The OrbiSac System: results and organizational impact

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Background and objectives. Growing health care demands, the uneven distribution of requirements for highly specialised services and the limits to the resources available to ensure an adequate response to the health care demands all make clear the managerial and macroeconomic need to adapt the organizational set-up of the health care facilities, redistributing the productive activities and care services in the territory, to meet the demands.

We also found that it had become necessary to identify a different organizational model from the one in use in order to match the availability of platelet concentrates to the dynamics of the increased requests for this blood component in the setting of an Interhospital Immunotransfusion Department that involves the hospitals of Rimini, Forlì and Cesena.

Methods. Observational and statistical methods were used to determine the production, productivity, efficiency, efficacy and cost-benefit ratio of the production of platelet concentrates and the appropriateness, with respect to the dynamics and territorial distribution of the requests, before and after a profound procedural and methodological reorganisation which included centralisation of the production and the adoption of an automatic instrument for processing platelets from buffy-coats (OrbiSac System).

Results. The reorganization enabled the Department to reach almost complete self-sufficiency, to produce concentrates with a platelet content conforming with the indications of ministerial decrees, to uniform the quality of this blood component within the Department and to improve the use of human resources.

Key words: platelet concentrates, productive potential, automated production, OrbiSac System.

Introduction

Since 1998 the Transfusion Medicine Unit of the *Bufalini hospital* of Cesena has collaborated with the Immunotransfusion Services (SIMT) of Rimini and Forlì in a functional interhospital co-ordination, named DITI (Interhospital Immunotransfusion Department).

The Services involved retain their autonomy and responsibility within the Local Health Authority to which they belong, but collaborate with each other, using the same protocols, having centralised productive activities (NAT HCV–HIV-HBV testing, platelet production, freezing of stem cells from umbilical cord blood) and managing a shared departmental blood bank, with overall evaluation of stores and excesses. It is the DITI, and not the individual Services, which is the interlocutor with regional governing bodies with regards to the practical and organizational aspects of the management of transfusion activities.

Most of the patients treated with platelet transfusions in the territory supplied by the DITI have haemorrhages, are cancer patients undergoing chemotherapy or are patients with oncohaematological diseases[1].

The catchment population is formed of 664,610 residents and there are 2,666 hospital beds available (data updated to 31/12/05).

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The increased request for platelet therapies, identified in 2002 from the indicators of performance monitored annually in the DITI, exposed the productive sector's difficulty in meeting the demands.

The management of the DITI, therefore, decided to conduct an analysis of the organization of the production and distribution of platelet concentrates in order to determine suitable organizational responses.

Materials and methods

Production and productivity

Conventional statistical instruments, supplied with the computerised management systems in use in the DITI (Eliot and WinSit), were employed to determine the production and consumption of platelet products in the individual Services, and monitoring programmes, implemented *ad hoc* in the Excel application, were used to control the characteristics of the platelet production. These evaluations included both the processing of the platelet concentrates and the production, use and usability of the buffy-coats.

Stages of the study

The study was carried out by comparing three distinct historical periods after 2002, the year in which the shortfall in platelet production, with respect to requirements, was identified. These three periods were: 2005, the year in which centralised production of platelet concentrates from pools of six buffy-coats was introduced at the SIMT of Cesena for the hospitals of Cesena and Rimini; 2004, the year in which the SIMT of Cesena introduced the production of platelet concentrates from pools of five buffy-coats using automatic assembly (OrbiSac System, Gambro Bct, Lund, Sweden)[2-4]; and 2005, the year in which the productive methods chosen were consolidated and controlled.

Logistical organization

The transport of the buffy-coats and platelet concentrates between the two SIMT, separated by 30 Km, was carried out at a controlled temperature (22±2 °C)[5-7] using temperature-regulated containers and exploiting the transport network previously set-up for the management of the departmental blood bank.

Quality controls

The platelet concentrates from the buffy-coat pools underwent quality controls to determine the volume and yield of each product[7].

Statistical analysis

The data were first analysed using common descriptive statistics (mean and standard deviation). The results obtained in the 3 years were compared using the *t*-test to determine the statistical significance of any differences.

