

Original Article

Long-term audit of the use of fresh frozen plasma in a university hospital



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المخلص

أهداف البحث: هناك قلق عالمي بشأن الاستخدام غير الملائم للبلازما المجمدة الطازجة. أجريت هذه الدراسة للكشف عن مدى الاستخدام غير الملائم للبلازما المجمدة الطازجة في مستشفى الملك خالد الجامعي، بالرياض، وللتأكد من ما إذا كانت هناك أي خطوط توجيهية يتم اتباعها أثناء الاستخدام السريري لها.

طرق البحث: قامت هذه الدراسة بتحليل الاستهلاك السنوي من البلازما المجمدة الطازجة في مستشفى الملك خالد الجامعي خلال الفترة من 1986 إلى 2007. بعد ذلك، تم استخراج نتائج اختبارات فحص التخثر من السجلات الطبية لـ 531 مريضاً متتالياً من عدة تخصصات في المستشفى لمزيد من التحليل.

النتائج: تم صرف ما مجموعه 68,480 وحدة من وحدات البلازما المجمدة الطازجة خلال الـ 22 عاماً من الدراسة. وارتفع الاستهلاك إلى هضبة، إلا أنه انخفض بشكل كبير بنسبة 30.9%، في عام 1995 إلى أدنى مستوى له في عام 2000. وكان هناك أيضاً انخفاض متزامن ومتداخل في استهلاك كل من البلازما المجمدة الطازجة ومجموع وفيات المستشفى لكل حالة دخول. وصُرف ما مجموعه 1620 وحدة من البلازما المجمدة الطازجة لـ 531 مريضاً، وأجري اختبار التخثر قبل وبعد إعطائه في جميع المرضى تقريباً لقسم التوليد وأمراض النساء و90% من المرضى في قسم الجراحة.

الاستنتاجات: تم الكشف عن الدرجة الكبيرة من الاستخدام غير الملائم للبلازما المجمدة الطازجة في مؤسستنا عن طريق الانخفاض الملحوظ في الاستهلاك بعد

”خوف فيروس نقص المناعة البشرية“ العالمي في أوائل التسعينات من القرن الماضي. ويعكس الانخفاض الناتج في إجمالي الوفيات في المستشفى المصاحب للانخفاض المتزامن في استهلاك البلازما المجمدة الطازجة فوائد الاستفادة من بدائل علاج الدم. تم تطبيق اختبار التخثر إلى حد مرض. يمكن لعمليات التدقيق في سياسات نقل الدم وبرامج التعليم أن تؤدي إلى استخدام أفضل للبلازما المجمدة الطازجة.

الكلمات المفتاحية: البلازما المجمدة الطازجة؛ العلاج بالدم؛ نقل الدم؛ التدقيق

Abstract

Objectives: There is universal concern about the inappropriate use of fresh frozen plasma (FFP). This study aimed to determine the extent of the inappropriate use of FFP at a university hospital in KSA.

Methods: Medical records on the annual use of FFP were analysed from 1986 to 2007. Then, the results of the coagulation screening tests were extracted from the medical records of 531 consecutive patients in various departments of the hospital.

Results: As many as 68,480 FFP units were used during the 22 year study period. Consumption increased and then plateaued in 1995, but dropped dramatically by 30.9% and reached its lowest level in 2000. There was also a concomitant and overlapping drop in both FFP usage and the hospital mortality rate per patient admission. One-thousand-six-hundred-twenty FFP units were issued for 531 patients. Coagulation testing, before and after infusion, was adopted in almost all patients in the

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Department of Obstetrics and Gynaecology, in 90% of patients in the Department of Surgery and in approximately 70% of patients in other departments.

Conclusions: Significant inappropriate use of FFP at our institute has been made evident by examining the remarkable drop in use following the universal “HIV scare” of the early 1990s. The resulting drop in the hospital mortality rate, accompanying the simultaneous drop in FFP use, reflects the benefits of resorting to the use of less blood therapy. Coagulation testing was used to a satisfactory extent. Transfusion audits and educational programs could result a better use of FFP.

