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A nationwide survey of clinical use of blood in Italy

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Background - In Italy, as in many developed countries, a decline in blood component (BC) consumption, especially red blood cells (RBC), has been described, but not studied at a national level. We, therefore, designed a nationwide survey to determine the main features of BC recipients and obtain a picture of the clinical use of BC for the first time in Italy, in order to understand BC demands better and identify specific fields in which to apply Patient Blood Management (PBM).

Material and methods - A nationwide survey of all Italian Blood Establishments working as Hospital Blood Banks (HBB) was performed. Data were collected through an online report form recording information on the number and geographic area of the responding HBB, year of birth and sex of the BC recipients, and clinical indications for every unit of RBC, platelets and plasma transfused in a 24-hour period.

Results - On the survey date, 153/237 (64.5%) of the HBB returned 4,356 forms, reporting 7,523 transfusions. The median and mean ages of the recipients were 73 (range, 0–106) and 67.5 years, respectively; 33.0% were >80 years old and 64.9% >65 years old, with no relevant differences between males and females. Overall, 6,309 RBC units were transfused to 3,850 recipients, 66.7% of them for a medical indication and 32.4% for a surgical indication. The commonest medical indication was acquired, non-cancer-related anaemia and more than 30% of the transfusions occurred in the Emergency Department. Five hundred and sixty platelet transfusions were given to 520 recipients, 62.7% of them for prophylaxis and 28.6% for bleeding before or during an invasive procedure or surgery or for thrombocytopenia. One hundred and ninety-four patients received 654 units of plasma, 71.1% of which were for therapeutic purposes in bleeding patients.

Discussion - We collected a picture of blood transfusion epidemiology in Italy. The data suggest that future PBM plans should be focused on medical anaemia especially in the setting of Emergency Departments.

Keywords: blood donors, Italy, epidemiology, blood component transfusion, surveys and questionnaires.

INTRODUCTION

In recent years, the use of blood has decreased overall in many developed countries, thanks to the implementation of Patient Blood Management (PBM) programmes, adherence to

Arrived: 12 March 2021

Revision accepted: 1 June 2021

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guidelines encouraging restrictive transfusion thresholds, and advances in technology and surgical techniques¹⁻⁵. Nevertheless, demographic changes are a threat to the balance of blood demand and supply in blood services, because both blood consumption and donation patterns vary according to age, as has been shown in different countries⁶⁻⁸. The decrease in younger age groups implies a reduction in the population eligible to donate blood, while the increase in the elderly population leads to a high demand for blood for older patients who are undergoing a growing number of complex therapeutic procedures, such as haematopoietic stem cell transplantation, cardiovascular surgery and solid organ transplantation^{9,10}. In order to gain a broad perspective of the clinical use of blood and determine the main characteristics of recipients, many countries have carried out specific surveys¹¹⁻¹³. In the USA, Shehata *et al.* found that, despite a reduction in the mean number of red blood cell (RBC) units administered, there has been an increase in the proportion of patients admitted to hospital who are transfused. They also found that most RBC units are given to patients in general internal medicine and haematology-oncology services¹¹. In both France¹² and the UK¹³, most patients are transfused in a medical context and the median age of transfusion recipients is over 65 years. A decline in blood component (BC) consumption, especially RBC, has been described in Italy too^{15,16}, but studies investigating whether this decline involves all recipients and occurs for both medical and surgical indications have not yet been done at a national level, and only occasionally performed at a local level¹⁷.

The concept of PBM was introduced as a tool to pursue the objective of national BC self-sufficiency¹⁸, and PBM recommendations were implemented in Italy by law in 2015¹⁹. These recommendations suggested that PBM protocols be applied for all adult patients who are candidates for elective major surgery^{20,21}.