Results

With regards to 2003, the 778 quality controls carried out revealed poor standardisation of the production, which could not be completely justified by the variability of the contents of the individual buffy-coats (mean volume = 293 mL, SD = 99.4; mean yield = $3.00x10^{11}$, SD = 0.9; Table I). The number of the pools produced and the human resources employed revealed the difficulties in standardising and optimising production. In contrast, a good productive potential was recorded, since many buffy-coat units, which would not have been processed in single transfusions, were recovered (Table II). In 2004, following the acquisition of the OrbiSac System, calibration of the system and training the staff to use it, we controlled about two-thirds of the production, then compared the results obtained with those of the preceding year (2003 vs. 2004).

Table I - Platelet yields in 2003 (manual method), 2004 and 2005 (OrbiSac system)

	Year 2003* Controls performed on 778 platelet pools		Year 2004** Controls performed on 939 platelet pools		Year 2005** Controls performed on 1,195 platelet pools	
	Mean values	**SD**	**Mean values**	**SD**	**Mean values**	**SD**
Weight	293 mL	99.4 mL	321 mL	25 mL	317 mL	20 mL
Residual WBC	$0.13x10^{9}$	0.35	Filtered product		Filtered product	
Platelets/U	$3.00x10^{11}$	0.9	$2.9x10^{11}$	0.5	$3.12x10^{11}$	0.46

* manual assembly of six buffy coats

** automatic assembly of five buffy coats with the OrbiSac System

Blood Transfus 2007; 5: 15-19 DOI 10.2450/2007.0010-05

Table II - Method of assembling the available buffy coats

Year 2003 – assembly of 922 platelet pools	
Source of buffy coats	% assembly of production of platelet pools
Only Rimini	33% (assembly of 1,848 buffy-coats, 308 pools produced)
Rimini + Cesena	37% (assembly of 2,040 buffy-coats, 340 pools produced)
Only Cesena	30% (assembly of 1,644 buffy-coats, 274 pools produced)
Year 2004 – assembly of 1,478 platelet pools	
Source of buffy coats	% assembly of production of platelet pools
Only Rimini	42% (assembly of 3,100 buffy-coats, 620 pools produced)
Rimini + Cesena	31% (assembly of 2,290 buffy-coats, 458 pools produced)
Only Cesena	27% (assembly of 2,000 buffy-coats, 400 pools produced)

Table III - Trend in the production and consumption of platelet pools derived from buffy-coats in the Transfusion Medicine Unit of Cesena

	Year 2002	Year 2003	Year 2004	Year 2005
Production of pools in the DITI	n.d. (Cesena 299)	922	1,478	1,503
Pools acquired from outside the DITI	n.d. (Cesena 33)	14	5	1
Buffy coats acquired from Forlì	n.d.	0	173	60
data refer only to the SIMT of Cesena				
Pools distributed to Forlì*	4	2	12	6
Pools distributed to Rimini*	5	533	993	1.098
Pools distributed to other SIMT*	3	7	7	7
Pools assigned*	170	171	396	226
Pools expired or discarded for various reasons*	146	223	147	117
* Ratio between platelet products eliminated (discarded, expired) and those available at the SIMT of Cesena	146/299 48%	223/389 57%	147/566 25%	117/334 35%
Ratio between platelet products eliminated (discarded, expired) and those available in the DITI	n.d. n.d.	496/1,196 41%	393/1,478 26.5%	423/1,503 28%

n.d.: not determinated

Overall, 1,478 platelet units were produced from pools of five buffy coats, and 939 platelet concentrates were controlled. The mean platelet yield was $2.9x10^{11}$, SD = 0.5 ($p<0.005$) and the mean volume of the concentrates was 321 mL, SD = 25 ($p<0.001$). The controls carried out on the pre-centrifugation assembled samples and on the discarded product showed that the platelet recovery was 75%.

Many of the pools produced in 2005 were also checked (79%) and the results obtained compared with those of the preceding years (2003 vs. 2005 and 2004 vs. 2005).