Keywords: Blood transfusion; Coagulation screening tests; Fresh frozen plasma; HIV

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Introduction

Fresh frozen plasma (FFP) is one of the most commonly used haemostatic blood products and its use is on the rise.¹ However, there are currently few firm indications or guidelines surrounding its use and, as a result, there are growing concerns that FFP is used inappropriately and without scientific rationale, at a time of general disquiet about the safety of blood transfusion products. The risk of transfusion-transmitted infections has decreased markedly, but there is still a prevailing worry about the non-infectious risks, specifically transfusion-associated circulatory overload, transfusion-associated graft-versus-host disease, transfusion-related acute lung injury and the transfusion of ABO-incompatible blood.^{2,3} Overall, this situation is more pressing in developing countries due to the shortage of donated blood and the wide prevalence of infections transmitted by blood transfusion, particularly HIV and hepatitis viruses.⁴

A survey of the literature uncovered numerous studies from developing countries on the trend of the use of FFP, showing a continuous reduction in its use. This reduction was generally attributed to the application of guidelines on the transfusion of blood products, the physicians that were educated on the proper use of FFP, and also the emphasis on the fact that no transfusion is completely free from the infectious and non-infectious risks of blood transfusion.^{1,5–8} Nonetheless, the inappropriate use of FFP is still widespread.^{8–12} Information in this area is lacking in our geographical region and is very scanty in developing countries. The present study is a retrospective review of the use of FFP by various clinical departments in a teaching hospital in KSA, with the aim of figuring out the long-term (22 years) trend in the use of FFP and to what extent coagulation screening tests are used as both a guide to its infusion and a measure of its efficacy.

Materials and Methods

This is a retrospective audit performed at King Khalid University Hospital (KKUH), which is an 850-bed, major teaching hospital of the College of Medicine, King Saud University, Riyadh. It has 33 clinical divisions including Accident and Emergency, Cardiac Surgery, Haematology/Oncology, Medical, Surgical and Neonatal Intensive Care Units. There is a Hospital Blood Bank that serves as a blood transfusion centre and is fully responsible for the recruitment of blood donors, collection and testing of donated blood, preparation, storage and issuing of blood products, including packed red blood cells, platelet concentrate, fresh frozen plasma, cryoprecipitate, and filtered and irradiated components. There are *Guidelines to the Transfusion of Blood and its Derivatives* that were issued by the Hospital Blood Transfusion Committee. The blood bank records have undergone gradual modernization to reach the current fully computerized portion of the general hospital management system. This study has received ethical approval from the Institutional Review Board (IRB) of the College of Medicine. The analysis and presentation of the data are divided into two parts:

Part I: The annual overall use of FFP by the blood-consuming hospital departments (General Surgery, Medicine, including Haematology/Oncology, Renal Dialysis Unit, Paediatrics, Obstetrics and Gynaecology and Cardiac Surgery), was extracted from the hospital blood bank records retrospectively, over a 22 year period from January 1986 to December 2007, and entered into a data spread sheet on a computer (Microsoft Excel) to facilitate the analysis. The FFP is conventionally prepared in the blood bank in the following manner: fresh plasma is separated from donated whole blood, collected in citrate-phosphate-dextrose (CPD) solution, after centrifugation and subsequent removal of plasma (approximately 250 ml) within 4–6 h after blood collection, and then is frozen immediately at -40°C or lower.

Part II: A review was conducted of the hospital blood bank records of 531 consecutive patients who received FFP during the period from December 2003 to June 2004, in the following clinical departments: Medicine ($n = 306$), Surgery ($n = 102$), Paediatrics ($n = 87$), Accident and Emergency ($n = 21$), Obstetrics and Gynaecology ($n = 15$). The available results were recorded on pre- and post-FFP transfusion coagulation tests: prothrombin time (PT), international normalized ratio (INR), activated partial thromboplastin time (APTT) and plasma fibrinogen (FIB) (Table 2).

