An international survey on measures to prevent transfusion-transmitted infectious diseases; study results 1: participation rates and the presence of laws, regulations, standards and best practices

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Conflict of interest statement:

Jean Stanley is a contractor and shareholder of Roche Diagnostics. The remaining authors have no relevant conflict of interest to declare.

Funding:

The author(s) received no specific funding for this work

Data availability statement:

Data reported in this paper are available from the first author upon reasonable request.

Word count: 5,004

Highlights (3 allowed):

- An international survey on measures to prevent transfusion-transmitted infectious diseases (TTIDs) was conducted; the presence of relevant laws, regulations, standards, and best practices for the collection and processing of whole blood and blood components was analyzed in relation to countries'/regions' World Bank Income level. Specific TTID responses are reported separately.
- Overall, 96% of participating countries/regions reported that regulatory authorities had jurisdiction over collection and processing of whole blood and blood components and 94% of the reported jurisdiction was at a national level.
- Low/lower-middle income countries/regions made less use of more advanced technologies including blood component separation, pathogen reduction, leukocyte reduction, and routine bacterial testing of platelets compared with those at higher incomes.

Abstract

Background and Objectives: A global survey on blood safety measures to prevent transfusion-transmitted infectious diseases (TTIDs) was performed examining variations in current usage. This analysis focuses on participation rates and the presence of relevant laws, regulations, standards, and best practices for collection/processing of whole blood/components.

Materials and Methods: Distribution occurred between October 2023-March 2024. States, provinces, or cities within China and India were analyzed as separate regions. Country/region (C/R) responses were categorized by World Bank Income (WBI) levels: Low/Lower Middle-Income (LLMI), Upper Middle-Income (UMI), and High-Income (HI). Consensus responses were used for multiple survey responses.

Results: Responses from 131 individuals representing 74 C/Rs (65 countries, Hong Kong, counted separately, and 8 regions in China/India) were analyzed. Affirmative responses for laws, regulations, and standards were similar across WBI levels. Regulatory jurisdiction for blood/components was present in 96% of C/Rs (HI 100%, UMI 100%, LLMI 87%) and 94% at a national level when present (HI 100%, UMI 94%, LLMI 85%). All HI, UMI and 74% LLMI C/Rs reported routinely separating whole blood into components. HI C/Rs were more likely to screen for bacterial contamination whereas periodic platelet quality control was more common in LLMI and UMI C/Rs. Pathogen reduction and universal leukocyte reduction were more common in HI C/Rs.

Conclusion: Laws, regulations and standards for collection/processing of blood was consistent across WBI groups. Resource-intensive practices of blood component

separation and use of advanced blood safety technologies were more variable, with less utilization in LLMI/UMI C/Rs.

Keywords: Global Blood Safety, Blood Processing, Blood Regulation

Introduction:

Laws, regulations, and standards regarding blood collection and processing are vital for a safe blood supply. While safety practices in blood collection including selection of low-risk donors, aseptic phlebotomy procedures and infectious disease testing are fundamental, the way in which collected blood is further processed also affects the safety and quality of transfused blood and blood products. The World Health Organization (WHO) provides guidance on blood collection and processing and recommends that all countries should have a national blood policy. Despite this longstanding recommendation, the WHO reported in 2021 that as of 2018 there still were low-, middle-, and high-income countries without a national blood policy.[1] The WHO publishes status reports using national survey data that are reported periodically to the Global Database on Blood Safety. These reports provide a snapshot on the status of blood safety and availability by country.[2] In addition to WHO guidance documents, there are other continental/regional guidelines for blood safety issued by entities such as the European Union, Caribbean Regional Standards, and the African Society for Blood Transfusion's Stepwise Accreditation Program (among others).[3, 4, 5] In concert with these efforts to provide standards and situational reporting, the International Society of Blood Transfusion (ISBT) can provide additional insights by identification of strategies for, and gaps in, global blood product safety and availability through contact with its members, who represent worldwide blood collection organizations and their leadership.

