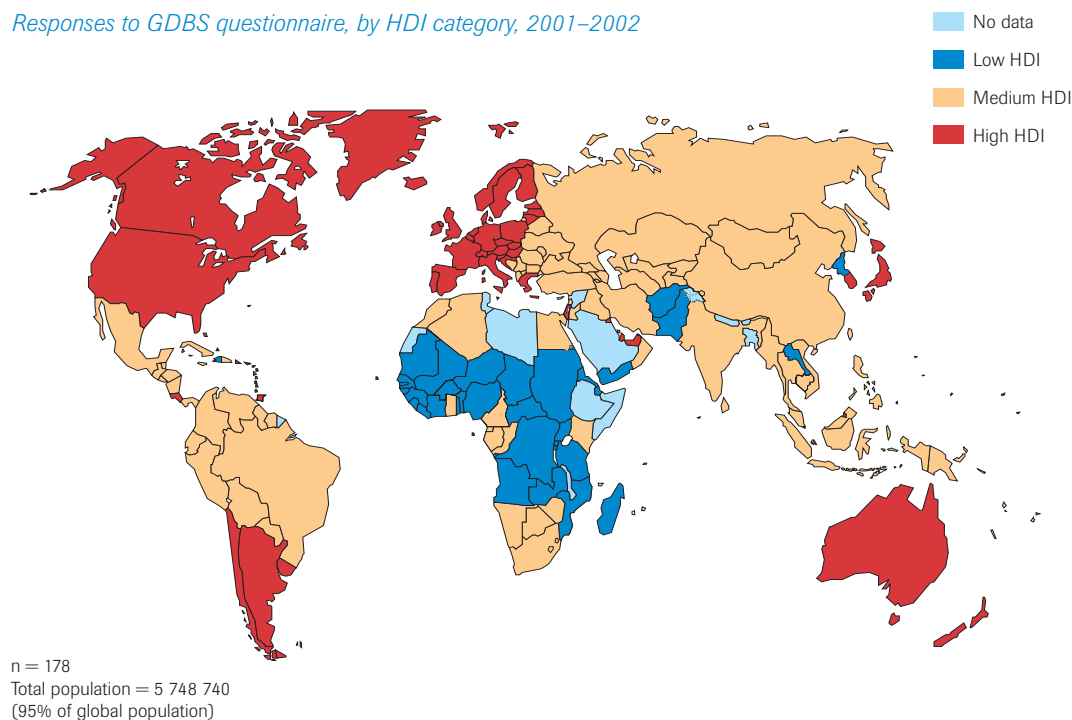
The first collection of data for the GDBS covered the period 1998–1999. A summary of the data analysis was provided in *Global Database on Blood Safety: Summary Report (1998–1999)*. In 2002, a revised questionnaire for data collection was distributed to all 191 Member States of WHO. Analysis of the data reported for a 12-month period in 2001–2002 shows that tangible progress has been made in many countries in strengthening systems to ensure the safety of blood transfusion.

Data collection and analysis

Data for 2001–2002 were obtained from 178 out of the 191 Member States, including one Associate Member (93% of Member States representing 95% of the world's population), and were analysed on a global and regional basis (Map 1).

Map 1 |

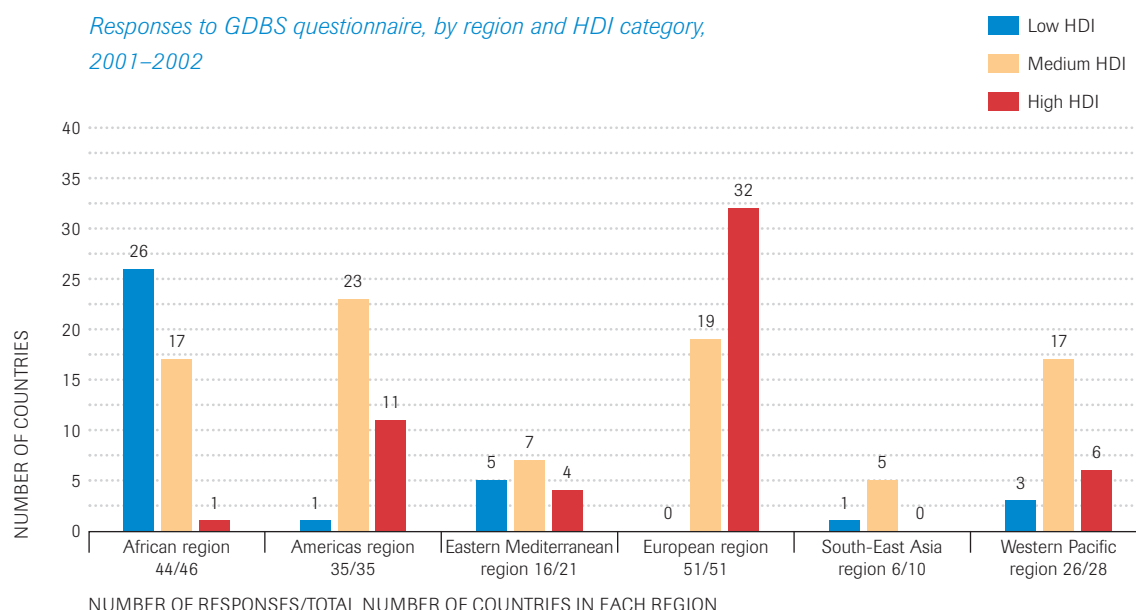
Responses to GDBS questionnaire, by HDI category, 2001–2002



As in the previous survey, the Human Development Index (HDI)(5)¹, developed by the United Nations Development Programme (UNDP), was used to provide a common factor to enable meaningful comparative analysis of data. The Index classifies countries as having a low (less than 0.500), medium (0.500–0.799) or high (0.800 or above) HDI, based on life expectancy, educational attainment and adjusted income. Of the 178 countries that provided data, 36 were classified as having a low HDI, 88 had a medium HDI and 54 had a high HDI (Figure 1).

Figure 1 |

Responses to GDBS questionnaire, by region and HDI category, 2001–2002



For the purposes of comparison, GDBS data collected for the period 1998–1999 have been cited in certain sections of the report. Data for 1998–1999 were obtained from 175 of 191 Member States. Out of these 175 countries, 41 were classified as having a low HDI, 89 had a medium HDI and 45 had a high HDI.

Provision of national data

In 1998–1999, 134 (78%) countries reported national data on blood transfusion services; the remainder were able to provide data only from selected centres in the main cities. This improved slightly to 142 (80%) countries in 2001–2002.

¹ The HDI classification published in Human Development Report 2002: *Deepening democracy in a fragmented world* (UNDP, 2002) was used for the analysis of 2001–2002 GDBS data. However, the Human Development Index has not been established for all Member States of the United Nations and, correspondingly, of WHO. Fourteen of the countries that reported data for 2001–2002 did not have an HDI classification in 2002. Based on data from other available indexes, a *provisional* HDI was therefore assigned to these countries for the sole purpose of the standardization of data analysis for the GDBS. This provisional HDI does not represent any comment on their human development status. The HDI classification of seven countries (4%) had changed since 2000, the year that was used in the analysis of GDBS data for 1998–1999: five countries moved from the medium to high HDI category and two countries moved from the medium to low HDI category.

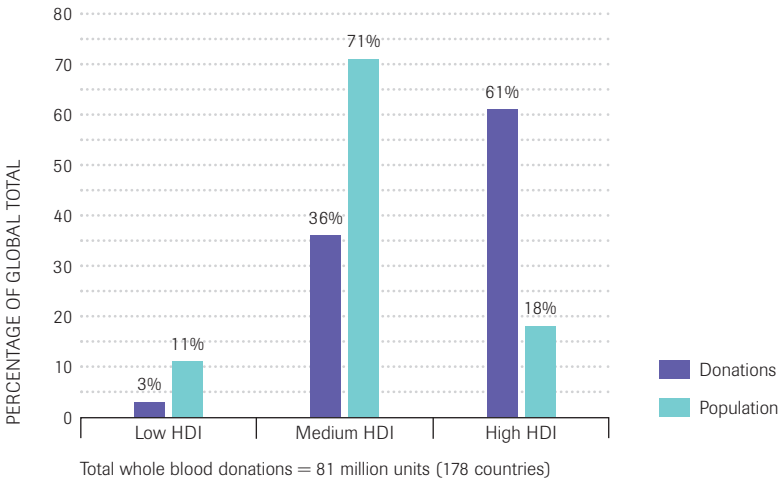
Key observations

Access to safe blood

Data from 178 countries indicate that about 81 million units of whole blood and 20 million litres of plasma were donated annually in the period 2001–2002. Analysis of blood donations versus the HDI of countries reveals a significant difference in blood donations between low, medium and high HDI countries; 61% of the global blood supply was donated in developed (high HDI) countries. Only 39% was donated in developing (low and medium HDI) countries where 82% of the world’s population lives (Figure 2). Differences in blood donation rates largely reflect differences in the level of development of health care systems in these countries.

Figure 2 |

Global population and whole blood donations, by HDI category



The blood donation rate in developing countries did not show any major trends in improvement since 1998–1999 and remained well below that of developed countries. The average number of donations per 1000 population was three times higher in medium HDI countries and 12 times higher in high HDI countries than in countries with a low HDI (Table 1).

Table 1 |

Whole blood donations, by HDI category

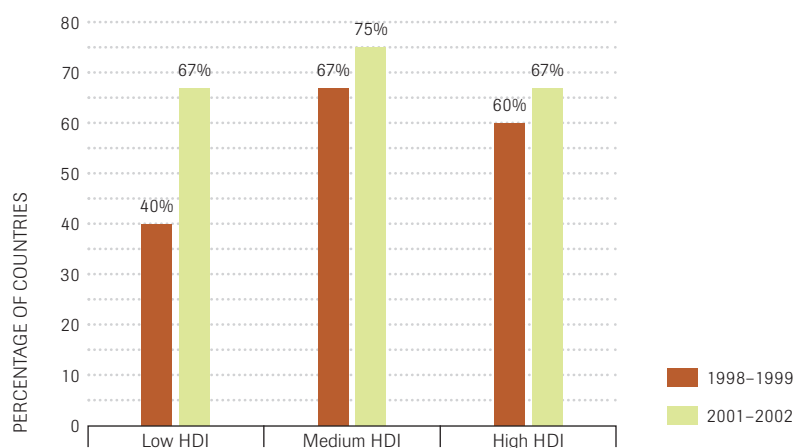
		Low HDI countries				Medium HDI countries				High HDI countries			
		1998–1999 (n = 41)		2001–2002 (n = 36)		1998–1999 (n = 89)		2001–2002 (n = 88)		1998–1999 (n = 45)		2001–2002 (n = 54)	
Donations, in millions and percentage		1.3m	1.7%	2.3m	2.9%	28.9m	38.5%	29.4m	36.2%	44.9m	59.8%	49.4m	60.9%
	Estimated blood donation rates per 1000 population	Average	2.0	Average	3.3	Average	10.0	Average	10.6	Average	40.0	Average	40.0
		Range	0.3–5.3	Range	0.1–17.2	Range	0.7–50.3	Range	1.0–51.6	Range	0.4–74.0	Range	7.4–75.5

Organization and management of blood transfusion services

The total number of countries with one specific organization responsible for blood transfusion services increased from 105 (60%) in 1998–1999 to 126 (71%) in 2001–2002. Figure 3 shows the increase in the percentage of countries with one specific organization responsible for blood transfusion services, by HDI category.