In Italy, blood transfusion and transfusion medicine are recognised as essential activities of the National Health Service. Healthcare services, including blood and BC collection, processing, testing, storage and distribution as well as all transfusion medicine activities, are delivered by regional health services within a federalist legislative framework. The National Blood Centre (*Centro Nazionale Sangue*; CNS) is the competent authority in Italy for blood and BC. Regional health authorities inspect, authorise

and accredit blood establishments (BE), according to regional, national and European legislation. In each of the 21 Italian regions, a regional blood centre is established by law. The regional blood centres coordinate the related local networks of BE, complying with national regulations and self-sufficiency, quality and safety plans. BE, which are mostly hospital-based, are responsible for collecting, processing, testing, storing and distributing blood and BC. Most of them also work as hospital blood banks (HBB), issuing BC to hospital inpatients, under the management of the hospital itself, with complete traceability from the donor to the patient, including haemovigilance. In 2019 the Italian population was 59,641,488 inhabitants²², while the number of RBC transfusions per 1,000 inhabitants was 40.6, as stated in the 2020 self-sufficiency national plan²³.

With the purpose of determining the main characteristics of BC recipients, acquire a broader perspective of national usage of BC, and to identify specific fields of PBM application, we conducted a national survey of BC use in all Italian BE working as HBB.

MATERIALS AND METHODS

All HBB in Italy were invited to participate in a survey of BC use by all patients who received a transfusion of RBC, platelet or fresh-frozen plasma (FFP) on a specific day. The numbers of RBC, platelet and FFP units transfused in Italy per year and per day were considered with respect to the number of BC transfused in one reference year. At the moment of the study, the most recently available national data were those referred to the year 2017¹⁵, which was therefore chosen as the reference year. The national data came from annual reports by the Italian National Blood Centre (CNS). The CNS coordinates the National Blood Information System (*Sistema Informativo dei Servizi TRASfusionali*; SISTRA) which collects the data related to the activities of the Italian Blood System. Daily BC use in 2017 was calculated as the total of BC transfused in 2017 divided by 365 days.

Participation per geographic area of the country (North-West, North-East, Centre, South, and Islands, based on the Nomenclature of Territorial Units for Statistics [NUTS])²⁴ was also investigated as the percentage of BC transfusions occurring in HBB participating in the study vs the number not participating in the survey.

Participants entered data electronically, using an online survey data collection sheet (*Online Supplementary Content, Figure S1*) which was a one-page pre-printed report form. The information collected was year of birth and sex of the BC recipient, and clinical indication, for every unit of RBC, platelets, and FFP transfused on Wednesday, 10th of April 2019. This date was selected as representative of an “ordinary” day; Saturday and Sunday were excluded because elective surgical procedures are not performed on these days.

The age of the patient receiving each unit was expressed as 2019 minus birth year. RBC, platelet and FFP are intended as therapeutic adult and neonatal units. FFP includes, as specified in Italian Blood System data¹⁵, recovered plasma, source plasma, source plasma from multiple apheresis and pharmaceutical inactivated plasma. The clinical indication was specified for every adult or neonatal unit of RBC, platelets and FFP transfused on the survey day. The categories of clinical indications were based on the Italian Guideline of clinical use of blood²⁵ and other national studies^{12,13}. The analyses were performed on both the recipients and the BC.

Regarding recipient data, the number of patients transfused, median and mean recipient age across all units used, the male-to-female ratios at all ages, the distribution of recipients by sex and age group, the number of BC transfused to males and to females, and the percentage of RBC, platelets and FFP transfused to males and females by 5-year age group were calculated.

Concerning BC data, the RBC, platelet and FFP units transfused for the main clinical indications were calculated. All platelet units are expressed as “therapeutic platelet dose”. An “adult platelet dose”, meaning $\geq 2 \times 10^{11}$ platelets, is conventionally composed of five single units of whole blood-derived buffy coats. Each unit of apheresis platelets is equal to an “adult platelet dose”; paediatric platelet dose is conventionally composed of one single unit of whole blood-derived buffy coats¹⁵. The mean number of units transfused per patient was determined for RBC and platelets, but not for FFP because the specific dose, calculated as mL/kg, was not available. The clinical indications for RBC transfusion were first divided by broad category (surgical and medical). The following indications were considered as surgical: cardiothoracic surgery, gastrointestinal (oesophageal, gastric, colorectal,

hepatic, pancreatic) surgery, orthopaedics and trauma, urology, vascular surgery, neurosurgery, obstetric and gynaecological surgery, and otolaryngology. Medical indications included anaemia (acquired non-oncological, neonatal/foetal, post-operative, oncological and onco-haematological, in solid organ transplantation, thalassaemia and haemoglobinopathies, not defined), gastrointestinal bleeding, and haemorrhage. For the main indications for RBC, platelet, and FFP transfusions, the most frequent sites in which the transfusions were administered were specified, as percentages of total transfusions.