Statistical analysis

This is an exploratory analysis that aims to identify station(s) at which significant changes occurred in the trend of the use of fresh frozen plasma (increasing, decreasing or unchanged) over a long time interval (22 years) and to quantify these findings and test for their significance at the 5% level. As the change in use is not expected to be linear from year to year (with no correlation between measurements collected at different times), we employed the Mann–Kendall Test for Monotonic Trend (MK test),¹³ rather than the parametric linear regression analysis that requires normal distribution of the residuals from the fitted regression; an assumption that is not required by the MK test.

Table 1: The 22 year (1986–2007) usage trend of FFP units by selected hospital divisions at KKHU expressed as total units consumed/division as well as a percentage of the total (68,470 FFP units).

Hospital division	No. of FFP units consumed (total)	No. of FFP units consumed (%)
Medicine	26675	38.95%
General Surgery	21712	31.7%
Paediatrics	9329	13.6%
Cardiac Surgery	7581	11.1%
Obstetrics & Gynaecology	1815	2.7%
Accident and Emergency	1368	4.6%

The linear trend (median drop per year in FFP use) was assessed using the robust linear regression Theil–Sen estimator.¹⁴ We chose this technique based on the fact that it is more accurate than a simple linear regression for skewed and heteroskedastic data and it compares well against non-robust least squares in terms of statistical power, even for normally distributed data. The strength of the trend was assessed using the MK test statistic. The years during which significant change occurred were identified. Categorical data were compared using the χ^2 test or Fisher exact test as appropriate.

Results

The results are presented in two parts:

Part I: Over 22 years the total number of FFP units transfused at KKHU was 68,480 units. Consumption increased in parallel with the gradual increase in the number of patients admitted to KKHU (Figure 1), reached a plateau in the ninth year, and then remained stable for the next four years. Thereafter, usage decreased from 4242/year in the year 1995 with a drop of 30.9%, to its lowest level (2933/year) five years later in the year 2000, representing an impressive saving of 1309 FFP units/year. Thereafter, there was a gradual increase resulting in a maximum of approximately 4500 units of FFP/year between the years 2005–2007. The total number of admissions increased gradually from over 2000 in 1986–32,000 ten years later and to below 34,000 in 1996 and remained stable up until 2007 (Figure 2).

An interesting finding from this study surfaced when we expressed both the total FFP used and hospital mortality rate per admission (Figure 3). The former (FFP Index) closely followed the pattern of the total use of FFP, and the latter displayed a concurrent drop (35.7% and 32%, respectively) that closely followed the drop noted in total

FFP in the late 1990s. The Departments of Medicine and Surgery consumed most of the FFP used at KKHU (39.95% and 31.7%), respectively (Table 1).

Part II (Table 2): One thousand six hundred and twenty units of FFP were consumed by 531 patients in the following departments: Medicine (962 units), Surgery (425 units), Paediatrics (95 units), Obstetrics and Gynaecology (76 units) and Emergency (62 units). Despite the small number of surveyed patients, the Department of Obstetrics and Gynaecology topped the rest in the completeness of the coagulation testing data, as both PT and APTT were performed in almost all of their patients. The Department of Surgery followed, with the pre- and post-transfusion PT and the APTT completed in more than 90% of their patients. The Departments of Medicine and of Accident & Emergency also performed well in the evaluation, particularly with respect to the post-transfusion coagulation testing, which was noted in approximately 70% of their patients. The post-transfusion use of the INR was noted in more than 60% of patients in all departments, reaching 86% in the Department of Medicine; however, in the Department of Paediatrics, the use of the post-transfusion INR was recorded in only 31% of FFP receivers.

