

Results of an integrated program of current autotransfusion techniques

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To face the problems of allogeneic blood transfusion safety and of blood inventory shortage a program of better use of blood and autotransfusion was implemented in 1980 at our hospital. During the last two decades a number of measures have been adopted to continuously improve the efficacy of the program and its cost-effectiveness.

The aim of this paper is to present the currently utilized strategies and the results obtained.

The Gaetano Pini Orthopedic Institute is currently composed by 14 surgical wards with approximately 400 surgical beds. Five major objectives have been identified in setting up the transfusion practice in our Institute.

1. Rationalization of the blood component utilization
2. Preoperative hematological evaluation of patients candidates for elective surgery.
3. Reduction of allogeneic blood use through the appropriate use of allogeneic blood alternatives (such as the autotransfusion techniques, erythropoietin).
4. Optimization of cost-effectiveness of the alternatives
5. Improvement of the safety of bedside transfusion practice

1) Rationalization of blood component utilization

A survey carried out at the beginning of the program revealed that the requests made by surgeons were generally in excess of the real needs for intra and postoperative blood transfusion requirements. This represents a relevant problem for blood supply management and forecasting and is a well known cause of high blood component wastage rate and increased costs.

Moreover, the most important cause for inappropriate use of blood component in surgery is the inappropriateness of blood use. Indeed a number of studies have documented a general tendency to overtransfusion in this group of patients. On the basis of these considerations it has been agreed upon to adopt a strict policy for preoperative blood ordering and blood component transfusion indication.

Preoperative blood ordering

For all the procedures performed in a consistent number of cases the recommended blood order (ie. no blood, or the number of units to be reserved for the patient) is defined by the local MSBOS (Maximum Surgical Blood Order Schedule). This guideline, prepared in cooperation with the surgeons and the anesthesiologist, are approved by the transfusion committee of the hospital and are revised every year on the basis of the current blood usage.

The adoption of the MSBOS procedure actually allowed to reduce the workload due for unnecessary pretransfusion tests. Indeed in the group of patients operated on for a procedure included in the MSBOS, only 16% of the patients for which pretransfusion tests were performed didn't require any transfusion support, while this figure was 46% in the group of patients operated on for procedures not included in the MSBOS. Moreover the strict application of the MSBOS contributed to limit the wastage of allogeneic blood unit to the value of 1.3%.

Blood transfusion indication

For each blood component, specific guidelines addressing its indication have been developed and approved by the transfusion committee. The compliance to the principle expressed is strictly monitored through concurrent and retrospective audit. The results obtained in 1998 are reported in tab. I

Tab I. Proper use of blood and blood component in 1998

Parameters	
Pts transfused the day of surgery whose Hct value is > 35% on day I postop.	15%
RBCs Units transfused in the postoperative period to pts with pretransfusion	
Hct > 28%. Total:	12,6%
Allogeneic units:	9,2%
Autologous units:	17%
Pts transfused with RBCs and Plasma units	2,7%

As it can be seen from the table there is still a tendency to overtransfuse surgical patient the day of surgery. This is partially due to the difficulty to evaluate the need for transfusion support in this phase, as in the majority of the case the decision to transfuse a patient is based on an evaluation of blood losses occurring during surgery and the early postoperative period. In the postoperative period hypertransfusion differently involved allogeneic and autologous units. Allogeneic units were rarely hypertransfused (9%) while this happened more frequently for autologous units. This indicates a more "liberal" utilization of autologous units in particular aimed to facilitate early rehabilitation program of the patient.

2) Preoperative hematological evaluation

A properly timed presurgery evaluation of patients undergoing major elective surgery by transfusion specialist is of relevance to optimize the patient surgical management.

In our institute we set up a program allowing to evaluate, 25-30 days prior to surgery, the patient's clinical and hematological conditions, its expected transfusion needs and the most appropriate transfusion strategy for the specific patient. According to the protocol all the patients candidates for elective surgical procedure expected to require transfusion support have to be referred to the Transfusion Center for the pre-admission evaluation.

As preoperative anemia is a major factor in conditioning transfusion requirements, patients having low Hct/Hb values are evaluated to define its causes and when possible, to correct them. A special care is devoted to detect iron deficiency conditions.