All data were first managed with the software programme Excel, v. 14.1.0 (Microsoft Inc., Redmond, WA, USA). Data quality control and analyses were performed using the STATA software package (Stata, version 11.2; StataCorp, College Station, TX, USA).

RESULTS

Participation and data

Of the 237 HBB invited to participate, 153 (64.5%) returned 4,356 reports.

The total number of BC transfused in all HBB in the reference year 2017 was 3,022,813 (2,473,714 RBC, 259,036 platelets, 290,063 FFP). The BC transfused in 2017 in HBB that participated in the survey and returned reports were 2,358,393, representing, when compared to the BC transfused in Italy in the same year, 78% of transfusions. *Online Supplementary Content, Figure S2* shows the number of BC transfused in HBB participating and not participating in the survey in the reference year (2017) and illustrates geographical variations among NUTS: North-West, 73.2%; North-East, 100%; Centre, 71.1%; South, 67.5%; and the Islands (79%).

The mean number of BC transfused in a day in 2017 was 8,282, while the number of BC transfused on the 2019 survey date in HBB from which reports were received was 7,523, equivalent to 90.8% of the mean number of BC transfused in a day in 2017.

Characteristics of the blood component recipients

On the day chosen for the survey, 4,356 patients were transfused of whom 2,096 were women (48.1%), and 2,254 were men (51.7%). Data on gender were missing for six patients.

The BC recipients' median and mean ages were 73

(range, 0–106) and 67.5 years, respectively. There were 1,437 recipients aged more than 80 years old, who accounted for 33.0% of all recipients. Almost two-thirds of patients (2,826; 64.9%) were aged more than 65 years, whereas 132 (3%) were younger than 15 years. The male-to-female ratio for all ages was 1.08.

The distribution of recipients by sex and by 5-year age group is shown in **Figure 1**. There were no relevant differences between the proportions of males and females, except in

the age band from 30 to 54 years and over 90 in which the mean male-to-female ratio was 0.7 and 0.5, respectively. The percentage distribution of RBC transfusions given to males and females, by 5-year age group (**Figure 2**), has a shape similar to that of recipient distribution by age group, probably because RBC are the most frequently transfused BC; the percentages of platelets and FFP transfused to males and females, by 5-year age group (*Online Supplementary Content, Figures S3 and S4*) did not

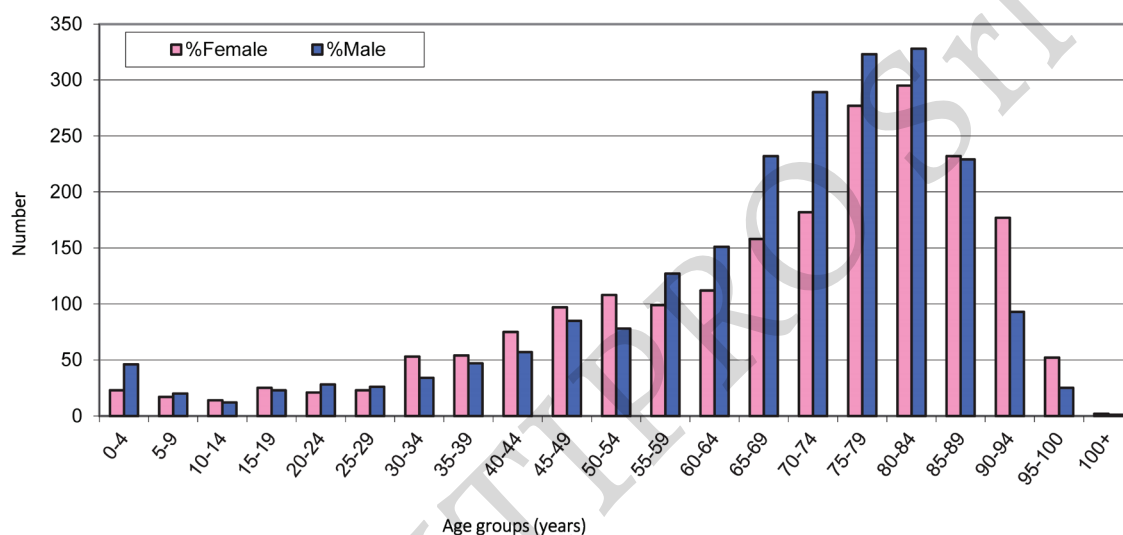


Figure 1 - The distribution of blood component recipients by sex and 5-year age group