Discussion

FFP is the replacement therapy used in the management of patients and haemostatic haemorrhagic disorders are a major source of coagulation factors. Like most blood products, the use of FFP is on the rise, which raises concerns about its inappropriate use and the possibility of exposing recipients to the infectious and non-infectious risks of transfusion.^{15,16} The situation is especially critical in developing countries, which suffer from frequent shortages in their blood supply, relatively high prevalence of transfusion-transmissible infections among apparently healthy individuals, and poor blood-testing facilities.^{4,17}

Numerous publications have highlighted the need for and proven benefit of auditing the use of blood products as a reliable tool to uncover not only their inappropriate use but also to monitor the extent of the compliance with the set guidelines for the use of these products.^{5–8,10–12} The guidelines that are frequently followed are mostly from regulatory bodies such as the British Committee for Standards in Haematology (BCSH) Guidelines in the United Kingdom,¹⁶ the American College of Pathologists (CAP) and the American Association of Blood Banks (AABB) in the USA.¹⁸ In addition, many institutions have their own guidelines. Published audits vary widely in the criteria that are used to judge whether FFP use is

Table 2: Coagulation testing before (pre-) and after (post-) fresh frozen plasma transfusion in various hospital divisions at King Khalid University Hospital, Riyadh.

	PT (pre)	PT (post)	PTT (pre)	PTT (post)	FIB (pre)	FIB (post)	INR (pre)	INR (post)
Medicine	37.6	86.6	36.6	86.3	21.2	53.6	35	78.1
Surgery	58.8	90.1	57.8	92.1	44.1	66.7	56.9	71.6
Paediatrics	36.8	69.0	35.6	69	0.2	10.3	16.1	31.0
Acc. & Emerg	47.6	90.4	42.9	85.7	4.8	14.3	47.6	81
O and G	53.00	100	53	100	3.3	40	26.7	66.6