In 1998 a total of 875 patients (74% of all the patients candidates for major surgical procedures expected to require transfusion support) have been referred for presurgical evaluation. A total of 40 patients (36 females and 4 males) had low baseline Hct values attributable to iron deficiency and were treated with intravenous administration of iron sucrose (average dose 791 ± 278 mg of elemental iron) before enrollment into the preoperative autologous blood donation (PABD) program. The treatment allowed to increase the hemoglobin value by a mean of 0.8 g/dl in a mean of 37 days (thus increasing their RBCs mass by 125 ml).

Further 137 patients, despite of good Hb/Hct values, have been detected to have suboptimal iron stores and were supplemented with intravenous iron during the PABD program thus optimizing the efficacy of the technique.

Moreover, 13 patient undergoing major elective surgery were found to have anemia not correctable with hematinics and received erythropoietin treatment. All these pa-

tients could predeposit a sufficient number of autologous blood units to completely cover their perioperative transfusion needs.

3) Alternatives to the use of allogeneic blood ***Preoperative Autologous Blood Donation***

All the patients undergoing major elective surgery expected to require transfusion support (according to MSBOS) are considered potential candidates for predeposit their own blood. Contraindications to enrolment are fever, severe coronary disease, poor general conditions and anemia (Hct <33%). As previously reported, anemic patients are evaluated to define the causes of anemia and when possible treated. In case of successful treatment, patients are subsequently enrolled into the PABD program.

The number of units to be collected is defined according to the patient's hematological conditions and the expected transfusion need. Donations (normally 400 mL each) are collected in single blood bag at 7 days interval.

Perioperative blood salvage

Recovery of blood lost during surgery or in the early postoperative period, washing and immediate retransfusion is carried out, on a shift basis, by staff members of the transfusion service.

For major orthopedic surgery if the forecast blood loss is greater than 1000 ml, intraoperative salvage is always proposed. Intraoperative blood salvage is not performed in cases of cancer, infected wounds, sepsis, or when the anticipated blood lost is less than 300 ml. In all the other cases the stand-by procedure is utilized a collection set, consisting of reservoir, vacuum line and anticoagulant line is assembled. When the reservoir contains the equivalent of more than 1 unit of blood the washing set is connected, and blood processing commenced. If the amount of RBCs collected into the reservoir is equivalent to less than 1 unit of blood, recovered blood is disposed off unless postoperative salvaging is indicated. As a routine, the surgeons are requested to control suction pressure to as low a level as possible, consistent with efficient aspiration of blood and minimal hemolysis. In tab.2 are reported the guidelines for intra and postoperative salvage utilization adopted in 1998.

Tab.2 Indications for perioperative blood salvage in different surgical procedures at the Gaetano Pini Institute

Surgical Procedure	Intraoperative Salvage	Postoperative Salvage
Total hip replacement	Stand by Optional (*)	Optional (*)
Bilateral hip replacement	Yes	Yes
Total hip prosthesis revision	Yes	Yes
Partial hip prosthesis revision	Stand by	No
Pelvis osteotomy	Stand by	No
Total knee replacement (with tourniquet)	Stand by	Yes
Vertebral arthrodesis	Yes	No
Osteosynthesis or partial hip prosthesis for femur fracture	Stand by	Optional (*)

(*) : when intraoperative blood loss is particularly relevant

Acute Normovolemic Hemodilution

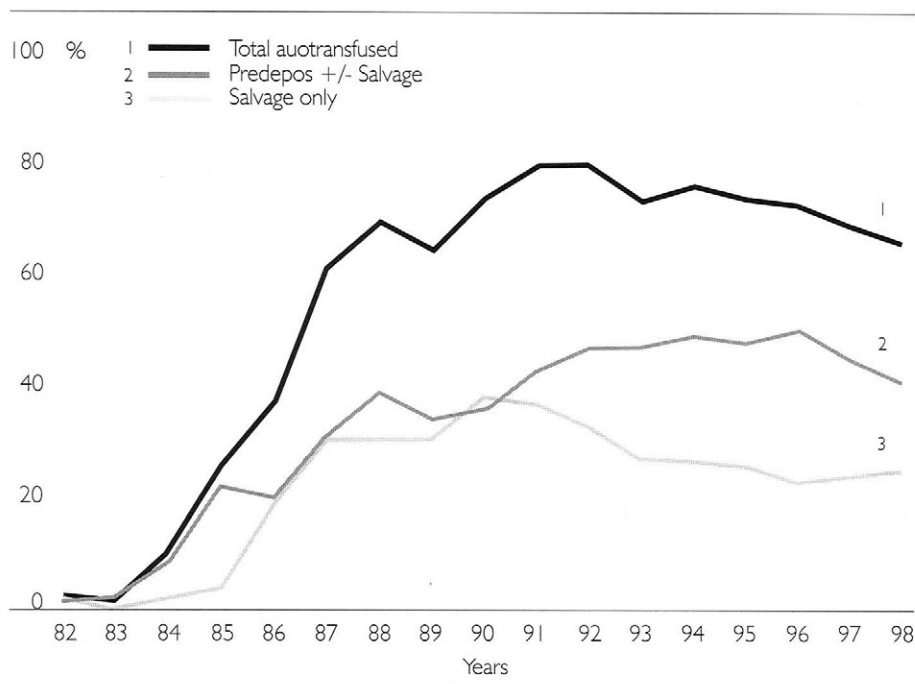
The technique is not routinely utilized in our Institute but is adopted only in limited and selected cases when other techniques are not feasible.