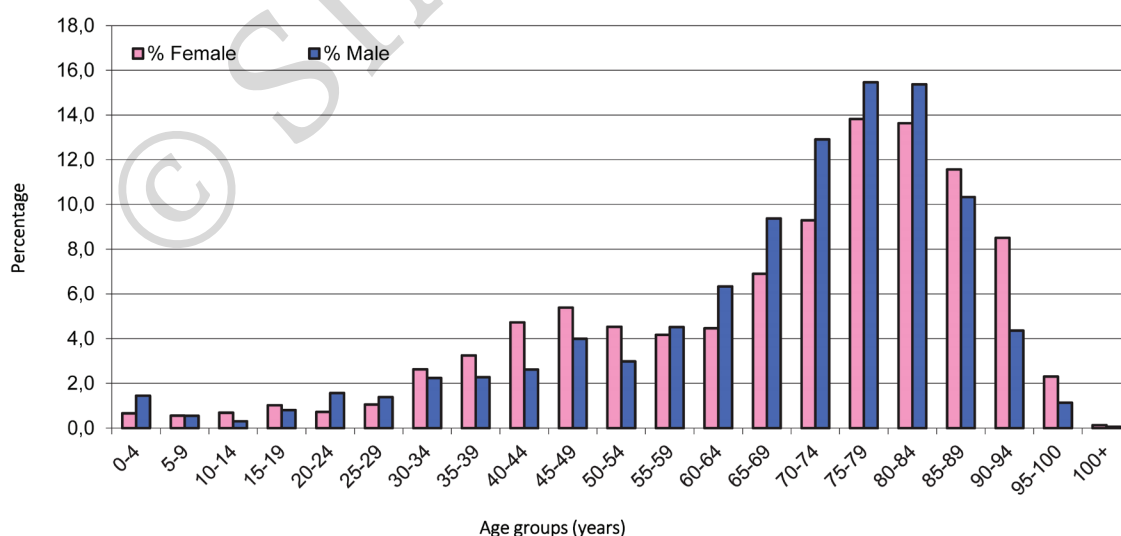


Figure 2 - The percentage of red blood cell units transfused to males and females, by 5-year age group

seem to show particular trends among age bands, possibly because of the small numbers of transfusions in the period surveyed (24 hours).

A total of 3,953 BC were transfused to males (52.5%) and 3,560 to females (47.3%), while the recipients' sex was not specified for 10 (0.4%) BC. With regard to the distribution of BC use according to sex, males received 3,254 (82.3%) RBC, 320 (8.1%) platelet and 379 (9.6%) FFP transfusions, while females received 3,045 (85.5%) RBC, 240 (6.7%) platelet and 275 (7.7%) FFP transfusions.

Use of blood components

Each of the 4,356 reports provided data from a patient who was prescribed one or several BC which were transfused into them on the survey day. **Table I** summarises the BC received by the 4,356 patients.

Among the patients who received at least one RBC unit, 50.0% were transfused with only one unit and 41.5% with two units (cumulative percentage, 92.49%). Among recipients of platelets or FFP, 93.8% received one platelet unit, while one unit of FFP was transfused to 24.7% of patients and two units of FFP to 27.8% (cumulative percentage, 52.6%). Regarding FFP transfusions, among patients in the year bands over 15 years, i.e., adult patients, 19.9% received only one FFP unit and 29.9% received two (cumulative percentage, 49.85%).

On the day of the survey, 6,309 RBC units were transfused to 3,850 recipients, 66.7% of them for a medical indication and 32.4% for a surgical indication. The number of RBC units transfused, the number of recipients, and the mean number of RBC transfused per recipient for medical and surgical indications are shown in **Table II**.