To assess current global blood safety policy and management, a survey was designed and distributed in 2023 and 2024 by the Subgroup on Harmonization of Regulations and Standards (Harmonization Subgroup) of the ISBT Working Party for Global Blood Safety (GBS WP). This survey covered a wide range of topics, including questions related to the extent and nature of laws, regulations, standards, and current practices for blood collection and processing, with a specific focus on transfusion-transmitted infectious disease (TTID) testing, and TTID donor vigilance. The first version of the survey was distributed in 2021 and resulted in a low response rate (27% of high income and 15% of low- and middle-income countries).[6] Preliminary findings of the 2021 survey suggested

that fewer mechanisms of oversight and standard setting are present in low- and middle-income countries compared with high-income countries, particularly in governmental licensing or registration of blood establishments. This subsequent survey was reduced in length and made more focused, with the aim of gaining representation from more countries through a web-link followed by targeted emails, especially among low and lower middle-income countries. The results of this second survey were separated into two reports; the current report focuses on participation rates, regulation and current practices in blood and blood component processing, and the second report, published separately, on TTID testing and donor vigilance.

Materials and Methods:

Data collection began in October 2023 and ended in March 2024 using the online platform Survey Monkey (San Mateo, California, USA). A copy of the full survey is included (Supplemental Appendix). All ISBT members were invited to respond to the survey as well as encouraged to share it with blood collection organization representatives from other countries. Separate targeted email invitations were also included with the goal of increasing participation particularly from Latin America and Africa. Responses were grouped into the World Bank Income (WBI) categories Low and Lower Middle-Income (LLMI), Upper Middle-Income (UMI), and High-Income (HI) based on country or territory of origin.[7]

Hong Kong, categorized as HI, versus three other responding Chinese cities and provinces, each categorized as UMI, were defined as separate geographic regions. This was done because even though China has a national blood policy, all blood establishments operate independently under the oversight of local government and health authorities.[8] Similarly for India, although there is a national blood policy, responses from individual cities and states were defined as unique geographic regions because activities related to blood safety are coordinated at the state level. All the Indian regions were classified at the same WBI level.[9] Accordingly, we refer to “countries/regions” (“C/Rs)” in the detailed analysis of the survey results.

A consensus response was used for C/Rs with multiple survey responses by taking the responses from all representing respondents and combining them into a predominant or

most logical single response. In the case of single response questions, the majority response was chosen. If no majority response occurred, the affirmative response was selected (e.g., if there were two responses for a given country and one indicated that a specific screening test was used while the other did not, the consensus was counted as using the test). Every response was counted when multiple options for a response were possible. The question regarding bacterial contamination interventions for platelets was treated as a multiple response question as targeted email responders could select multiple responses (though those answering via the online survey could not).

Responses from Low-Income and Lower Middle-Income C/Rs were combined into a single category (LLMI), due to a low response rate from the Low-Income group (3 responses). The first section of the survey focused on laws, regulations, and standards, and the second section queried respondents on whole blood and component processing, all of which were compared across the three WBI categories.

Survey questions were compared (qualitative proportions) between the three WBI categories using SAS version 9.4 (SAS Institute, Cary, NC).

Results:

Of the 156 responses, 32 were manually entered from emailed surveys (either printed, completed, and returned by scan or emailed directly) and 124 were completed online through SurveyMonkey; 25 surveys with mostly incomplete or duplicate data were excluded leaving a total of 131 surveys analyzed. Of the 131, 44 were single country responses and 87 were duplicate country responses. The 87 duplicate country responses were converted into 30 single consensus responses for a total of 74 C/Rs used for analysis (Figure 1). All 74 C/Rs were categorized by WBI group. Regions in China included Beijing, Hong Kong, Liaoning Province, and Shanghai (N=4). Regions in India included the states of Chhattisgarh, Kerala, Maharashtra, Punjab, Uttarakhand, and Uttar Pradesh, as well as the National Capital Territory of Delhi (N=7). With the individual regions within mainland China (all classified as UMI) counted as one country, and individual regions of India (all classified as LLMI) counted as one country, there were 65 unique countries plus Hong Kong (classified as HI and counted as if a unique country) categorized in the study (17 LLMI, 16 UMI and 33 HI). Of the 217 countries and

territories globally ranked using the WBI, this survey encompassed 17/80 (21.3%) LLMI countries (including India as one), 16/54 (29.6%) UMI (including China as one), and 33/83 (39.8%) HI C/Rs (including Hong Kong). Since the survey was distributed among ISBT members, but was also externally shared with non-members, a traditional ISBT response rate was not calculated. However, 58 of 66 individual responding countries were from the 116 ISBT member countries (for a total ISBT response of 50%), while the other 8 were non-ISBT member countries (Aruba, Botswana, Burundi, Curaçao, Libya, Mali, Paraguay, and Zambia).