Overall, of 1,503 platelet concentrates from pools of five buffy-coats, 1,195 were controlled, and had a mean platelet yield of $3.12x10^{11}$ with a SD of 0.46 ($p<0.001$ for both comparisons) and a mean volume of 317 mL with a SD of 20 ($p<0.001$ for both comparisons).

The results obtained in terms of productivity and self-sufficiency are presented in table III, while the cost-benefit ratios are summarised in table IV.

Discussion

The following problems were tackled, when defining the new organization model:

a. The organization of a daily network of transport of buffy coats and platelet pools at a controlled temperature of 22±2 °C[2,3].
The pre-existing transport network for the management of other shared activities of the DITI (management of the departmental blood bank) was exploited *ad hoc*; only in exceptional cases were journeys added specifically for the transport of platelets. Specific containers, with a temperature regulated at 22 °C were bought in order to transport the platelets.

Table IV - Analysis of the resources and relative costs of processing platelet pools assembled from buffy coats using the manual method and the automated OrbiSac System

Manual method	OrbiSac System	*Advantages of OrbiSac*	*Disadvantages of OrbiSac*
6 buffy coats	5 buffy coats	Saving of one buffy coat (4 euros)*	
Transfer bag		Saving of one transfer bag (9 euros)*	
7 sterile seals	6 sterile seals	Saving of one seal (3 euros)*	
300 mL additive solution	300 mL additive solution (4.27 Euro)		
Filter		Saving of one filter (30 euros)*	
	Kit OrbiSac		Need to buy the OrbiSac kit (80 euro)*

* approximate prices

b. The impact on the organization of the Transfusion Medicine Unit of Cesena with:
   - doubling of the daily productive activity,
   - management requirements, complicated by the need to synchronise the production on the basis of the transport between two Services about 30 Km apart and on the times of the validation of the units for transfusion (the NAT test currently used in our organisation provides the validation of units for transfusion within 9:00 a.m. of the day following the donation),
   - the intrinsic problem of the platelet product, with difficulties in standardising production and the short and delicate storage.

Given the above, it was decided to buy an OrbiSac System. This choice was made in the light of the following advantages:

1) recovery of a buffy coat from every process, such that one extra platelet product can be obtained from every five donations,
2) as a consequence of point 1, an increase in the productive potential of the DITI,
3) better standardisation of the product and the productive yield,
4) less platelet concentrate infusions per patient (as a consequence of the greater yield),
5) possibility of reducing the stores of platelet pools ready for use thanks to the high speed of production,
6) as a consequence of point 5, better use of the staff dedicated to the production of blood components.

The advantages of having acquired this system were noticeable within a few months, thanks to a better objectification of working procedures.

Monitoring of the performance indicators showed a rather gratifying production profile, having brought our standard to a mean platelet yield of $3.12x10^{11}$ using five buffy-coats, with only minor variations (SD = 0.46); the capacity of platelet recovery reached 75%.

All the current staff of the Transfusion Medicine Service of Cesena hospital are trained in the production of platelets with the OrbiSac System and can be employed interchangeably for the production process.

This factor has enabled us to verify, through predetermined indicators, that the automatic system can guarantee the Transfusion Service a better standardisation of the product, by reducing the human variable to a minimum. The DITI has reached and maintained self-sufficiency in platelet products despite the continuous increase in demands. In 2005, almost 100% of the platelet products in Cesena and Rimini were produced autonomously, with only one platelet pool bought from outside the DITI and 60 buffy coats obtained from the SIMT of Forlì (equivalent to 12 pools).

The percentage of platelet products discarded because of having reached their expiry date is also very limited, being about 27-28%.

Conclusions

The acquisition of the automated production system has brought the Immunotransfusion Department of Forlì, Cesena and Rimini undoubted advantages in terms of organisation and quality. The initial financial outlay,

Blood Transfus 2007; 5: 15-19 DOI 10.2450/2007.0010-05

decided in the light of the considerations described above, has been amply repaid by the longer-term improvements.

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Received: 30 April 2006 – Revision accepted: 20 September 2006
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