Table I - Blood components received by the patients on the survey date

Blood components	Patients (n=4,356)	
	N	%
Red blood cells only	3,670	84.3%
Plasma only	111	2.6%
Platelets only	387	8.9%
Red blood cells and plasma	55	1.3%
Red blood cells and platelets	105	2.4%
Plasma and platelets	8	0.2%
Red blood cells, plasma and platelets	20	0.5%

Among medical indications, the highest number of RBC were transfused for acquired non-oncological and onco-haematological anaemia, then thalassaemia and haemoglobinopathies. The majority of RBC transfusions for acquired non oncological anaemia were administered in Emergency Departments/Intensive Care Units (30.9%) and Medicine services (23.6%), while 42.7% of RBC transfusions for onco-haematological anaemia were in Oncology/Haematology services and 12.7% in HBB. RBC

Table II - Red blood cell transfusions

Indications	N. of RBC transfusions	%	Patients	Units/patient
Medical				
Acquired non-oncological anaemia	1438	22.8	971	1.5
Oncological anaemia	996	15.8	741	1.3
Thalassaemia and haemoglobinopathies	651	10.3	342	1.9
Cancer	488	7.7	340	1.4
Gastrointestinal bleeding	449	7.1	249	1.8
Multiple trauma	79	1.3	39	2.0
Haemorrhage (AUB, haematuria, haemoptysis)	46	0.7	19	2.4
Undefined anaemia	46	0.7	32	1.4
Neonatal/foetal anaemia	17	0.3	17	1.0
Total Medical	4,210	66.7	2,750	1.7
Surgical				
Orthopaedics and trauma	717	11.4	429	1.7
Cardiac surgery	372	5.9	168	2.2
Gastrointestinal surgery	290	4.6	144	2.0
Urology	178	2.8	89	2.0
Obstetric and gynaecological surgery	145	2.3	64	2.3
Vascular surgery	136	2.2	68	2.0
Solid organ transplantation	76	1.2	28	2.7
Neurosurgery	68	1.1	38	1.8
Thoracic surgery	28	0.4	14	2.0
Postoperative anaemia	25	0.4	16	1.6
Otolaryngology	12	0.2	9	1.3
Total Surgical	2,047	32.4	1,067	2.0
Not reported	52	0.8	33	1.6
Total	6,309		3,850	

RBC: red blood cells; AUB: abnormal uterine bleeding.

transfusions for thalassaemia and haemoglobinopathies were mainly administered in Day Hospitals (40.9%) and in Oncology/Haematology services (29.8%).

Of the RBC transfused for surgical indications, 11.4% were used in the context of orthopaedics and trauma, with 90% of them being administered in general wards and not in operating theatres, Emergency Departments or Intensive Care Units. Cardiac and gastrointestinal surgery accounted for 5.9% and 4.6%, respectively, of RBC transfusions for surgical indications.

Five hundred and sixty platelet units were transfused to 520 recipients: 62.7% of the units were transfused for prophylactic purposes and 28.6% for bleeding

(before or during an invasive procedure or surgery or in thrombocytopenia). Clinical indications were not specified for 8.8% of the units transfused. Of the platelet units transfused for prophylaxis, 64.1% were administered in Oncology/Haematology services. The mean number of platelet units transfused per recipient was uniform among the categories of clinical indications (**Table III**).

Regarding FFP transfusions, 654 units were transfused to 194 recipients: 464 (71.1%) of them were for therapeutic purposes in 194 bleeding patients; 32.6% of them occurred in General Surgery and 20.6% in Cardiac Surgery. Eighteen FFP transfusions (2.8%) were for prophylaxis in patients with inherited clotting factor deficiency for whom virally inactivated specific clotting factors were not available, 109 (16.6%) were transfused during plasma exchange procedures or neonatal exchange transfusions (**Table IV**). The mean number of FFP units transfused per recipient was not calculated because the definition of a FFP unit¹⁵ comprises more than one standardised product.

DISCUSSION

This study is the first ever conducted on the epidemiology of BC transfusion in Italy at the national level. The survey found that 66.6% of BC recipients are more than 65 years old, with no relevant differences between males and females, as observed in other studies^{12-14,26}, except in the age band from 30 to 54 years old, in which the mean male-to-female ratio was 0.7, perhaps related to obstetric and gynaecological indications for transfusions. Females were also prevalent among BC recipients over 90 years old (male-to-female ratio 0.5), probably in relation to the longer life expectancy of the female population who, in 2018, at 65 years of age had a residual life expectancy of 22.4 years (+0.3), compared to the 19.3 years (+0.2) for men²⁷.