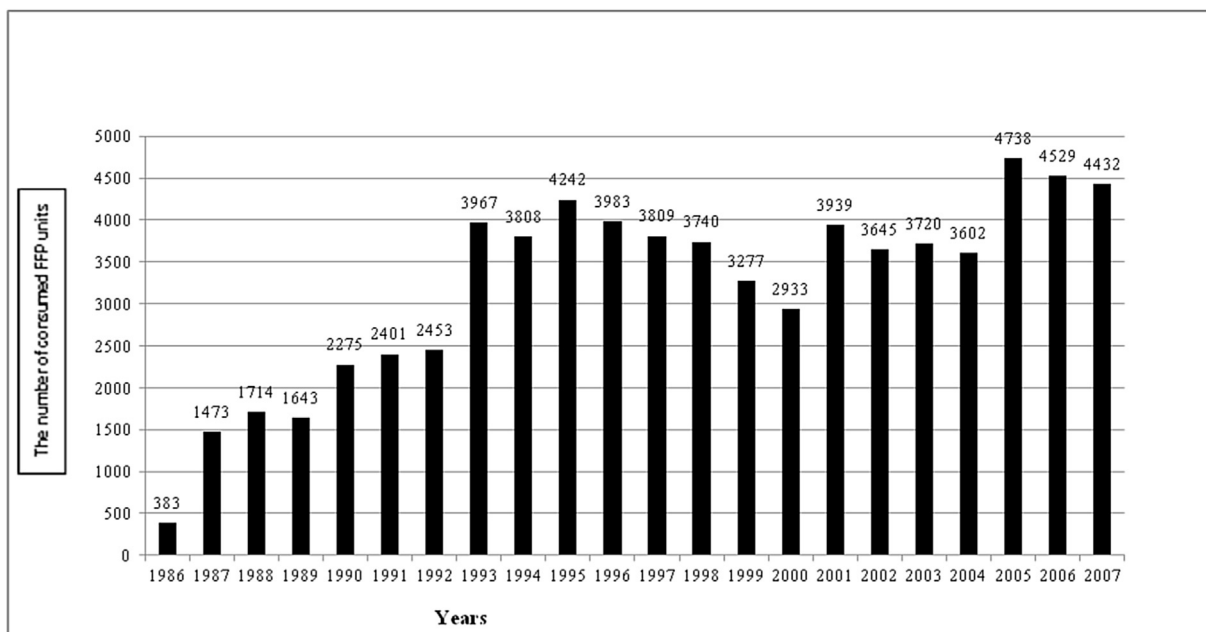


Figure 1: The 22 year total use of units of FFP at King Khalid University Hospital (KKUH) Riyadh. Mann–Kendall trend test: $P = 0.024$, Sen slope estimation (median rise/year) = 0.22, 95% confidence interval = 0.17 to 0.29. Change-point test: $P = 0.003$; the change occurs after the year 1995. Numbers are %s unless otherwise indicated. p-value: χ^2 test. †: Fisher exact test.

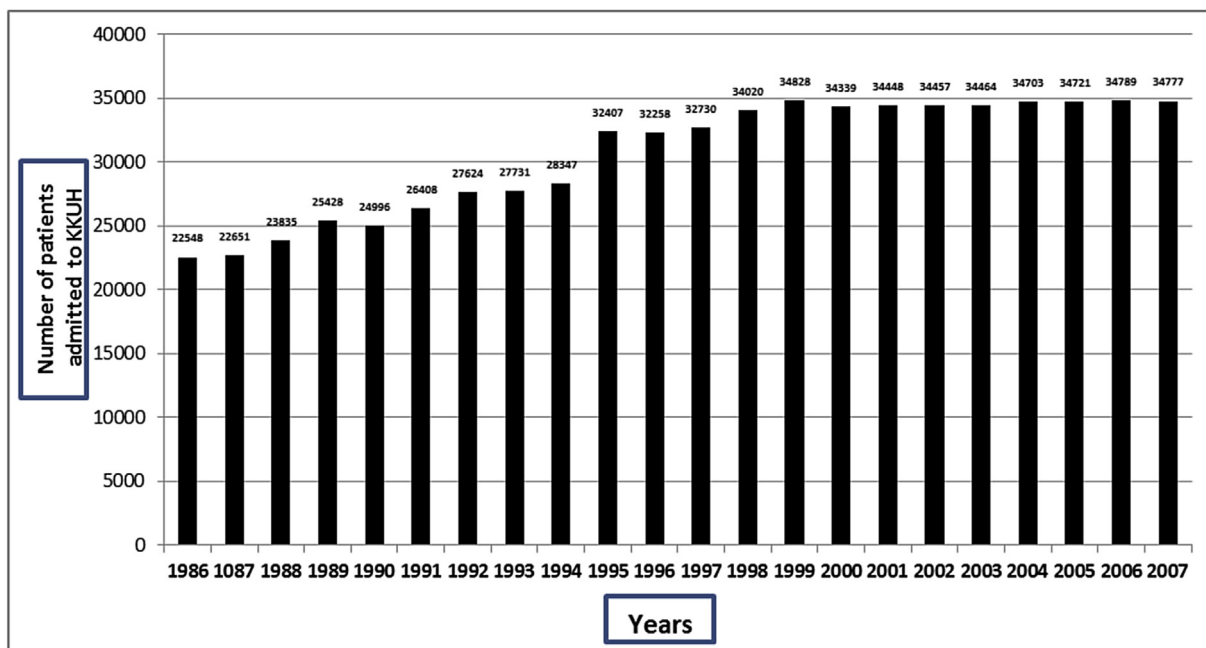


Figure 2: The total patient admissions/year to King Khalid University Hospital (KKUH), Riyadh, 1986–2007.

appropriate or not. Considerations should also take into account the disparity in sample sizes, whether the audit is prospective or retrospective, physician habits, clinical settings, and variations in severity within specific diseases^{19–22}; it is no wonder, therefore, that the reported prevalence of the inappropriate use of FFP varies widely, from 31–32%^{6,12} to 63.3%.⁹ This variability makes it difficult to decipher meaningful comparisons from different published audits.