A concurrent increase from 55 (31%) to 97 (54%) was reported in the number of countries in which government has sole responsibility for the blood programme. This was largely attributable to improved government commitment and support for national blood programmes at country level.

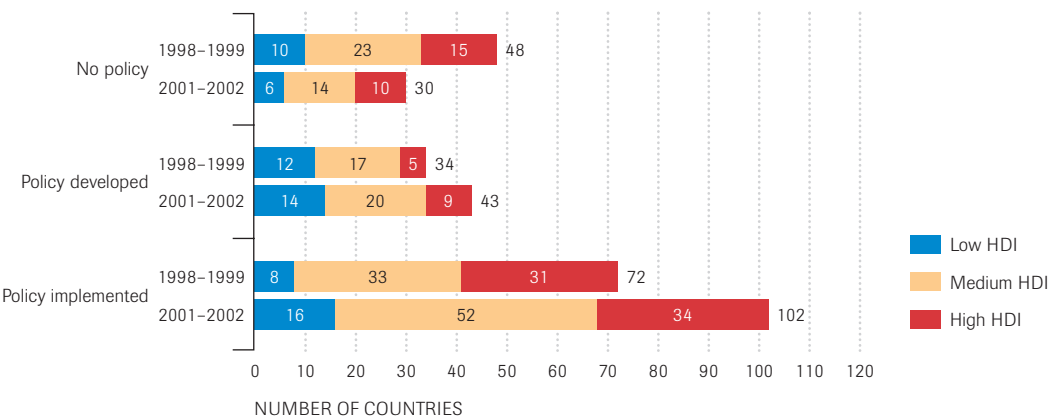
Figure 3 | *Countries with one specific organization responsible for blood transfusion services, by HDI category*



National blood policy

In 1998–1999, a total of 106 countries reported that a national blood policy had been developed or implemented, and 48 reported no national blood policy. In comparison, in 2001–2002, 145 countries reported that a national blood policy had been developed or implemented. Of these, 43 countries had either developed or were in the process of developing a national blood policy and the other 102 reported having implemented the national blood policy, as shown in Figure 4. This represents an overall increase of 37% in the number of countries that had either developed or implemented a national blood policy. Comparative analysis shows that of the 48 countries that lacked a national blood policy in 1998–1999, 18 countries had developed a policy by 2001–2002.

Figure 4 | *Development and implementation of national blood policies, by HDI category*



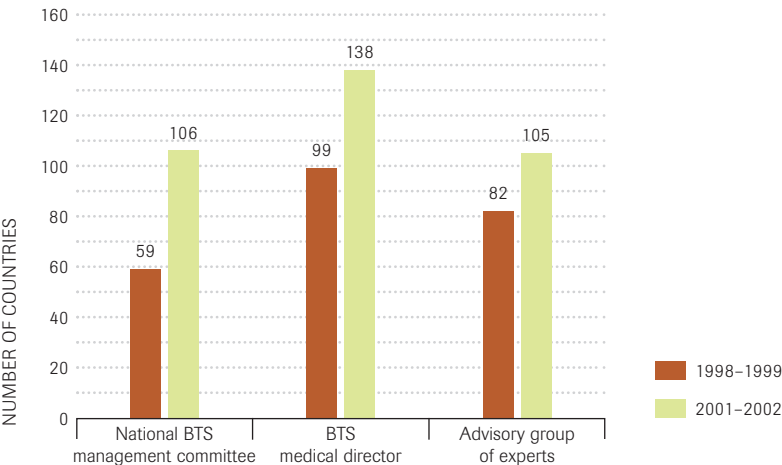
Legislative framework

The number of countries that reported the establishment of a legislative framework for the national blood programme increased from 103 (59%) countries in 1998-1999 to 122 (69%) countries in 2001-2002. However, the 2001-2002 questionnaire addressed the issue of legislation and regulation in greater depth than the previous questionnaire. Of the 122 countries that reported, only 83 had a national authority responsible for the regulation of blood transfusion services and, of these, only 29 provided the name of the regulatory authority.

Management of blood transfusion services

Figure 5 shows an obvious trend in improvement in relation to three important elements of the management of blood transfusion services: a national BTS management committee, a designated medical director of the BTS and an advisory group of blood transfusion experts.

Figure 5 | *Management of blood transfusion services*



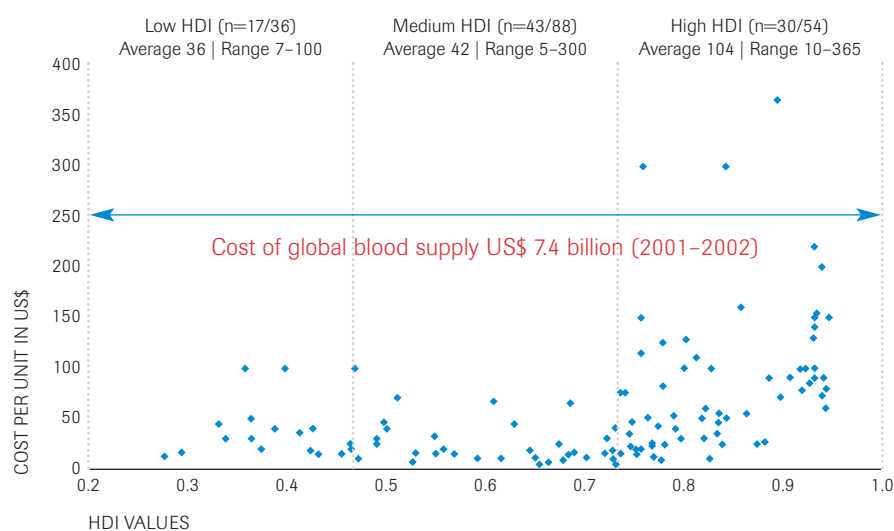
Costing blood transfusion services

A marked improvement was observed in the number of countries in which a specific budget was allocated for blood transfusion services, with an increase from 81 (47%) countries in 1998–1999 to 117 (66%) countries in 2001–2002. In addition, 115 (65%) countries, compared with 70 (40%) countries in 1998–1999, reported that mechanisms for costing blood transfusion services had been fully implemented (88 countries) or partially implemented (27 countries). However, figures given by some countries for the cost of producing a unit of blood suggested that costing procedures may have been inadequate. One country, for instance, reported the unit cost of production of a unit of blood as US\$ 0.47, although this figure most likely represented the cost of an HIV test. Another country reported a very high cost that was inconsistent with the level of sophistication of blood testing and processing in that country; the high cost may also have been attributable to the fragmentation of services in that country.

From the data provided by individual countries on the cost of a unit of blood, the total annual cost of the global blood supply was estimated to be at least US\$ 7.4 billion in 2001–2002; however, this is almost certainly an underestimate since complete data on costs were provided only by 122 countries with a total production of 72.5 million units of blood. There was a general trend of higher costs in relation to higher HDI values (Figure 6). Figures were provided by each country and are quoted in US dollars. No adjustment was made for purchasing power parity due to a disparity in the methods used by countries in costing the production of a unit of blood and differences in the proportion of traded factors to local factors in the distribution of costs in blood transfusion services.

Figure 6 |

Cost of producing a unit of blood (2001–2002), by HDI category

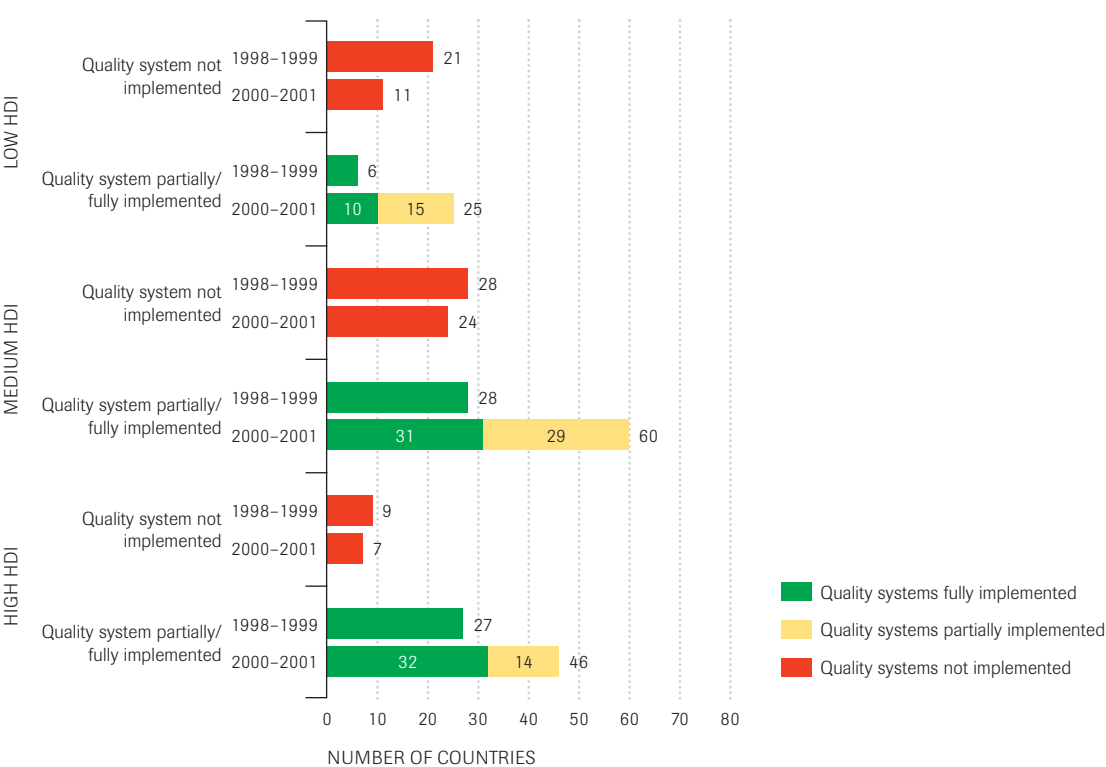


Little change was reported in the establishment of stock control systems for general supplies, with 105 countries reporting that a system was in place. Of these, 17 countries indicated that their systems were only partially implemented. Seventy-two countries reported interruptions to the availability of general supplies, including those indicating that a stock control system was "partially" in place, which could have a direct impact on the quality of blood transfusion services.