Among the 131 individual responders (before creating consensus responses), 39 were from LLMI C/Rs (29.8%), 36 were from UMI C/Rs (27.5%), and 56 were from HI C/Rs (42.7%) (Figure 2). LLMI C/Rs had high proportions of respondents from hospitals (56%) and national blood collection organizations (28%); UMI C/Rs had high proportions of respondents from hospitals (42%) and government/state/not for profit organizations (42%); and in contrast, HI C/Rs had the highest proportion of respondents from national blood collection organizations (52%) with lower representation from hospitals (20%), and government/state/not-for-profit organizations (18%).

All UMI and HI C/Rs and 87% of LLMI C/Rs (96% overall, 71/74) indicated that regulatory authorities had jurisdiction over whole blood and blood components (Table 1). C/Rs responding affirmatively to regulatory jurisdiction included 100% of HI, 94% of UMI, and 85% of LLMI, where 94% (67/71) reported that this jurisdiction was national versus 91% (67/74) among all surveyed C/Rs. Overall, 97% (72/74) of surveyed C/Rs indicated that there was governmental licensing of blood collection establishments, with approximately 60%, across all three WBI categories, indicating voluntary accreditation of blood collection establishments. Finally, 65% of LLMI, 72% of UMI, and 70% of HI C/Rs indicated that professional associations establish best practices for the overall preparation of whole blood and blood components for blood collection organizations.

All UMI and HI C/Rs and 74% of LLMI C/Rs reported routinely separating whole blood into components. The other 26% of LLMI C/Rs reported separating whole blood into components sometimes, a combination of routinely and sometimes, or never (for consensus C/Rs) (Table 2). HI C/Rs were more likely to use a rapid test or culture for

routine testing of platelets for bacterial contamination (45%), whereas periodic quality control was more common in LLMI and UMI C/Rs (74% and 50%, respectively). Pathogen reduction (PR, although the term pathogen inactivation was used in the survey instrument) usage varied greatly by WBI, but HI C/Rs had higher rates of usage, especially for platelets (52%) and plasma (42%), compared to LLMI (9%, 17%) and UMI (22%, 33%) C/Rs. Two LLMI countries in Africa (Tanzania and Zambia) reported PR of whole blood. Although not specifically asked, it is assumed (as practiced in the US) that the use of PR would eliminate the need for any other bacterial safety intervention. Six countries (Burundi, Ivory Coast, and Mali (LLMI), Botswana and Paraguay (UMI), and Israel (HI)) indicated they do not use bacterial testing or PR for platelets.

The final questions within the second section of the survey were focused on leukocyte reduction (LR). All UMI and HI C/Rs and 65% of LLMI C/Rs reported performing LR for components and/or whole blood (Table 3). HI C/Rs reported high rates of universal LR, including 39% for whole blood, 73% for red blood cells and platelets and 55% for plasma. UMI C/Rs had amongst the most variable responses, with high proportions of voluntary LR, including 39% for whole blood and plasma, and 44% for red blood cells and platelets. LLMI C/Rs had the highest proportion responding that LR was used for select indications only (of the 15 responding that they used LR), including 40% for whole blood, 73% for red blood cells, 93% for platelets, and 53% for plasma.

Discussion:

The survey distributed by the Harmonization Subgroup of the GBS WP explored the global presence of laws, regulations, and standards relating to blood and blood products as well as the use of TTID testing, and related donor notification and vigilance. The focus here is on initial reporting of participation rates and overall blood regulation and processing practices using WBI levels for country/regional comparisons. The results of the TTID and related donor aspects of this survey will be included in a separate manuscript, but it should be noted that all C/Rs met the WHO minimum testing requirements for HIV, HCV, HBV and syphilis (except that Denmark deems syphilis testing to be unnecessary and only selective testing is performed for syphilis in Norway).