The current survey is retrospective, based on the available databases in our blood bank and has facilitated the long-term review of FFP use. This enables us to reveal the extent of overuse/wastage of FFP in our institution. It has also made it possible to find out how often clinicians use coagulation testing when ordering FFP.

It is clear from the 22 year review of the overall annual use of FFP at KKUH (Figure 1) that there was a phenomenal 30% drop in use from a maximum in 1995 to its lowest

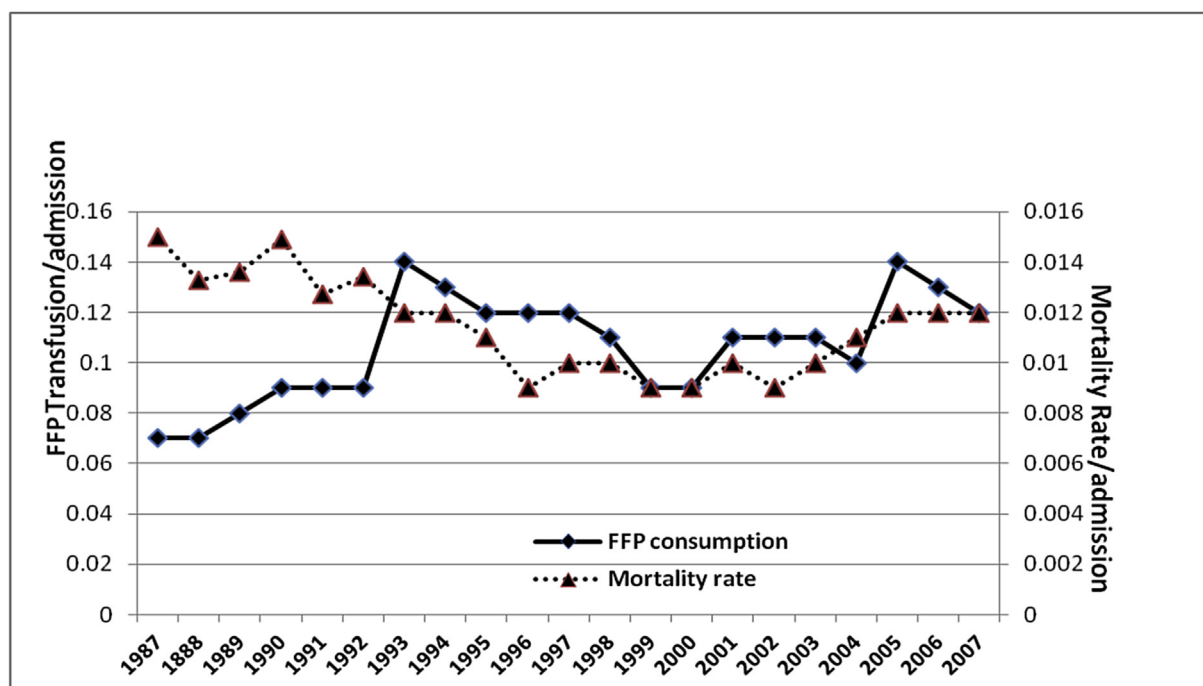


Figure 3: The 22 year usage trend showed the annual use of fresh frozen plasma units and annual hospital mortality rate expressed by per patient admission to King Khalid University Hospital, Riyadh.