Quality systems

In 1998–1999, only 61 (35%) countries reported that a national quality system for the BTS was in place. By 2001–2002, the number of countries with a fully implemented national quality system increased to 73 (41%) countries and an additional 58 (33%) countries reported that they were in the process of implementing a quality system (Figure 7). However, 42 countries did not indicate any progress towards the implementation of a quality system.

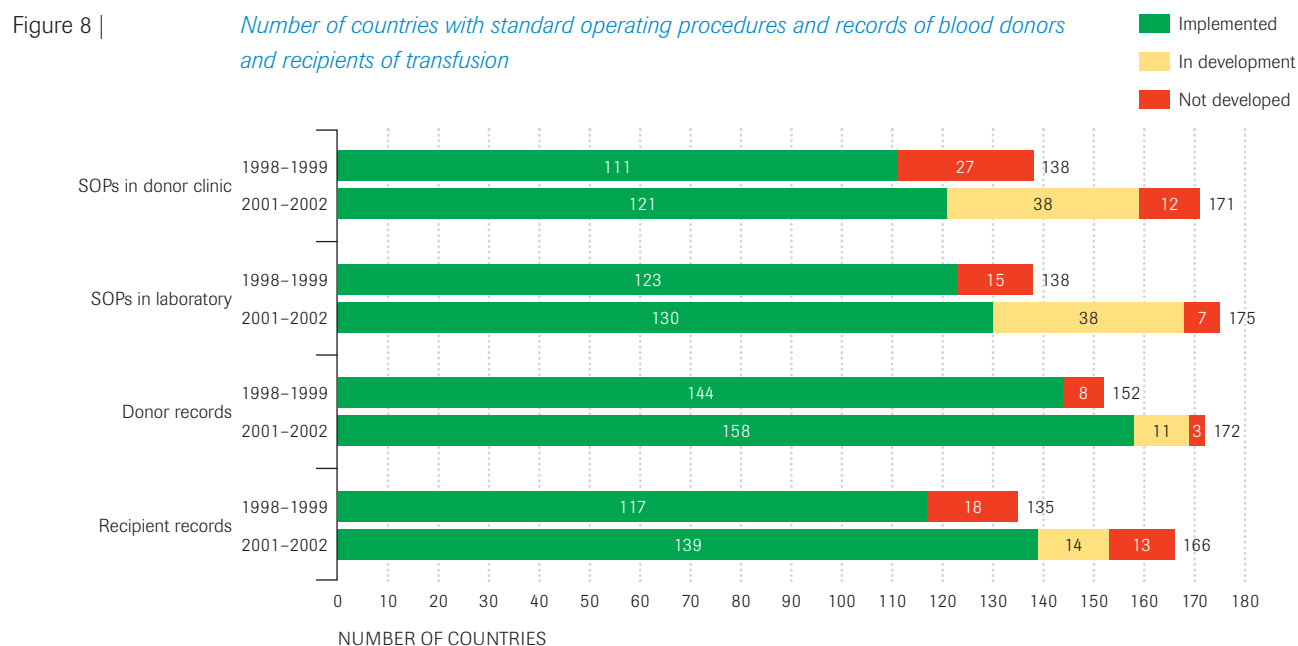
Figure 7 | *National quality systems for blood transfusion services, by HDI category*



The number of countries that reported the designation of a national quality officer increased from 87 (50%) in 1998–1999 to 118 (66%) in 2001–2002. An additional 23 (13%) countries reported that the designation or appointment of a national quality officer was in progress.

Documentation

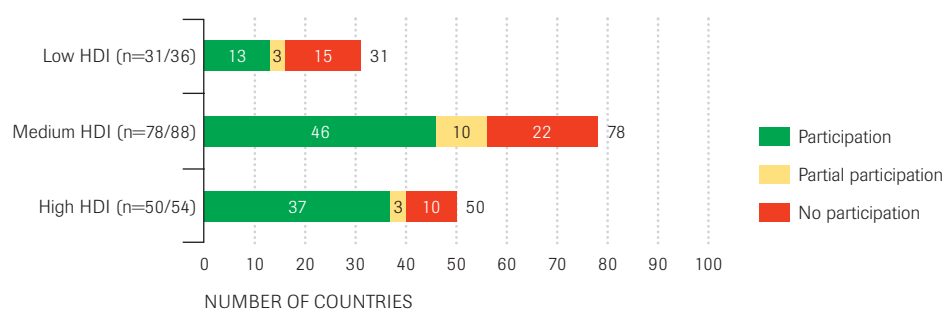
Slight improvements in documentation were evident by the increased use of standard operating procedures (SOPs) in two of the main areas of blood transfusion services: blood donor clinics (121 countries compared to 111 countries in 1998–1999) and laboratories (130 countries compared to 123 countries in 1998–1999). Thirty-eight countries indicated that SOPs were still being developed in these two areas. In addition, an increased number of countries reported a system of blood donor records (169 countries compared with 144 countries in 1998–1999) and 153 countries reported maintaining records of recipients of blood and blood products compared with 117 countries in 1998–1999 (Figure 8).



External quality assessment

Only 96 (60%) of the respondent countries reported that their BTSs participated in a national external quality assessment (EQA) scheme in testing for transfusion-transmissible infections and/or blood group serology (Figure 9). The data also indicated that another 16 countries had external quality assessment (EQA) schemes at provincial/local level; however there were no EQA schemes in 47 countries.

Figure 9 | *Participation in EQA schemes at national level, by HDI category*



Training

GDBS data indicate that opportunities for in-service training of staff responsible for key areas of work in the BTS were not always available in medium HDI countries and, in particular, low HDI countries in 2001–2002 (Figure 10). Less than 50% of countries had formal training for all categories of staff (Figure 11a and 11b). Figure 12 shows the extent to which no training of any type was available for different categories of BTS staff.

Figure 10 | *Provision of in-service training for staff involved in the transfusion process, by HDI category*

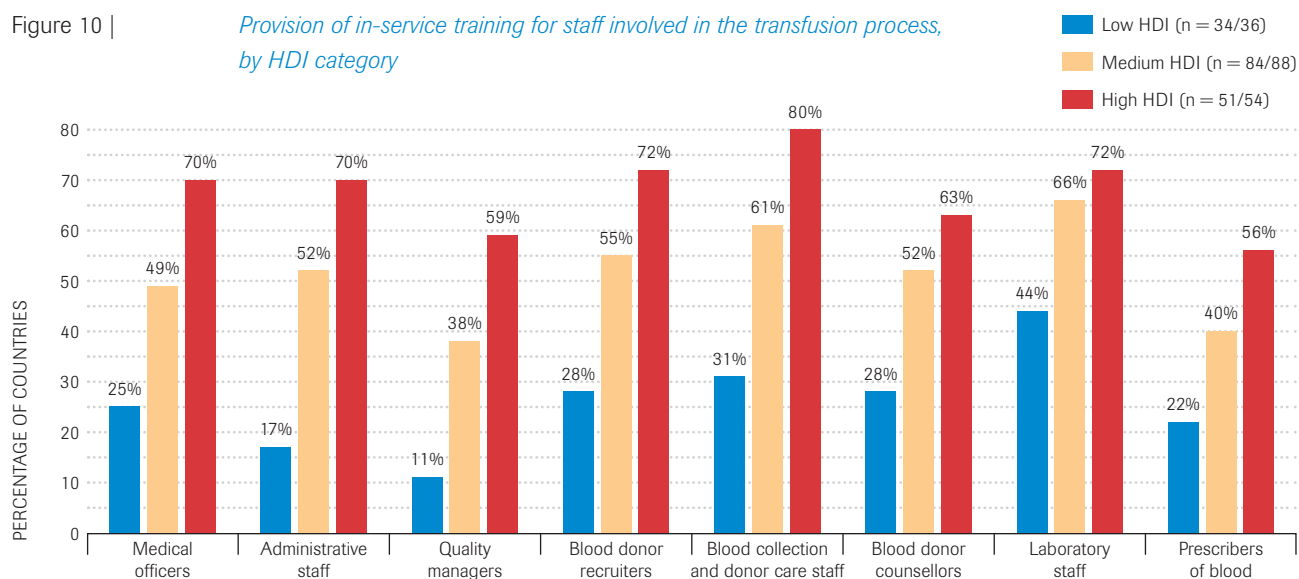


Figure 11a | *Availability of formal education courses for different staff involved in the transfusion process, by HDI category*

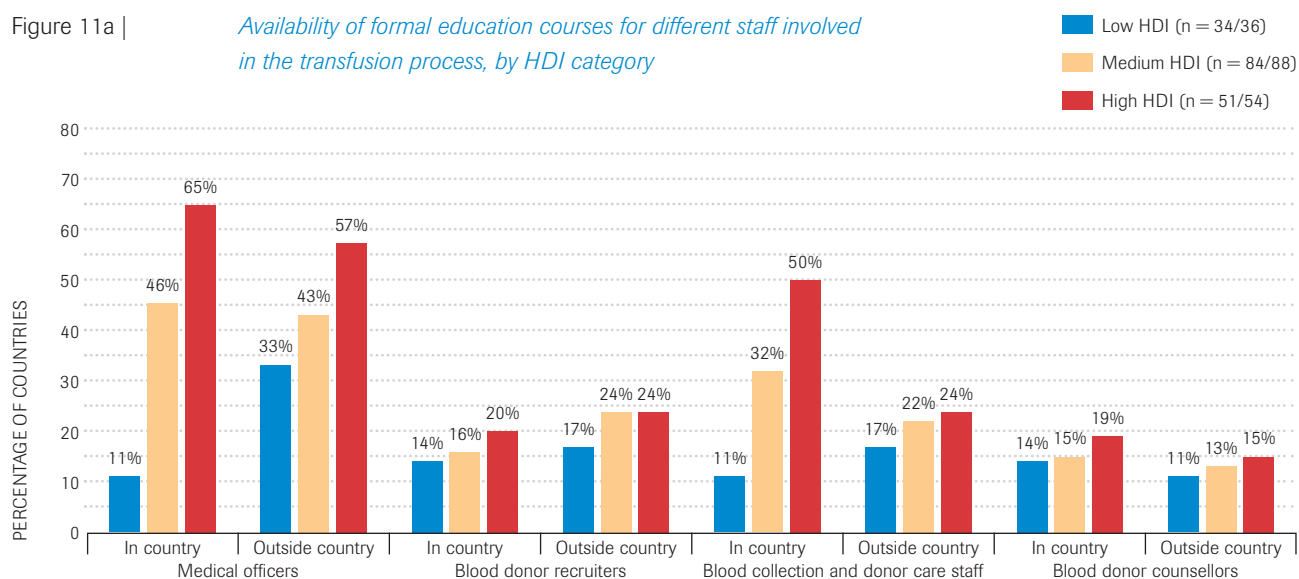


Figure 11b | *Availability of formal education courses for different staff involved in the transfusion process, by HDI category*