Results

The results obtained with the utilization of the alternative strategies to the use of allogeneic blood have been evaluated on the basis of the three major objectives enrolment, allogeneic blood conservation and avoidance from the exposure to the use of allogeneic blood.

The systematic and integrated use of the different autotransfusion techniques has allowed to constantly increase the number of patients who benefit from the use of autologous blood (Fig 1).

Figure 1. Enrollment through the years into the autotransfusion program of the patients undergoing major elective surgery at the Gaetano Pini Orthopedic Institute



In 1998, 66% of all the transfused patients have been enrolled into the autotransfusion program (41% of the transfused patients could predeposit their blood in association with perioperative salvage, while the remaining 25% of patients could only benefit from perioperative blood salvage). When the use of each single technique is concerned it can be observed that PABD utilization varied according to type of surgery. Indeed in major elective surgical procedures, PABD was utilized in 64% of the transfused patients while its utilization was significantly lower in minor elective surgery (28%) and in non elective surgery (0.5%). The most relevant causes preventing the use of PABD were, beside the absence of indications, anemia (37% of the cases), cardiopathy (10%) and inadequate venous access (5%). Organizational reasons averted from using PABD only in 4% of the transfused patients who were actually suitable for predeposit their blood.

The utilization of the perioperative blood salvage is reported in tab. 3. As it can be seen the compliance with guidelines has been satisfying, however in a consistent number of cases it has been performed in absence of indication.

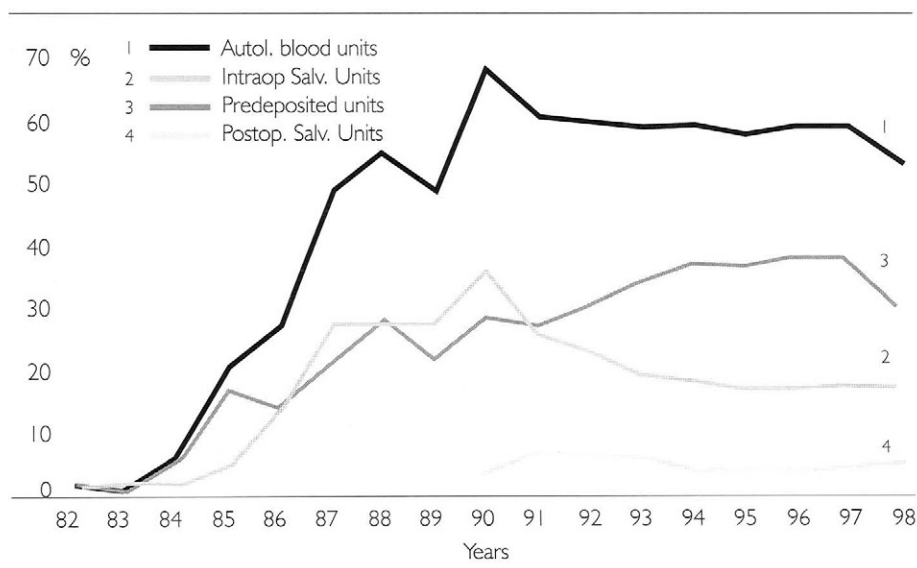
Tab. 3 Utilization of perioperative blood salvage

	IOS (performed / indicated)	POS (performed / indicated)
Pts for which salvage was indicated	207/333 (62%)	164/300 (55%)
Pts for which "stand by" procedure was indicated	694/1358 (51%)	0
Pts for which salvage was "optional"	0	194/1190 (16%)
Pts for which salvage was "not indicated"	160/500 (32%)	88/701 (12%)

Pts: Patients; IOS = intraoperative salvage; POS= postoperative salvage

Blood conservation obtained through the use of the autotransfusion techniques is measured by the ratio between autologous blood units transfused and the total units transfused. As it can be seen from fig. 2 in the last 10 years, more than 50% of blood requirement have been covered with autologous units.