level (2399/year) in 2000, with no parallel significant changes in the annual number of patient admissions (Figure 2). This reflects the magnitude of the inappropriate usage and wastage of FFP that existed in our institute before 2000. This massive drop in use is most likely due to the increasing awareness about the safety of blood transfusion, particularly the general public's unease and worry about the transmission of HIV by blood transfusion. This HIV "scare" seems to have been widespread among both patients and their treating physicians since the early nineties, which significantly impacted the practice of hemotherapy.^{23–25} We have recently reported a similar trend in a long-term survey of the use of packed red blood cells.²⁶

Another interesting finding of this survey emerged when both the total annual FFP usage and hospital mortality rate were expressed per patient admitted to the hospital (Figure 3). There was a remarkable drop in both parameters (35.7% and 32%, respectively) in the late 1990s, reaching the lowest level in 2000–2001. The overlapping trends in the drop of both FFP usage and hospital mortality, reflects two important points: first, physicians are prescribing less units of FFP per patient than they were before the 'HIV' scare'; second and most interestingly, the decreased use of FFP was accompanied by a concurrent drop in patient mortality. This point is further confirmed by per patient mortality showing a gradual increase after the year 2001, showing a concurrent, parallel, gradual increase in FFP used per patient (Figure 3). Other than improved medical care offered to patients, it is now the general understanding that the decrease in the use of blood transfusion results in better rates of patient morbidity and mortality.^{27–29}

In our institute we have a Blood Transfusion Committee that issues a booklet of guidelines on the transfusion of blood

products, which are taken with some modifications from the AABB guidelines. The instructional/educational message of this booklet may have resulted in increased awareness by physicians on hemotherapy, which in turn may have generated a change in their attitude and encouraged them to resort to blood therapy products less liberally. According to these guidelines, the indications for the use of FFP can be summarized in the following way: active bleeding resulting from multiple acquired and congenital coagulation factor deficiencies (such as in bleeding liver disease, disseminated intravascular coagulation and massive blood transfusion); reversal of warfarin in a patient with active bleeding; rarely, as a replacement fluid when performing plasma exchange, particularly in the treatment of thrombotic thrombocytopenic purpura, if cryoprecipitate extracted plasma is not available.

It should be noted that the data obtained in the current audit, particularly the dramatic drop in use of FFP between 1995 and 2000, could not be related directly to the time of the issue of successive guidelines in the years 1987, 1992 and 2000. To produce a consistent change in blood ordering practices, guidelines must be supported by educational programs that are conducted by the blood bank staff and combined with the pre-approval of the transfusion by the blood bank physician.³⁰ However, others found 'the compliance with transfusion policies poor and over-ordering of blood products commonplace'.³¹

Guidelines and education must be given time to cause a change in the attitudes of physicians towards blood therapy. Therefore, the decision to transfuse to patients will remain a mainly clinical decision in the hands of the attending physician, who takes the clinical conditions of patients into account based on previous experience in similar clinical situations and decides whether the benefits of the transfusion

of blood products outweigh the risks.^{31,32} The decision to transfuse could also be influenced by a 'trigger' or a lower limit of circulating blood level constituents, below which the transfusion of FFP or any other blood product is recommended.³³ However, numeric triggers do not override the decision of the attending physician on whether to transfuse blood products.^{33,34}

Other than the careful implementation of guidelines supplemented by education, communicating the outcome of audits of the use of blood products was shown to improve the inappropriate use of blood products, including FFP.³⁵ These steps can be further boosted by the employment of a transfusion nurse, which was shown to be an effective way to facilitate transfusion efficiency and patient safety, in addition to the close monitoring of the use of FFP and other blood products.⁶

The gradual increase in the use of FFP that occurred in our institute after 2000, which we also noted in the use of packed red blood cells,²⁶ can be accounted for by the expansion of patient services in the Haematology/Oncology, the Cardiac Surgery and the Accident and Emergency Departments, which are all known to be major consumers of blood products.³⁶