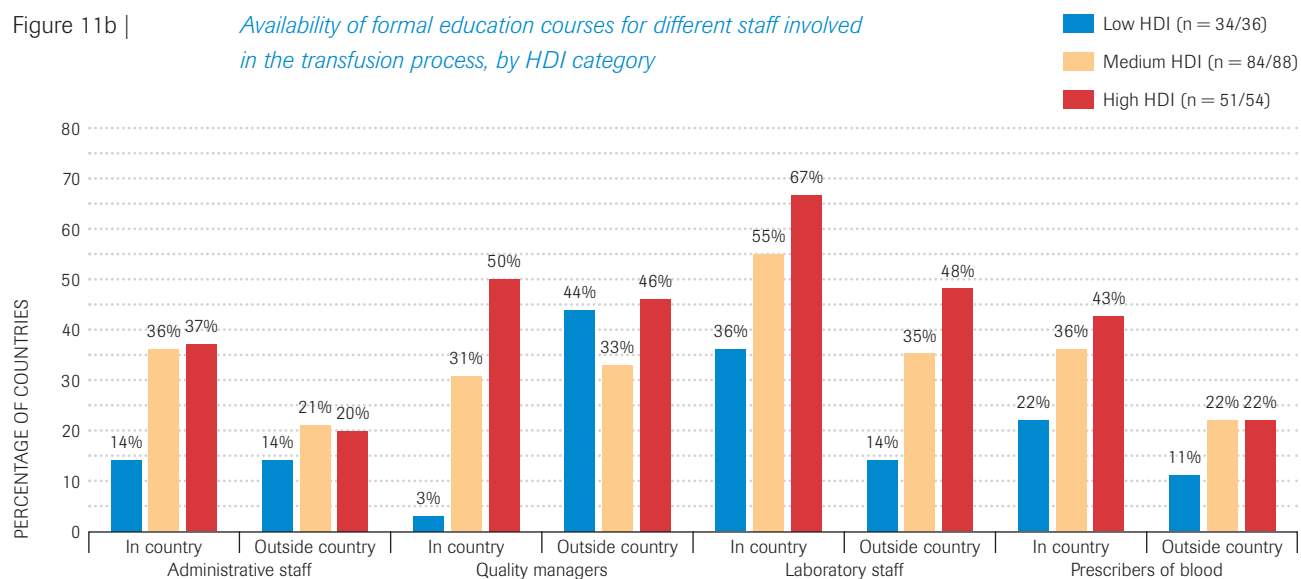
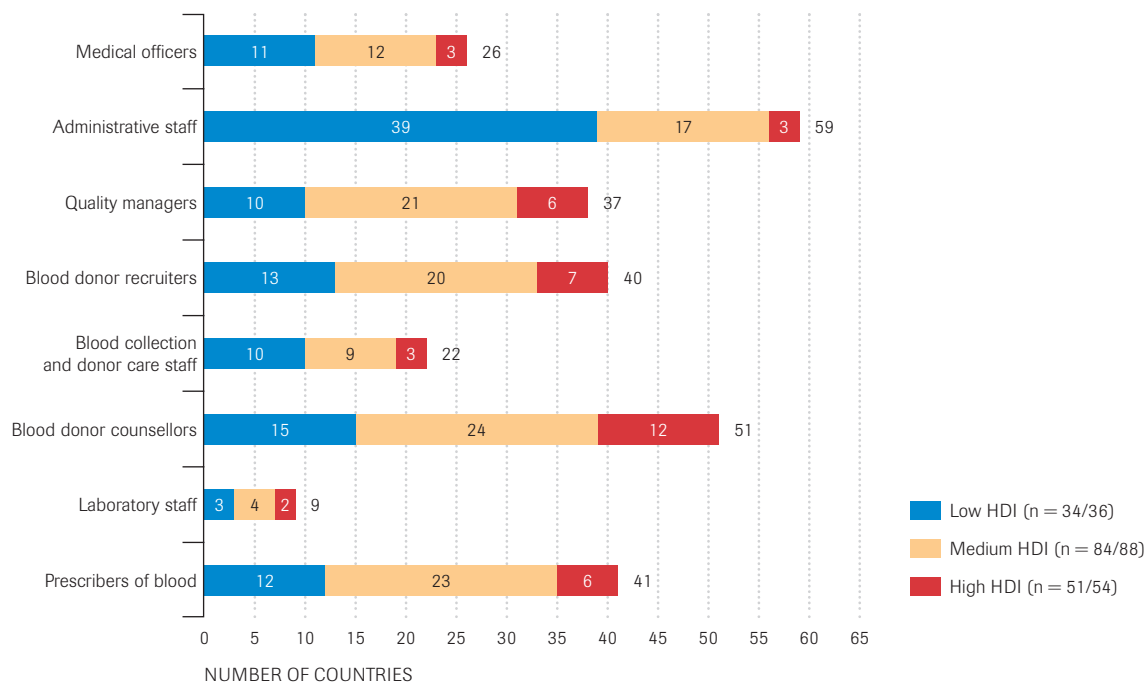


Figure 12 | *Number of countries with no training available for different staff involved in the transfusion process, by HDI category*



Blood donors

- **Low and medium HDI countries contribute only 25% of the total donations collected globally from voluntary non-remunerated blood donors**
- **94% of donations in high HDI countries are from voluntary non-remunerated blood donors**
- **Only 39 countries had achieved 100% voluntary non-remunerated blood donation.**

Voluntary non-remunerated blood donation

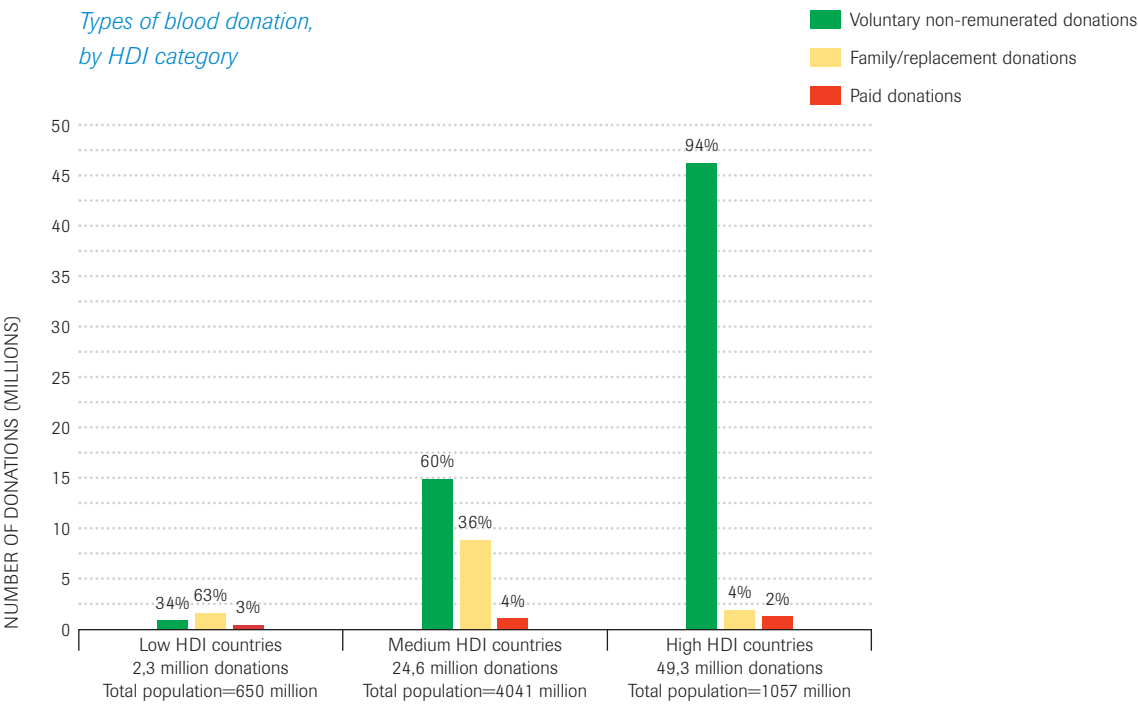
Data for 2001–2002 show an increase in the percentage and absolute number of donations obtained from voluntary non-remunerated blood donors, with a concurrent decrease in paid donation in medium and low HDI countries, as shown in Table 2. Nevertheless, family/replacement donors still remain a significant source of blood for transfusion in low HDI and medium HDI countries (Figure 13 and Map 2). Out of the 62 million units given by voluntary non-remunerated blood donors, only 25% were collected in developing countries.

Table 2 | *Types of whole blood donation, by number and percentage and by HDI category*

	Low HDI countries				Medium HDI countries				High HDI countries			
	1998–1999 n = 41		2001–2002 n = 36		1998–1999 n = 89		2001–2002 n = 88		1998–1999 n = 45		2001–2002 n = 54	
Voluntary non-remunerated donations	0.4 m	31%	0.8 m	34%	11.6 m	40%	14.8 m	60%	43.9 m	98%	46.3 m	94%
Family/replacement donations	0.8 m	61%	1.5 m	63%	11.7 m	41%	8.8 m	36%	1.0 m	2%	1.8 m	4%
Paid donations	0.1 m	8%	0.07 m	3%	5.6 m	19%	1.0 m	4%	0.03 m	<0.07	1.2 m	2%
Total*	1.3 m	100%	2.37 m	100%	28.9 m	100%	24.6 m	100%	44.93 m	100%	49.3 m	100%

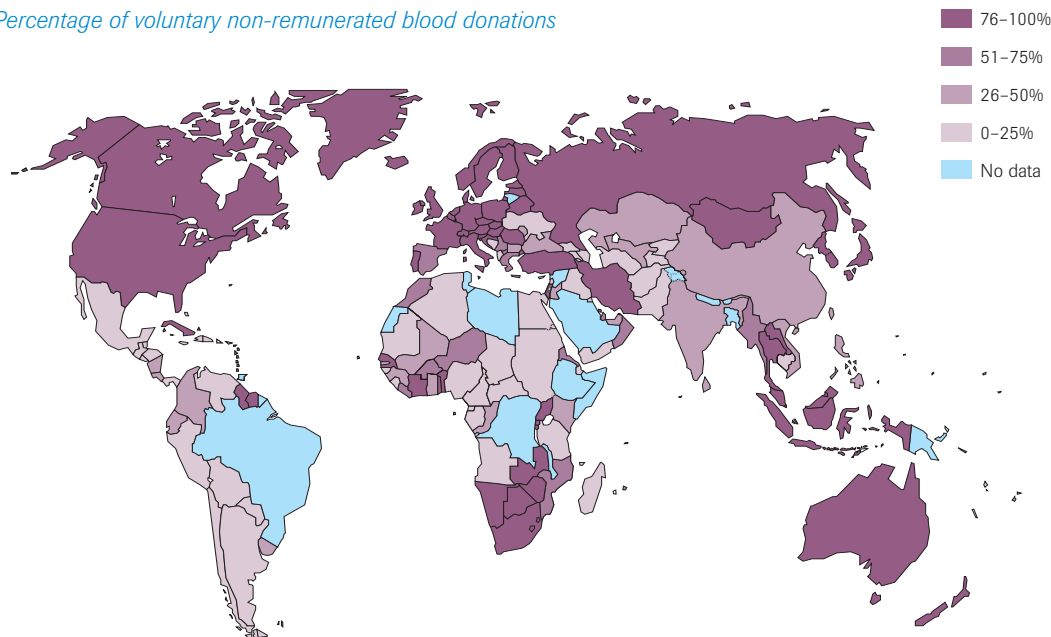
* Full data available for only 76.3 million units