In agreement with previous epidemiologic surveys of blood usage¹²⁻¹⁴, our study shows that RBC transfusion has been aimed at the elderly, with almost 50% of RBC transfused into patients older than 70 years. As expected, RBC are the most frequently transfused BC: more than 84% of BC recipients received only RBC and 50.0% of them were transfused with only one unit^{14,24}. The transfusion of only one unit could be in line with the use of restrictive transfusion thresholds and the application of the “only one strategy” i.e. in clinically stable inpatients needing

Table III - Platelet transfusions

Indications	N. of platelet transfusions	%	Patients	Units/Patient
Prophylaxis	287	51.3	280	1.0
Bleeding during invasive procedures or surgery	113	20.2	96	1.2
Prophylaxis before invasive procedures or surgery	64	11.4	61	1.0
Not specified	49	8.8	43	1.1
Bleeding in thrombocytopenia	47	8.4	40	1.2
Total	560		520	1.1

Table IV - Fresh-frozen plasma transfusions*

Indications	N. of FFP transfusions	%	Patients
Bleeding in surgical procedures/trauma/delivery	319	48.8	104
Plasma exchange in TTP	97	14.8	10
Bleeding in DIC	75	11.5	27
Not specified	63	9.6	23
Bleeding in inherited clotting factor deficiency*	35	5.4	10
Bleeding in massive transfusion	35	5.4	9
Prophylaxis in inherited clotting factor deficiency*	18	2.8	9
Neonatal exchange transfusions	12	1.8	2
Total	654		194

*The mean number of FFP units transfused per recipient was not calculated because the definition of a FFP unit¹⁵ comprises more than one standardised product.

FFP: fresh-frozen plasma; TTP: thrombotic thrombocytopenic purpura; DIC: disseminated intravascular coagulation; *Virally inactivated specific clotting factors not available.

RBC transfusions a single-unit blood transfusion policy shall be adopted and further RBC units should only be transfused after a thorough clinical reassessment of the patient²⁰.

The majority of RBC units (66.7%) were transfused to medical patients, while most of the platelet transfusions were for prophylactic purposes and FFP was mainly used for bleeding in patients undergoing surgical procedures, trauma or delivery.

The most frequent indication for RBC transfusion was acquired non-oncological anaemia, an undefined diagnosis; interestingly, 30.9% of transfusions were administered in Emergency Departments or Intensive Care Units and 23.6% in Medicine Departments. Clinically significant anaemia, requiring RBC transfusions, is frequently observed in Emergency Departments where, according to several studies, at least 20% of packed RBC transfusions are administered²⁸⁻³¹. Recently, it was shown that 4.6% of anaemic patients referred to Emergency Departments were transfused, the iron balance test was rarely ordered among microcytic patients and that intravenous iron was prescribed for fewer than 10% of eligible patients. The Authors concluded that PBM principles should also be applied in Emergency Departments in order to promote a more appropriate and effective clinical approach to anaemic patients³². The same Authors later confirmed that early intravenous iron administration in the Emergency Department reduces the transfusion of RBC units, hospital admissions, re-transfusions, duration of stay in hospital and costs³³. Although not all cases of severe or moderate acquired non-oncological anaemia referred to Emergency Departments should be treated with intravenous iron administration, a quick and effective definition of a highly probable iron deficiency status in patients with stable haemodynamics and few clinical symptoms, could sometime avoid RBC transfusion.

As seen in previous surveys^{10,12-14} and recently confirmed in a large observational multicentre study³⁴, orthopaedic conditions represent the most frequent indication for RBC transfusion in the surgical setting. In Italy, PBM protocols were promoted nationally in 2015¹⁹ and regulatory guidelines for the implementation of PBM in candidates for major orthopaedic surgery in adults and elective major surgery were published in 2016 and 2017, respectively^{20,21},

but preliminary data on the clinical use of BC at a national level were not available before this study. The findings of future surveys of the clinical use of blood could be compared with those of the present survey in order to detect developments.