Participation rates were high, with 156 total responses of which 131 could be analyzed from 65 unique countries plus, separately, Hong Kong, particularly after targeted email invitations solicited from GBS Harmonization Subgroup members encouraging greater participation from countries in Latin America and Africa. This response rate is over double that of another ISBT Working Party survey on global nucleic acid testing.[10] The higher response rate in the current survey was expected given that it was circulated to a larger pool of possible responders, whereas the survey in reference 10 was only sent to the members of the ISBT TTID Working Party. The apparent trend towards greater reporting from members of national or state level entities rather than from hospitals may reflect increased organization of community-based rather than hospital-based blood collections in the C/Rs of higher income groups.[11]

The results from this survey indicate that there are income-related differences for some aspects of blood safety, mainly aspects pertaining to resources and not as much for policy and regulation. The 2021 WHO Global Status Report on Blood Safety and Availability reported primarily on data for 2018 obtained from 108 countries in which 73% of participating countries had a national blood policy and 66% indicated specific legislation covering the safety and quality of blood and blood products.[12] These previously obtained statistics are somewhat lower than the proportions observed in this more recent study reporting national jurisdiction (67/74 or 91% overall), though the WHO report includes more LLMI countries. Importantly, the existence of laws and regulations does not imply compliance or enforcement within a given country; however, there is no relevant global literature describing compliance or enforcement of laws and regulations with respect to blood safety. The WHO reported that a total of 101 countries of 171 (59%) responding member states had a system of regular inspection of transfusion services by a national regulatory agency or other entity. These same countries had a system of licensing national transfusion services of which 57 (33%) had an accreditation system. This compares to almost 100% across all WBI categories in the current study for licensing and around 60% across all WBI categories for accreditation.

All UMI and HI C/Rs reported separating whole blood into components, and the majority (74%) of LLMI C/Rs reported routinely separating whole blood into components, but around a quarter (26%) reported a mix of routinely, sometimes, and never. According to the WHO report for the year 2018, 38% of low-income (LI), 75% of lower middle-income (LMI), 96% of UMI, and 96% of HI countries separate blood into components, which aligns with the findings in the current study. Component therapy is commonplace in HI countries but is associated with higher costs due to manufacturing and complex inventory management tasks. However, component use has logistical and clinical disadvantages in some emergency situations in which the use of whole blood in HI countries is seeing a resurgence.[13] The results reported for the LLMI C/Rs would be expected to mirror the WHO LMI group given there were only three LI countries within the LLMI group in this study. It should be noted that the WHO report only had this question as a "yes" or "no" response, whereas the current survey had the options of routinely, sometimes, or never.

HI C/Rs had the highest proportion responding that platelets were routinely tested for bacterial contamination by rapid test and/or culture, followed by UMI C/Rs, whereas periodic QC was more likely in LLMI C/Rs. These results are expected as LLMI countries often lack the resources for testing technology, which unfortunately means they are disproportionately burdened by the risks of infectious disease transmission including from bacterially contaminated platelets.[14] PR is another technology that could be extremely beneficial to LLMI countries, especially those in which parasites, such as *Plasmodium,* are endemic; however, 91% of the LLMI C/Rs indicated they did not use this technology, again likely due to lack of resources.[15, 16]

The reduction of leukocytes helps to minimize transfusion reactions, human leukocyte antigen alloimmunization, and platelet refractoriness, and prevents transmission of leukotropic viruses, including human T-cell lymphotropic viruses, Epstein-Barr virus, and cytomegalovirus.[17, 18] Results from the current study indicate that HI C/Rs commonly use universal LR; UMI C/Rs had a range of responses but about 40% favored voluntary LR with LLMI C/Rs often using LR for select indications only. As is the case for PR and bacterial contamination testing, limited resources are likely the reason for these

findings. None of the three low-income countries used PR, LR, and only one reported bacterial contamination testing of platelets.

Important limitations of this study include the fact that responses from a given individual for a particular country may not necessarily represent the practices of the entire country and may only represent an area within the country or a given institution for which the responder was familiar. Also, the balances in reporting from different levels of the blood system (i.e., hospitals, national blood collection organizations, government/state entities, etc.) might reflect the membership of ISBT rather than fundamentals of the blood systems in those C/Rs. Conversely, the membership of ISBT may accurately reflect international trends in blood collection. Questions may not have been interpreted equally by all respondents, since the survey was conducted in English; the validity of responses hinged upon the responder's proficiency in English. When responses were deemed likely incorrect (e.g., a HI country indicating no HIV screening), efforts were made to confirm the response with the responder and were corrected if necessary; however, not all survey responses were validated in this manner. Additionally, a few questions were meant to be a single response question but were ultimately treated as multiple response based on emailed surveys; therefore, not all responders had the ability to select multiple options. Finally, there is potential bias with treating regions within China and India separately, however there was heterogeneity of the responses across regions within these countries, confirming the relevance of this stratification.