Figure 13 | *Types of blood donation, by HDI category*



Map 2 |

Percentage of voluntary non-remunerated blood donations

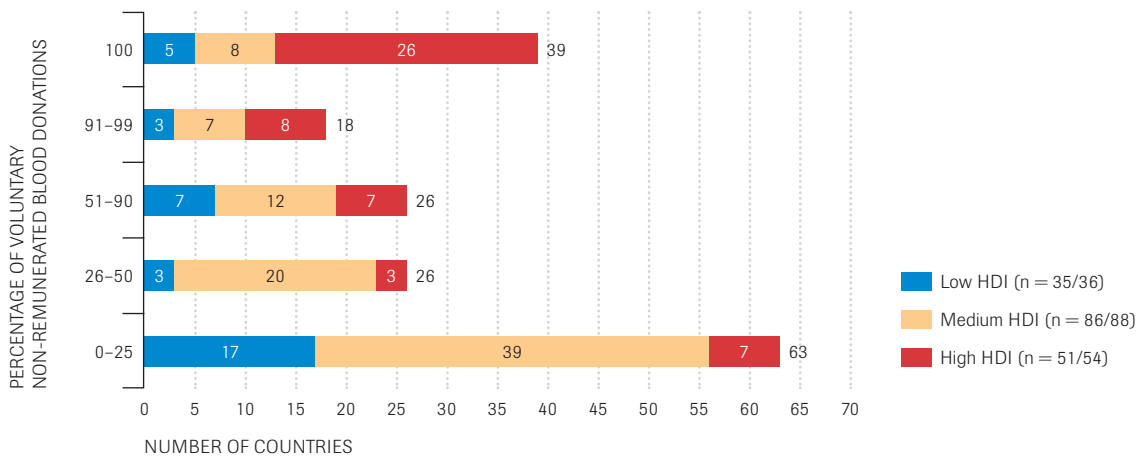


The increase in paid donation in high HDI countries is largely attributable to a change in policy on voluntary blood donation by a single European country.

Reports to the GDBS indicated that 39 (22%) countries had achieved 100% voluntary non-remunerated blood donation in 2001–2002 (Figure 14), compared with 36 (21%) countries in 1998–1999. However, further comparative analysis revealed that only 32 countries reported 100% voluntary non-remunerated blood donation in both 1998–1999 and 2001–2002. By 2001–2002, therefore, four countries had been unable to maintain 100% voluntary non-remunerated donation, while an additional five countries had achieved this target.

Figure 14 |

Countries with 100% voluntary non-remunerated blood donation, by HDI category

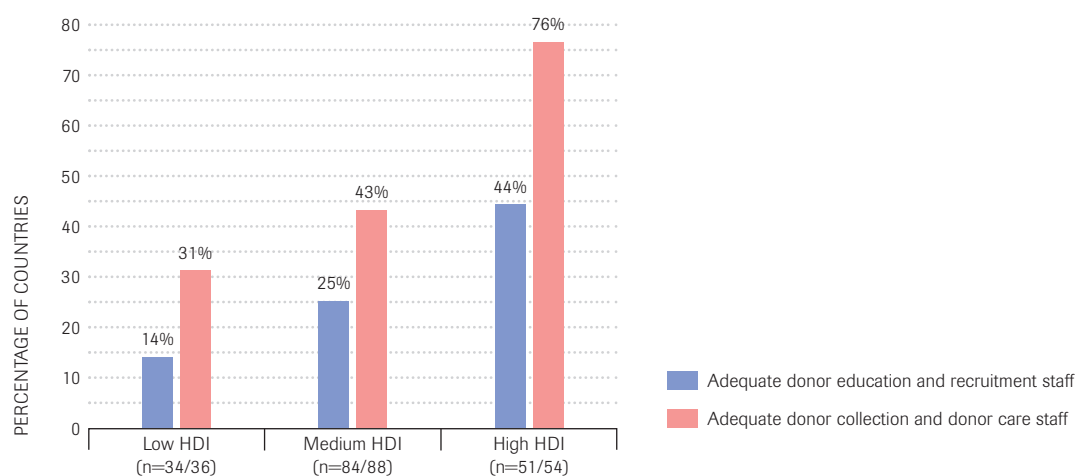


Seventy-two countries reported an increase in the percentage of voluntary non-remunerated blood donations from 1998–1999 to 2001–2002. More significantly, 26 of these countries reported that over two-thirds of donations were given by voluntary, non-remunerated blood donors. The data also showed that the percentage of voluntary non-remunerated blood donations decreased in 39 countries from 1998–1999 to 2001–2002; no correlation with HDI or known civil strife could be established.

Blood donor programme

In 2001–2002, 116 (65%) countries reported having a separate department or section responsible for all activities related to blood donation compared with 104 countries (60%) in 1998–1999. There was a small increase from 98 to 104 in the number of countries that reported that a blood donor recruitment officer was in place, with an additional 31 countries reporting limited staffing for donor recruitment activities. Only 51 (29%) countries reported an adequate number of trained staff for blood donor education and recruitment and 90 (51%) countries reported an adequate number of trained staff for blood collection and donor care. The situation is critical in low and medium HDI countries; less than 50% of countries have adequate staff for donor education and recruitment or for blood collection and donor care, as shown in Figure 15.

Figure 15 | *Adequacy of number of donor staff, by HDI category*



The negative impact of a lack of trained staff combined with poor donor recruitment strategies is clearly demonstrated by the low number of voluntary non-remunerated blood donors in low and medium HDI countries and the low proportion of those who donated blood regularly (at least two donations per annum). Available data indicate that of the 37.6 million units of blood collected globally from regular voluntary non-remunerated blood donors, 33.5 million (89%) were collected in high HDI countries. Seventy-one countries (40%) reported that they had no regular voluntary non-remunerated blood donors.

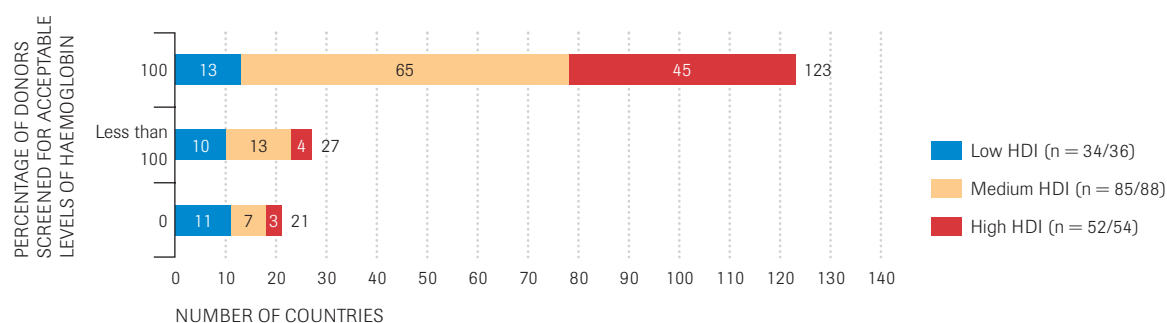
The establishment of a register or database of voluntary non-remunerated blood donors is reported by 122 countries (69%). One of the main reasons for maintaining a donor database is to ensure a mechanism for the recall and retention of donors; however, the number of countries that reported a donor register or database did not correlate well with the low percentage of regular donors in low and medium HDI countries and the small number of countries that reported that they had regular blood donors. Of the 122 countries with a donor register or database, only 37 had a computerized system in all blood centres to link the donor and each donation of blood.

Blood donor selection and counselling

There was an increase from 77 (45%) to 93 (52%) in the number of countries that reported the availability of donor information and education materials to encourage self-deferral by unsuitable donors. Similar improvements were reported in all three HDI categories. The number of countries that reported the use of criteria for assessing the suitability of blood donors increased from 134 (78%) countries in 1998–1999 to 153 (86%) countries in 2001–2002. There was an increase from 109 (63%) to 155 (87%) countries that reported that a blood donor counselling system was being implemented. The system was fully implemented in 104 countries and partially implemented in 51 countries.

A question on the use of haemoglobin estimation, as part of the process for assessing the suitability of donors, was included for the first time in 2001–2002; 123 (69%) countries reported that all donors are screened for acceptable levels of haemoglobin each time of blood donation (Figure 16). No response was received from seven countries.

Figure 16 | *Haemoglobin screening as part of the process for assessing the suitability of blood donors, by HDI category*



Testing and processing

Screening of donated blood for transfusion-transmissible infections

GDBS data from 1998–1999 indicated that, globally, 13 million tests were not performed for HIV, HBV, HCV and syphilis. Data for 2001–2002 indicated an improvement in the number of tests performed for markers of these infections, largely due to a number of countries having introduced HCV testing since the previous collection of data (Table 3).

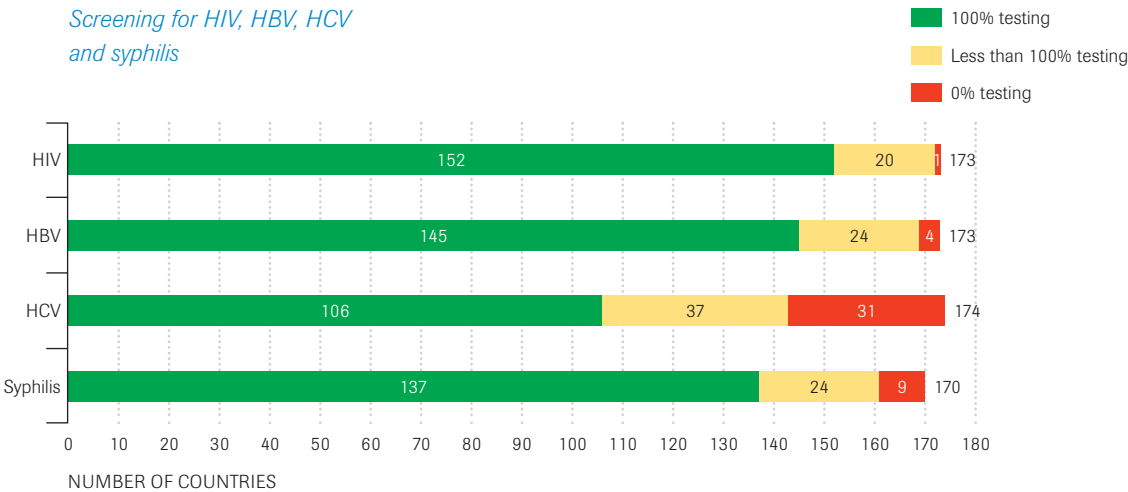
Globally, the number of tests not performed for the markers for four main infections (HIV, HBV, HCV, syphilis) decreased from 13 million in 1998–1999 to 6 million in 2001–2002.