With regard to platelet transfusions, most units were given prophylactically, with the commonest indication for platelet use being prophylaxis in haematological diseases, as found in other studies^{12,14,35}. However, our survey did not collect information on the platelet count before transfusion and a subsequent survey should investigate transfusion thresholds. The large share of platelet usage allocated to prophylaxis of bleeding calls for efforts aimed at optimising this use. Indeed, overall use in prophylaxis in onco-haematological disease could be substantially reduced by lowering the platelet count threshold in selected patients without compromising safety^{36,37}. There are still debates about prophylactic platelet transfusions in thrombocytopenic patients prior to surgery. A Cochrane review found insufficient evidence to recommend the administration of pre-procedure prophylactic platelet transfusions in this situation, with a lack of evidence that transfusion resulted in a reduction in post-operative bleeding or all-cause mortality. These authors hoped for future trials, including those involving major surgery and reporting on bleeding, adverse effects, mortality (as a long-term outcome) after surgery, duration of hospital stay and quality of life measures³⁸.

With regard to FFP, the survey showed that 71.1% of transfusions were for therapeutic use; in fact, plasma is used extensively in the treatment of bleeding patients, even though evidence from randomised controlled trials comparing its effects in this context with those of other therapeutic interventions is still lacking³⁹. On the other hand, investigations about BC therapy with a targeted ratio of packed RBC, platelets, and plasma as a treatment for massive haemorrhage in trauma or pre-hospital administration plasma in traumatic haemorrhagic shock⁴⁰⁻⁴² are still ongoing and may re-evaluate the use of plasma in the setting of trauma.

It is noteworthy that, among recipients who received at least one unit of FFP, 24.7% were transfused with only one unit and 27.8% received two units. Among patients over 15 years old, i.e., adult patients, 19.9% received only one FFP transfusion and 29.9% received two FFP (cumulative

percentage, 49.85%). Although the dosage per patient is not known, because the definition of a unit of FFP comprises more than one product¹⁵, the data do suggest inadequate doses and, therefore, inappropriate use, as found in other studies on the epidemiology of blood transfusion¹². In order to evaluate the appropriateness of plasma transfusions the dose per patient should be determined in future investigations.

Our study has some weaknesses. The sample of units transfused nationally in 24 hours only was limited and may not be adequately representative. Another limitation, again related to the study's duration, is that it was not possible to determine transfusion requirements associated with a specific pathology, because the management recorded for each patient was only 1 day and hence incomplete. It is, therefore, possible that infrequent conditions and procedures associated with high BC use, such as massive haemorrhages, extracorporeal cardiac pumps, or thrombotic thrombocytopenic purpura, might have been under- or overrepresented in our sample. On the other hand, our study does have several strengths, first of all, the participation was very good: although the response rate of the HBB was 64.5%, we estimated that the activity of responding HBB represented 78% of the yearly national activity (when expressed as number of BC transfused in the reference year), or, more than 90% when expressed as mean number of BC transfused nationally in the day included in this survey; participation was also uniform among Italian geographic areas. Furthermore, the study examined the clinical indications on the transfusion request, which are more likely to provide the real reason for the transfusion.

CONCLUSIONS

Our study is the first ever conducted on the epidemiology of BC transfusion in Italy at the national level. It gives an indication of current transfusion practice in Italy, which could facilitate demand planning by blood services and guide application of PBM initiatives.

The survey provides a snapshot of the epidemiology of blood transfusion in Italy in the year 2019. It would be necessary to repeat this survey in the future to have a dynamic view of BC use and to capture the most relevant trends.

Another future development could be a national web-based

blood management application. Based on the clinical indications for the BC used in this survey, a national clinical benchmarking database could be developed with the goal of collecting information on the reason for blood use and linking it with patient-specific data and laboratory results.

ACKNOWLEDGEMENTS

We thank Roberta Frisenda (Italian Society of Transfusion Medicine and Immunohaematology, Rome, Italy) who managed and facilitated data exchange between the Authors and the SIMTI group for Clinical use of blood in Italy. We also acknowledge the Italian National Blood Centre (National Institute of Health, Rome, Italy) for providing the data on blood component utilisation in the country.

AUTHORSHIP CONTRIBUTIONS

GF, FB, FF and PB designed the study and reviewed the paper. GF wrote the manuscript and, together with CG and CM managed the data and performed the quality control and statistical analyses. The SIMTI group for Clinical use of blood in Italy was responsible for data entry. All the Authors approved the final version of the paper.

The Authors declare no conflicts of interest.

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