In conclusion, the findings from this survey indicate that differences in blood safety among C/Rs by income level most often occur when interventions that require greater resources, such as LR, PR, and bacterial testing of platelets, are needed. Blood safety measures that require fewer resources, such as having a national blood policy or requiring licensing of blood collection establishments are nearly universal across WBI categories, indicating that their global establishment may have increased safety measures since 2018, as was reported in the 2021 WHO Global Status Report on Blood Safety and Availability. We believe this survey provided an enhancement to the 2021 WHO report in at least three respects. First, by the recency of the data collection, and secondly by the focus on reporting by individuals engaged in operations of the blood

system at multiple levels rather than solely by Ministries of Health. Gathering information in this way can provide independent validation of reports provided by health ministries as well as offer greater detail on actual practices. Thirdly, categorization of C/R responses by WBI groups provided an objective basis to comment on the presumed impact of national resources on the implementation of blood safety measures. We further believe that partnerships among members of international societies like ISBT can help facilitate access to, and adoption of, more advanced blood safety technologies even in the face of resource constraints. For example, as more detailed information on the adoption of safety practices becomes available, members in LLMI countries that have managed to integrate more advanced technology into their establishments, despite limited resources, may share with members in other LLMI countries how this was accomplished. To date, evaluations of TTID prevalence and interventions, such as PR, have been studied but not yet widely implemented.[19, 20] The results of this ISBT survey, which build on and enhance previous attempts to provide a common understanding of the status of global blood safety, thus may further highlight areas where efforts for improvement may be focused. The ISBT survey, as is or modified, could be repeated in future years as an adjunct to the periodic WHO surveys to assess progress being made in global blood safety and to foster international cooperation in this effort.

Acknowledgements:

S.L.S., R.Y.D., H.K. and J.E. designed the study. G.C. sent targeted surveys with assistance from S.L.S., C.T.T. and S.W.; G.C. compiled the data. G.C., S.L.S, R.Y.D., and J.E. reviewed the data and created consensus responses. G.C. analyzed the data and drafted the first version with input from S.L.S., R.Y.D. and J.E.; all authors reviewed, provided input and approved the final version of paper.

We thank Eszter Herczenik and her colleagues at the ISBT Central Office for survey distribution and administrative support; we also would like to thank Jenny White for her support of our survey. We further thank the ISBT TTID Working Party for their constructive review of the survey, and all respondents to the survey for their contributions.

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Figure 1. Participating country/region by World Bank Income level (n=74)*

*Of 217 countries/territories ranked using the World Bank Index, this survey represents 17/80=21.3% Low and lower middle-income countries (individual regions within India were counted as a single response), 16/54=29.6% upper middle-income countries (individual regions within China were counted as a single response), and 33/83=39.8% high-income countries (including Hong Kong as separate from China consistent with the World Bank classification). There were 16/54 countries from Africa, representing approximately 55% of the total population. Aruba, Curaçao, Hong Kong, and Singapore (not visible), categorized as high income.

Figure 2: Responder's associated organization type (n=131)*

*BCO: blood collection organization

Table 1. Laws, regulations, and standards for responding countries/regions by World Bank Income level

	Low & Lower Middle Income (N=23) N (% Yes)	Upper Middle Income (N=18) N (% Yes)	High Income (N=33) N (% Yes)
Do regulatory authorities have jurisdiction over whole blood and blood components?	20 (87%)	**18 (100%)[1]**	**33 (100%)**
If so, is it national?	17 (85%)	17 (94%)	**33 (100%)[2]**
Is there governmental licensing of blood collection establishments?	22 (96%)	17 (94%)	**33 (100%)[3]**
Is there voluntary accreditation of blood collection establishments?	13 (57%)	**11 (61%)**	18 (55%)
Do professional associations establish best practices for blood collection establishments for overall preparation of whole blood and blood components	15 (65%)	**13 (72%)**	23 (70%)

[1]Highest percentages across each category bolded.
[2]Hong Kong responded “no” but was categorized as a “yes” since China has national policies.
[3]Israel, Hong Kong, and Oman are regulated by the Ministry of Health.