Table 3 | *Number of blood units screened for HIV, HBV, HCV and syphilis, by HDI category*

Number of blood units to be tested	Low HDI			Medium HDI			High HDI		
	2 326 354			29 428 212			49 380 110		
	Screened	Unscreened	Unknown	Screened	Unscreened	Unknown	Screened	Unscreened	Unknown
HIV	91.9%	6.9%	1.2%	98.5%	0.5%	1.0%	99.9%	0.1%	n/a
HBV	92.5%	6.3%	1.2%	98.3%	0.7%	1.0%	99.9%	0.1%	n/a
HCV	51.3%	47.5%	1.2%	96.3%	2.7%	1.0%	99.9%	0.1%	n/a
Syphilis	34.1%	61.2%	4.7%	97.2%	1.8%	1.0%	98.7%	1.3%	n/a

Figure 17 shows the number of countries that reported 100% testing, less than 100% testing and no testing for markers of each of the four infections.

Figure 17 | *Screening for HIV, HBV, HCV and syphilis*



Although the majority of donated units of blood were reportedly screened for at least one of these infections, 39 (22%) countries reported the issue of blood without screening during the period 2001–2002 due to the non-availability of test kits and/or reagents (low HDI: 8, medium HDI: 26 and high HDI: 5).

An analysis of the technology used for HIV tests indicates that simple/rapid tests were most widely used in low HDI countries, despite the generally higher cost per test than for EIA technology. This could be attributable to the fragmentation of blood transfusion services.

Prevalence of transfusion-transmissible infections among blood donors

A marked improvement was reported in the number of countries in which the prevalence of transfusion-transmissible infections (TTIs) was monitored in the blood donor population. This increased from 93 (54%) countries in 1998–1999 to 123 (69%) countries in 2001–2002. Partial implementation of a system for monitoring TTIs in the donor population was reported in an additional 21 countries (12%).

The analysis of the reported prevalence (%) of HIV, hepatitis B, hepatitis C and syphilis in blood donors is summarized in Table 4. Since some respondent countries did not provide complete information, analysis of new and regular donations was possible for only 96 countries (24 low HDI, 41 medium HDI and 31 high HDI countries). Even where these data were provided, some countries reported only partial data on prevalence rates for markers of each of the four infections: HIV, HBV, HCV and syphilis. The overall percentage for each of the HDI categories where data were valid for analysis is shown in brackets.

As shown in Table 4, the reported prevalence of all four infections is generally higher in low and medium HDI countries. Family/replacement or paid donations are estimated to comprise 43% of the total donations from new donors in the low and medium HDI countries that provided data. GDBS data on regular blood donors relate only to voluntary non-remunerated blood donors.

Table 4 | *Prevalence of four TTI infections in blood donors, by HDI category*

		HIV		HBV		HCV		Syphilis	
		DONORS							
		New	Regular	New	Regular	New	Regular	New	Regular
% data complete	Low HDI	0.95	0.72	4.78	2.03	3.89	1.54	2.78	2.77
	Range	0.02–14	0–6	0.1–21	0–9.6	0.2–9.22	0–2.72	0.1–12.7	0–4
	Median	2.8	0.2	9.81	0.4	2.8	0.5	2	0.04
		(96.2)	(28.7)	(96.2)	(27.1)	(89.9)	(14.7)	(15.4)	(28.7)
% data complete	Medium HDI	0.36	0.074	3.35	0.42	1.49	0.21	0.49	0.31
	Range	0–9	0–2.5	0–15	0–15	0–13.1	0–10	0–10	0–2.58
	Median	0.109	0	3.4	0.84	0.8	0.3	0.88	0.115
		(99.9)	(61.6)	(100)	(61.2)	(97.6)	(60.8)	(98.4)	(41.3)
% data complete	High HDI	0.007	0.0009	0.14	0.003	0.21	0.007	0.11	0.002
	Range	0–0.09	0–0.3	0–7	0–0.55	0–0.83	0–0.5	0–1.94	0–0.09
	Median	0.001	0	0.2	0.0013	0.14	0.005	0.065	0.002
		(100)	(71.8)	(100)	(71.8)	(99.9)	(71.8)	(95.6)	(68.7)

A higher proportion of voluntary non-remunerated blood donation correlates with a lower HIV prevalence among blood donors than in the general population.

The data also show that prevalence rates are generally lower in donations obtained from regular, voluntary non-remunerated blood donors. The HIV prevalence in the blood donor population and the general population was correlated with the reported percentage of voluntary non-remunerated blood donors. The analysis showed that, even in countries with a high prevalence of HIV in the general population, it is possible to achieve a low prevalence of HIV in the blood donor population. Figure 18 shows the percentage of voluntary blood donors and the ratio between the reported HIV prevalence in the blood donor population and the general population (6) in 16 countries in Africa for which information was available. The available data showed a correlation between voluntary non-remunerated blood donation and lower HIV prevalence rates among blood donors than in the general population. Figure 18 demonstrates that the lower the percentage of voluntary, non-remunerated blood donors, the closer the HIV prevalence in the blood donor population becomes to that in the general population, even exceeding it in a few cases.

Figure 18 | *Correlation between the percentage of voluntary blood donations and the ratio of HIV prevalence in the blood donor population to the general population in 16 countries in the African region*

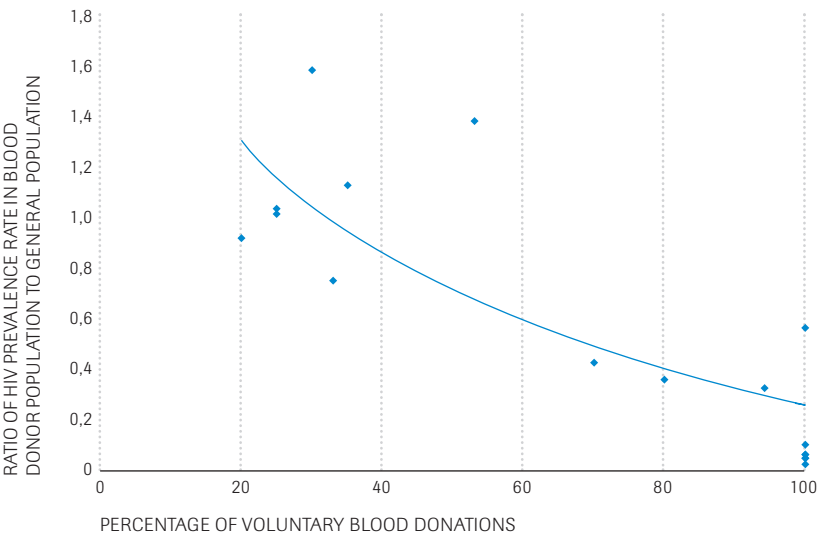
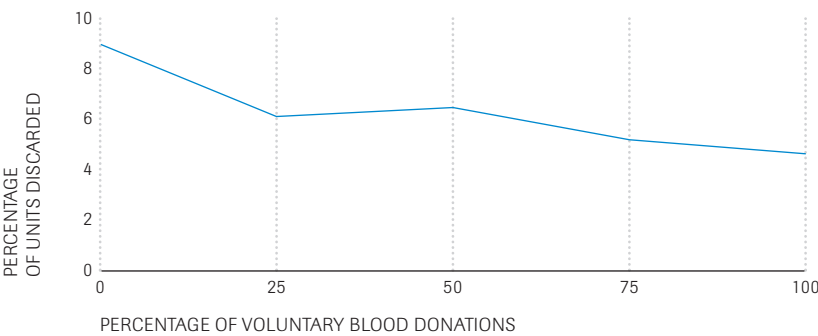


Figure 19 | *Correlation between the proportion of voluntary non-remunerated blood donors and discarded units*



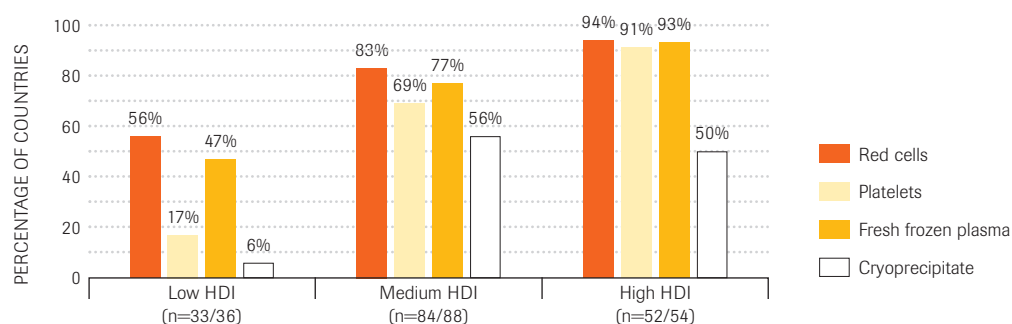
Analysis of the number of units reported to have been discarded after testing (2.5 million units) showed that the cost of collecting and processing these discarded units represented a wastage of at least US\$ 214 million annually, although complete data were available only for 92 countries (57.5 million donations). Given this substantial loss, a detailed analysis was undertaken to identify strategies that might reduce the costs associated with the discard of seropositive blood units. Available data demonstrated a correlation between higher proportions of voluntary non-remunerated blood donors and lower rates of discard and consequently decreased costs (Figure 19).

Use of manual and automated methods for blood group serology

Analysis of data indicates that ABO (red cell grouping) and RhD testing of donated blood were routinely performed (100% ABO and 98% RhD) in 172 countries. Testing was performed mainly by manual methods (102 countries: 57%), with 35 (20%) countries reporting partial automation. Six countries did not respond or gave the answer "Unknown". In total, 81% of low HDI countries, 68% of medium HDI countries and 24% of high HDI countries used manual methods for blood group serology.

Data obtained through the GDBS questionnaire cannot provide information on the level of standardization and accuracy of testing and processing. However, 94 (53%) countries reported having a quality assurance programme in testing and processing laboratories, with an additional 53 countries reporting partial implementation.

Figure 20 | *Blood component preparation, by HDI category*



Blood component preparation

The 1998–1999 GDBS questionnaire did not seek information on blood component preparation. Data for 2001–2002 indicate that the preparation of red cells, platelet concentrates, fresh frozen plasma and cryoprecipitate is carried out more frequently in high and medium HDI countries (Figure 20).