In the second part of this audit, we sought to find out how frequently physicians resort to using coagulation tests, particularly the PT and the APTT, before and after FFP infusion, as a monitor of the haemostatic status of the patient before infusion, and also as a guide of its efficacy; the use of the PT and APTT has been stated in the guidelines of the BCSH,¹⁶ the WHO guidelines,³⁷ the CAP,¹⁸ the American Red Cross and the AABB.³⁸ The PT and the APTT are currently the most popular indicators of coagulation that are used by clinicians; newer overall tests of haemostasis, such as thromboelastography and the thrombin generation test are still awaiting validation.^{39,40} On the other hand, the INR, which was originally devised as a monitor of warfarin therapy, has not gained popularity in relation to the monitoring of FFP transfusion, but it is still being used for this purpose. A recent report on non-bleeding, critically ill patients found no significant improvement in the thrombin generation test, the thromboelastography parameters or the correction of the INR, when comparing pre- and post-FFP infusion measurements.⁴¹

The findings of our audit indicate that the application of the guidelines relating to the use of coagulation tests before and after FFP transfusion is very satisfactory in our institute, as it was followed in more than two thirds of the surveyed patients in all clinical specialities (Table 2). In two departments (the Department of Obstetrics and Gynaecology and the Department of Surgery), the PT and APTT were performed before and after FFP transfusion in more than 90% of their FFP-transfused patients. Other surveyed departments, particularly the Departments of Medicine, Accident and Emergency resorted to coagulation testing in over 70% of patients. This likely reflects the high level of awareness and compliance with guidelines among the treating physicians on the potential benefits of utilizing the currently available objective laboratory tests for monitoring FFP therapy. Similar popularity in the use of coagulation tests was also noted in some earlier published audits,^{8,11,12,18,42} but was far less popular in others.³⁹ The disagreements surrounding the use of coagulation testing, when resorting to FFP transfusion,

underscores the need for good-quality randomized controlled trials to confirm, or otherwise, the benefit of coagulation tests, particularly the PT and APTT, to support the prophylactic infusion of FFP and also to validate the use of the new global tests of haemostasis, such as thromboelastography and the thrombin generation test, as reliable markers of *in vivo* coagulation.^{40,43,44}

The current study has some limitations. It is retrospective, and accordingly, there was no detailed information on the clinical indications for the transfusion of FFP, patient's clinical state or whether the transfusion decision was based on laboratory results or trigger levels. Moreover, was not possible to ascertain the number of admissions in each clinical unit to obtain a definitive estimate of FFP usage per patient. This missing information, if available, could have added more depth to this audit. These limitations should be considered when planning future prospective audits.

Conclusion

The current 22 year audit of FFP use uncovered the extent of inappropriate use of FFP at our institute; usage peaked between 1992 and 1995 and dropped 30% to its lowest level in 2000, when the number of admissions and hospital mortality rate remained stable. Thereafter, usage increased gradually with the expansion in Accident & Emergency, Hematology/Oncology and Cardiac Surgery services. We believe that the observed drop in usage is attributable to the HIV infection scare that dominated transfusion practice in the early 1990s. The use of coagulation screening tests, before and after FFP transfusion, is popular at our institute. In the future, physicians should be requested to provide full documentation of their justification for prescribing FFP, and this information should be used when re-writing guidelines. Lastly, communicating the findings of audits on FFP usage to physicians to supplement educational efforts will add greater value to the efforts in compiling them. These steps will guarantee proper transfusion efficacy and patient safety as well as help to reduce wastage of limited blood bank resources and lower the cost of the service.

Conflict of interest

The authors have no conflict of interest to declare.

Authors' contribution

AGMAG: Conception of the research idea, research design, acquisition and interpretation of data, drafting, and revision and approval of the final version. AKA: Conception of the research idea, interpretation of the data, and revision and approval of the final version. AKMA: Conception of the research idea, interpretation of data, and revision and approval of the final version. SBAA: Analysis and interpretation of data, artwork, and revision and approval of the final version. MB: Analysis and interpretation of the data as well as revision and approval of the final version.

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