Table 2. Whole blood and component processing for responding countries/regions by World Bank Income level

	Low & Lower Middle Income (N=23) N (% Yes)	Upper Middle Income (N=18) N (% Yes)	High Income (N=33) N (% Yes)
Is Whole Blood separated into components?			
Routinely	17 (74%)	**18 (100%)[1]**	**33 (100%)**
Sometimes	**6 (26%)[2]**	0 (0%)	0 (0%)
Are platelets routinely tested for bacterial contamination?[3]			
Rapid test and/or culture	0 (0%)	3 (17%)	**15 (45%)[4]**
Periodic QC only	**17 (74%)**	9 (50%)	13 (39%)[5]
Rapid test, culture, and/or Periodic QC	3 (13%)	**3 (17%)**	2 (6%)[6]
Not tested	3 (13%)	**3 (17%)**	3 (9%)[7]
Is pathogen reduction used (select all that apply)?			
Whole Blood	**2 (9%)[8]**	0 (0%)	0 (0%)
Cryoprecipitate	**2 (9%)[9]**	1(6%)	2 (6%)[10]
Platelets	2 (9%)[11]	4 (22%)	**17 (52%)[12]**
Plasma	4 (17%)	6 (33%)	**14 (42%)[13]**
Not used	**21 (91%)**	14 (78%)	16 (48%)

[1]Highest percentages across each category bolded.
[2]Includes responses of "sometimes" from Burundi and Ghana, as well as combinations where "routinely" and "sometimes" were provided from countries including Cameroon, Nigeria, and Pakistan, and "routinely" and "never" from Zambia.
[3]Online responders could only choose one response but emailed/paper survey responders could choose multiple, therefore combinations are included. If a combination response included a "no" response, the higher-level response was used.
[4]Australia, Canada, Croatia, Denmark, Hong Kong, Ireland, Netherlands, New Zealand, Norway, Oman, Saudi Arabia, Singapore, UAE, UK, US.
[5]Aruba, Austria, Belgium, Chile, Curacao, Finland, Greece, Italy, Japan, Poland, Romania, Slovenia, Spain.
[6]Germany and Portugal.
[7]France, Israel, Switzerland.
[8]Tanzania and Zambia.
[9]Egypt and Zambia.
[10]US (Mayo Clinic) and UAE.
[11]Tanzania and Zambia.
[12]Aruba, Austria, Belgium, Canada, Chile, Curacao, France, Greece, Hong Kong, Italy, Netherlands, Poland, Portugal, Slovenia, Switzerland, UAE, and the US.
[13]Belgium, Canada, France, Greece, Hong Kong, Italy, Netherlands, Poland, Portugal, Spain, Switzerland, UAE, UK, and the US (Mayo Clinic).

Table 3. Leukocyte reduction usage for responding countries/regions by World Bank Income level

	Low & Lower Middle Income N (% Yes)	Upper Middle Income N (% Yes)	High Income N (% Yes)
Is any kind of leukocyte reduction performed?	15 (65%)[1]	**18 (100%)[2]**	**33 (100%)**
If so, what is the policy for (select all that apply):			
Whole blood			
Required	4 (27%)	**5 (28%)**	9 (27%)
Voluntary	2 (13%)	**7 (39%)**	4 (12%)
Universal	2 (13%)	1 (6%)	**13 (39%)**
For select indications	**6 (40%)**	6 (33%)	2 (6%)
Not used for whole blood	5 (33%)	5 (28%)	**17 (52%)**
Red Blood Cells			
Required	5 (33%)	6 (33%)	**18 (55%)**
Voluntary	3 (20%)	**8 (44%)**	4 (12%)
Universal	6 (40%)	3 (17%)	**24 (73%)**
For select indications	**11 (73%)**	10 (56%)	5 (15%)
Platelets			
Required	6 (40%)	5 (28%)	**16 (48%)**
Voluntary	3 (20%)	**8 (44%)**	5 (15%)
Universal	3 (20%)	5 (28%)	**24 (73%)**
For select indications	**14 (93%)**	6 (33%)	3 (9%)
Plasma			
Required	4 (27%)	5 (28%)	**13 (39%)**
Voluntary	3 (20%)	**7 (39%)**	4 (12%)
Universal	4 (27%)	3 (17%)	**18 (55%)**
For select indications	**8 (53%)**	5 (28%)	2 (6%)

[1]All subsequent questions regarding leukocyte reduction for low and lower middle-income countries/regions are of the 15 that responded yes.
[2]Highest percentages across each category bolded.