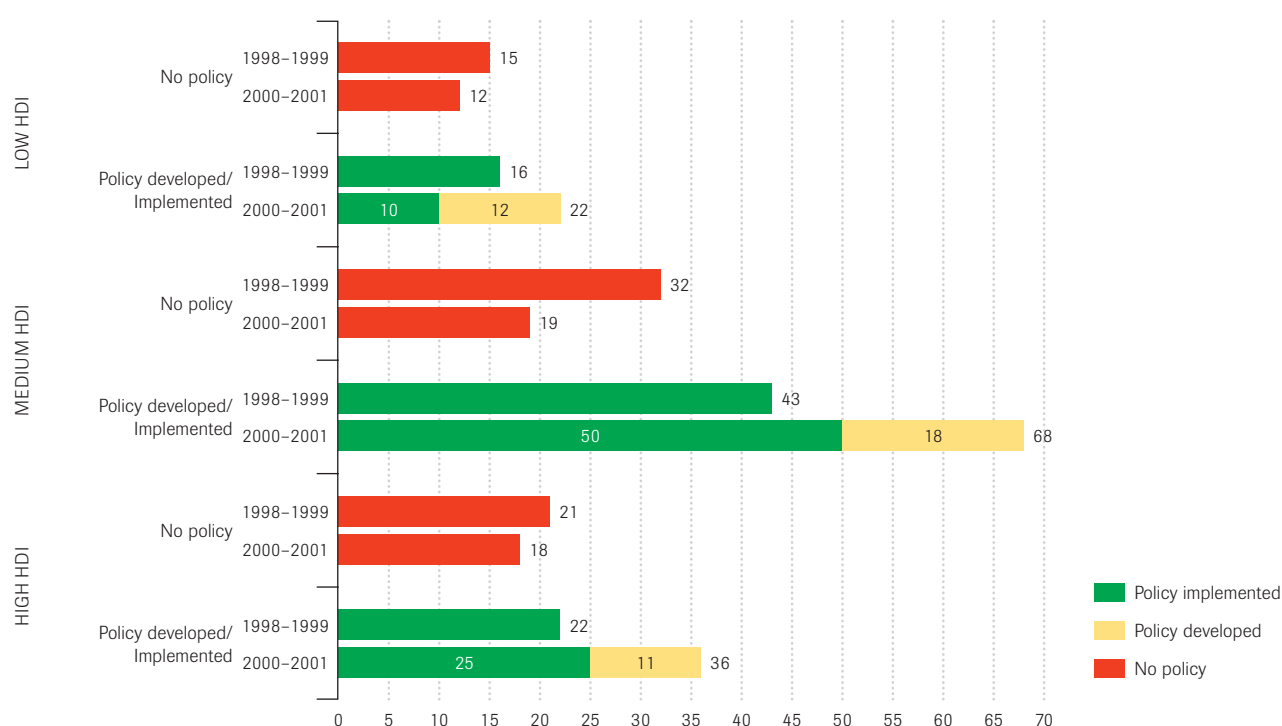
Blood storage and transportation

One hundred and forty-two countries reported the storage of blood and blood products in temperature-controlled equipment. A major concern, however, is that only 55 (39%) of these countries reported having a fully implemented system for monitoring temperatures during the transportation of blood and blood products.

The clinical use of blood

GDBS data for 2001–2002 indicate that a national policy on the clinical use of blood was in place in more countries in all three HDI categories than in 1998–1999. A total of 85 (48%) countries reported having a policy on the clinical use of blood and a further 41 (23%) countries reported that a policy was in development, as shown in Figure 21. Thirty (17%) countries reported that a system for the monitoring and evaluation of clinical transfusion practice was in place, with a further 65 (37%) countries reporting that a system was still in development (Table 5).

Figure 21 | *National policy on the clinical use of blood*



Data from 2001–2002 indicate that only 83 countries had hospital transfusion committees (range 1%–100% of hospitals) even though they are an important element in the implementation of national guidelines on clinical blood usage and the monitoring of their implementation. The coverage was higher in developed countries, with a larger proportion of countries reporting transfusion committees in all hospitals where transfusion was prescribed and given. No low HDI countries reported that all hospitals had transfusion committees. The distribution of countries with hospital transfusion committees is shown in Table 5.

Only 84 (47%) countries reported that mechanisms for the reporting and investigation of post-transfusion reactions were in place and 64 (37%) countries reported systems for the reporting and investigation of post-transfusion infections. There was a marked difference in relation to mechanisms for the reporting and investigation of post-transfusion infections between the various HDI categories (Table 5).

Table 5 |

Clinical transfusion practice, by HDI category

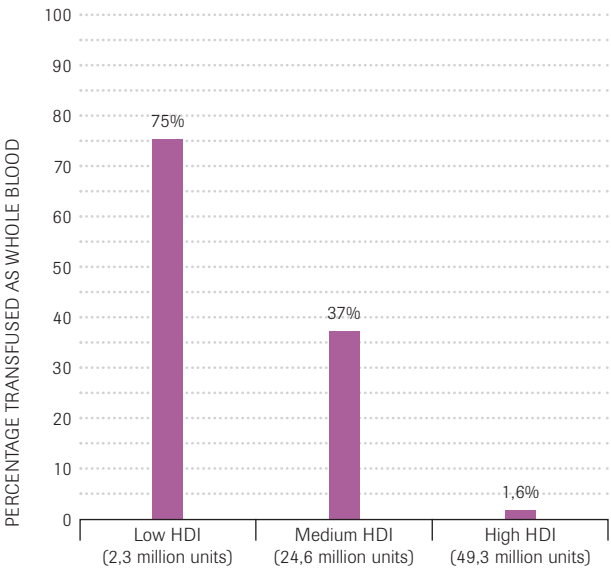
Low HDI countries		Medium HDI countries		High HDI countries	
Number (n=30/36)	Percentage	Number (n=83/88)	Percentage	Number (n=46/54)	Percentage
National system for monitoring and evaluation of clinical transfusion practice					
System in place	2 7%	16 19%	12 26%		
System in development	12 40%	31 37%	22 48%		
Hospital transfusion committees in place					
Some hospitals	7 23%	32 39%	27 59%		
All hospitals	0 0%	4 5%	13 28%		
Mechanisms for the reporting and investigation of post-transfusion reactions and post-transfusion infections					
Post-transfusion reactions	8 27%	40 48%	36 78%		
Post-transfusion infections	1 3%	27 33%	36 78%		

Use of whole blood for transfusion

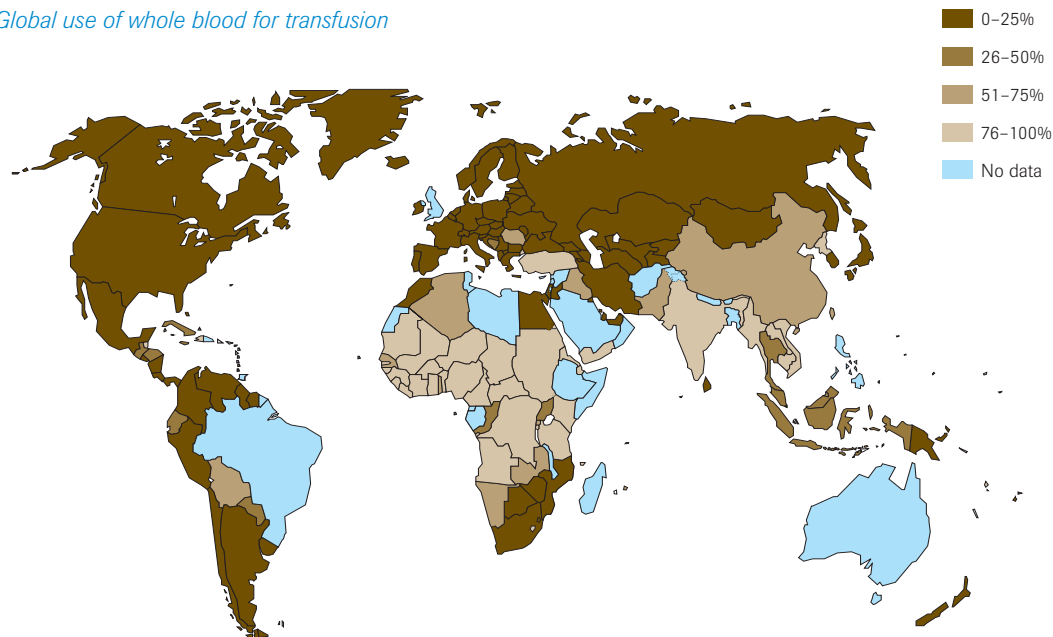
Only 1.6% of blood is used as whole blood in high HDI countries compared with 75% in low HDI countries (Figure 22 and Map 3). Although 128 (83%) countries reported the availability of crystalloids and of colloids, accessibility to these plasma volume expanders has not been assessed. Nevertheless, field observations demonstrate that plasma substitutes and volume expanders are often not accessible when required in low and medium HDI countries.

Figure 22 |

Percentage use of whole blood for transfusion, by HDI category



Global use of whole blood for transfusion

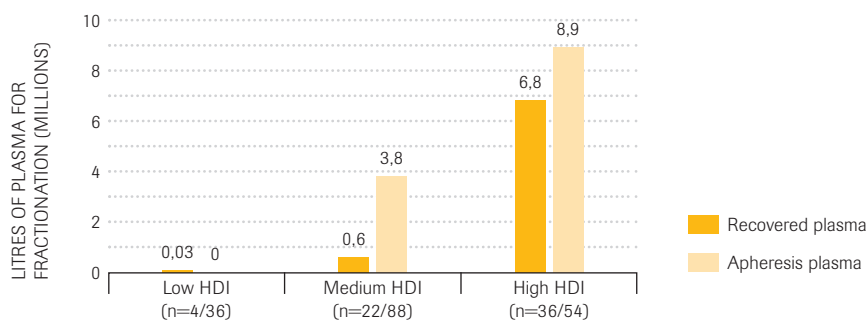


Plasma derivatives

Only 88 (49%) countries reported the availability and use of plasma derivatives such as Factors VIII and IX. An additional 22 (12%) countries reported their partial availability and use. The proportion of countries with access to these products was lowest in low HDI countries, only nine (25%) of which reported full or partial availability. GDBS data provide some information regarding the availability of plasma for fractionation, both recovered plasma obtained from whole blood donations and plasma obtained from apheresis donations. Only a small volume of recovered plasma was designated for fractionation in low HDI countries. In contrast, relatively very large volumes of both recovered and apheresis plasma were designated for fractionation in high HDI countries (Figure 23).

Figure 23 |

Plasma designated for fractionation, in litres, by HDI category



Conclusions

The need for global data on blood safety is driven by the urgent need to prevent the transmission of HIV and other potentially life-threatening infections through the transfusion of unsafe blood and blood products. Accurate data are equally important in identifying factors that contribute to an inadequate supply of blood and blood products, inequitable access to transfusion and the unnecessary use of blood. For Member States, these data are essential as a basis for planning and implementing strategies to ensure the safety and availability of blood and monitoring their effectiveness. For WHO, they are vital in refining strategies and identifying priority areas for advocacy, training, technical support and the development of new tools and guidelines.

Methodology

GDBS data for 2001–2002 were provided by countries through responses to a structured, closed questionnaire that specifically addressed the strategy for blood safety and availability advocated by WHO. The questionnaire was prepared in the six official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish) and was disseminated to national health authorities.

The 1998–1999 questionnaire was modified for the period 2001–2002 to expand the scope of the data to be collected and also to restructure the questions for better understanding. For the majority of questions, the earlier questionnaire had offered the following possible options: "Yes", "No" and "Unknown". The 2001–2002 questionnaire offered an additional option of answering "Partial/in process".

The GDBS provides the most comprehensive information available on blood transfusion services to assess the safety of blood transfusion globally. However, the data provided may not be fully representative of national situations in countries which lack systems for data collection. In addition, the data for 2001–2002 were not validated by independent sources, although site visits by WHO staff and consultants indicate that in countries without systems for national data collection, the information provided as national data often applies only to large centres. WHO has therefore developed an assessment tool to support countries in establishing or strengthening national data collection systems as a basis for policy making and programme planning. This will also enable countries to provide more accurate and complete data for the GDBS.

An analysis of responses to the 2001–2002 questionnaire indicated the need for revision of the questionnaire to remove any remaining ambiguities, particularly in relation to the organization of blood transfusion services, quality systems and plasma fractionation.

The questionnaire for data collection was distributed in 2002 and was intended to collect data for 2001. However, some responses were not received until mid-2003. This again reflects the difficulties in generating data faced by countries that do not have national systems for data collection and analysis.

Complete comparative analysis between 1998–1999 and 2001–2002 was not possible due to a lack of response to all questions by all Member States. Nevertheless, comparative analysis was valid for 159 (89%) of the 178 countries that provided data for both 1998–1999 and 2001–2002. Thirteen countries that responded in 1998–1999 did not respond in 2001–2002, while 18 countries that had not previously provided information responded in 2001–2002.

Discussion

Responses to the 2001–2002 GDBS questionnaire indicate that the majority of countries are still in a transitional phase in the implementation of the strategy for blood safety and availability recommended by WHO. The option to respond "Partial/In process" to many of the questions was widely used by respondents, indicating that while there is positive forward movement in the strengthening of blood transfusion services, much remains to be done. WHO will continue to provide support to all Member States in implementing appropriate and cost-effective strategies to ensure the safety and availability of blood transfusion.

Organization and management

Substantial improvement in the organization and management of blood transfusion services is indicated by the increased number of countries that reported a single organization with responsibility for blood transfusion services, including a rise in the number of countries in which sole responsibility lies with government. This is largely attributable to improved government commitment and support for the strengthening of national blood programmes. The biggest increase was observed in low HDI countries. The trend towards the national coordination of blood transfusion services was accompanied by an overall increase of 37% of countries that had either implemented or were in the process of developing and implementing a national blood policy. The most notable increase was observed in medium HDI countries.

Nevertheless, 52 countries still have a fragmented blood supply system. Studies by the WHO Region for the Americas/Pan American Health Organization (6, 7) indicate that a hospital-based system is inefficient, resulting in a financial burden that is 10 to 30 times higher than in a nationally coordinated model. Economies of scale, such as in the use of ELISA technology rather than simple/rapid tests, cannot be achieved where small numbers of blood units are collected and tested in multiple small blood centres and hospital blood banks.

Despite an increase in the number of countries reporting the development of legislation and regulation, 56 countries still had no legislation relating to blood transfusion, indicating a need to develop a legislative framework for their national blood programmes.

WHO has therefore conducted a series of workshops and provided technical support to assist countries in strengthening national blood programmes. It is also preparing guidelines and recommendations on the organization and management of blood transfusion services, including the development of a legislative framework for the national blood programme.

Quality systems

Despite evidence of some improvements in the establishment of quality systems, GDBS data indicate that 149 countries (84%) did not have all of the following elements of a national quality system fully in place: a national quality officer, standard operating procedures, a quality assurance programme for blood testing and processing, and participation in an external quality assessment scheme. However, improvements were reported in the use of standard operating procedures and records of blood donors and recipients of blood and blood products.

Uniformity in standards and operations cannot be achieved in countries which lack national quality systems. Recognizing the urgent need to support countries in establishing quality systems, WHO has therefore established the Quality Management Programme (QMP) for Blood Transfusion Services. The QMP was launched in 2000 with the objectives of helping to build national capacity in effective quality management, supporting the development of national quality systems and increasing the awareness of BTS staff of the need for quality in all activities. Since then, institutions have been designated as Regional Quality Training Centres and staff from over 120 countries have been trained as quality managers. Quality management training has now begun to cascade down to national level.

Responses to questions on training provided insights into the relative emphasis that is placed on the training of different categories of staff in blood transfusion services. The training of laboratory technical staff has received much more attention than the training of other categories of staff involved in the transfusion process. There is a great need for the training of blood donor recruiters, blood donor counsellors, quality managers, prescribers of blood and nurses involved in the administration of blood and blood products.

Blood donors

The recruitment and retention of safe, voluntary blood donors remains the weakest area, with only a marginal increase in the number of countries achieving 100% voluntary blood donation. During 2002–2002, only 39 countries reported having achieved 100% voluntary blood donation. A further 18 countries had achieved 90–99% voluntary donation. However, the blood donation rate in developing countries did not show any major trends in improvement since 1998–1999 and remained well below that of developed countries. This is largely attributable to limited voluntary blood donor programmes, a continuing dependence on family/replacement donors and low donor retention rates, associated with fragmented blood transfusion services. Differences in blood collection rates largely reflect differences in the level of development of health care systems in these countries.

GDBS data demonstrate that patients who receive blood from regularly voluntary donors are at the lowest risk of acquiring blood-borne pathogens through transfusion. It was observed that HIV prevalence rates in voluntary non-remunerated blood donors were significantly lower than those in the general population. However, the prevalence of infection among paid and family/replacement donors was generally as high as the rates found in the general population. A continuing dependence on family/replacement donors, and especially on paid donors, therefore has particular significance for countries with high burdens of infections that can be transmitted through transfusion.

Countries with a high prevalence of transfusion-transmissible infections also face increasing limitations to their potential blood donor base. Emerging infectious diseases such as variant Creutzfeldt-Jacob disease, West Nile virus infection and Severe Acute Respiratory Syndrome (SARS) pose a potential threat to the stability of national blood supplies in affected countries due to strict criteria for assessing the suitability of blood donors.

An increased number of countries indicate that various elements of a voluntary blood donor programme are in place. However, the effectiveness of these programmes is questionable in countries that report a continuing low percentage of new and regular voluntary non-remunerated blood donors and a low proportion of blood donors in the population. With the advent of HIV/AIDS and other transfusion-transmissible infections, the field of blood transfusion has widened to a more multidisciplinary approach with due emphasis on the application of psychology, communications and other social sciences to promote regular, voluntary non-remunerated blood donation. Blood donor programmes require substantial human and financial resources in order to recruit and retain more regular donors.

To support countries in their campaigns to increase regular voluntary blood donation, WHO has initiated a collaborative venture with the International Federation of Red Cross and Red Crescent Societies, the International Federation of Blood Donor Organizations and the International Society of Blood Transfusion to promote the global celebration of World Blood Donor Day, which is held annually on 14 June. It has also developed a set of training materials for blood donor organizers for use in regional and national training activities.

Screening of donated blood

Significant improvements have been achieved in reducing the number of units of blood that are not tested for infectious markers. By 2002, 152 countries reported testing 100% of donated blood units for HIV. Globally, the number of tests not performed for the markers for four main infections (HIV, HBV, HCV, syphilis) decreased from 13 million in 1998–1999 to 6 million in 2001–2002.

Nevertheless, while essential, testing alone is insufficient to prevent transfusion-transmitted infection because of the possibility of window period infection or inaccurate test results caused by poor quality or incorrectly stored test kits. Laboratory errors resulting from inadequate staff training or a lack of standard operating procedures and other elements of a quality system present further risks to the safety of blood for transfusion.

Furthermore, universal screening of donated blood for HIV and other transfusion-transmissible infections cannot be achieved without mechanisms to ensure continuity in testing. Interruptions to supplies of test kits/reagents, resulting in the issue of blood without screening for one of the four major infections, were reported by 22% of countries. The development of systems for the reliable supply of low cost, high quality test kits/reagents within nationally coordinated blood transfusion services is required to ensure universal screening of donated blood.

The collection of blood only from the safest possible blood donors remains the foundation of a safe blood supply. Higher rates of discarded units of donated blood due to positive test results were reported by countries with a dependence on family/replacement donors and, especially, paid blood donors. This indicates that an investment in voluntary blood donor programmes results not only in improvements in the quality and safety of blood, but also in reduced costs for testing donated blood.

WHO supports countries in improving the safety and reliability of testing by evaluating test kits for HIV, hepatitis B and hepatitis C and providing information on their quality and performance. It also operates a bulk procurement scheme to provide access to high quality test kits at relatively low prices and advises countries about the types of kit that are most suitable for use in their own health care systems.

The clinical use of blood

Limited information is available on the clinical use of blood at global level, but studies indicate that many transfusions are given unnecessarily (8, 9, 10). The information obtained from the database indicates a continuing need for the development and implementation of national guidelines on the appropriate clinical use of blood. National policies on transfusion had been developed or were in the process of development in 126 countries, but site visits by WHO staff and consultants have identified significant variations in prescribing patterns between – and even within – hospitals. This is attributable to a lack of training, poor implementation of guidelines and the absence of functional hospital transfusion committees.

WHO has published recommendations on developing national policies and guidelines on the clinical use of blood and a handbook that can be used as the basis for national guidelines. It has also produced learning materials for clinicians and is developing materials for the training of nurses and junior doctors on safe bedside transfusion practice.

The use of whole blood transfusion remains high in low HDI countries in contrast to medium HDI countries and, in particular, to high HDI countries where whole blood is rarely used. The capacity to provide blood components for the treatment of patients requiring such support is still limited in low HDI countries.

While encouraging the use of appropriate blood components, WHO recommends that blood component programmes should be in keeping with the level of development of the health care infrastructure and the medical services available.

WHO is developing a series of recommendations, guidelines and learning materials on establishing a blood component programme. These emphasize the importance of assessing the clinical demand for blood components as well as the feasibility of establishing a sustainable programme.

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Blood Transfusion Safety

Essential Health Technologies

World Health Organization

20 Avenue Appia

CH-1211 Geneva 27

Switzerland

Fax: +41 22 791 4836

E-mail: bloodsafety@who.int

<http://www.who.int/bloodsafety>