Figure 2 Autologous blood units transfused through the years in elective surgery patients at the Gaetano Pini Orthopedic Institute



The contribution of autologous blood techniques to allogeneic blood conservation according to type of surgery is reported in tab. 4.

Tab 4 Utilization of autologous and allogeneic blood units in different groups of orthopedic surgical procedures in 1998

Type of surgery	N° of Pts	Predep units n° (%)	Salvaged units n° (%)	Allogeneic units n° (%)	Total units n° (%)
Major elective surgery	1132	1595 (44)	1051 (29)	938 (27)	3584
Minor elective surgery	54	18 (21)	28 (33)	39 (46)	85
Not elective (trauma)	577	5 (0.3)	72 (5.2)	1342 (94.5)	1419
Unclassifiable (cancer)	136	63 (13)	88 (19)	315 (68)	466

The use of the autotransfusion techniques, in conjunction with the other adopted strategies, significantly reduced the patient's requirement for allogeneic blood support.

In 1998, 44% of all the operated and transfused patients received their own blood only. This figure varied significantly according to the type of operation (Tab.5).

Tab 5 Patients transfused with autologous blood only, autologous plus allogeneic blood and allogeneic blood only in different type of orthopedic surgery in 1998

Type of surgery	N° of Pts n° (%)	Auto only n° (%)	Auto+Allo n° (%)	Allo only n° (%)
Major elective surgery	1132	705 (62)	342 (30)	85 (8)
Minor elective surgery	54	38 (70)	4 (8)	12 (22)
Not elective (trauma)	577	39 (7)	52 (9)	468 (86)
Unclassifiable (cancer)	136	55 (41)	34 (25)	47 (34)

The integrated use of PABD and perioperative salvage emerged to have a critical role in limiting the exposure to allogeneic blood. Indeed in major orthopedic surgery if perioperative salvage is used alone the chance of a patient also receiving donor blood is 79%, while the probability of receiving autologous blood only is more than 85% when salvage is integrated with predeposit.

4) Optimization of Cost-Effectiveness of the Alternatives

Autologous blood transfusion, although generally accepted as a standard of care, is considered more costly than allogeneic blood transfusion. Thus, improving the cost-effectiveness of autologous blood transfusion programs is becoming more and more important as financial pressure on the health-care system place great emphasis on the cost-containment and prioritization of medical interventions.

To optimize the cost to benefit ratio of the autotransfusion techniques a number of measures aimed at the reduction of their direct costs and at the improvement of their efficiency have been adopted in our Institute. Some of the adopted measures to reduce the direct cost of autologous blood procurement on:

- the definition of guidelines and flowcharts for the patient's presurgical evaluation and scheduling,
- simplifying the patients interview and donation process
- avoiding serological tests for infectious disease markers
- collecting autologous blood in single collection bag and storing it as whole blood

Moreover a special care has been devoted to optimize the efficacy of the autotransfusion technique, and to avoid the collection.

Optimization of efficacy of the autotransfusion technique

Specific measures have been adopted to optimize the efficacy of both predeposit and perioperative salvage.

It has been clearly demonstrated that to optimize the efficacy of PABD it is necessary to collect autologous blood far in advance to surgery so to allow the production of as many as possible new RBCs. If we don't give the patient enough time to compensate for the collected red cells through the physiologic erythropoietic mechanisms, PABD offers very little advantage to the patient because in this case only a reduction of intra-operative RBCs loss is obtained through the moderate hemodilution induced by blood collection.

For these reasons specific protocols have been adopted to allow a 4 week interval between the collection of the first unit of autologous blood and surgery. This target has been very successfully reached as the mean interval between the starting of the PABD program and surgery resulted to be 26+8 days. The appropriateness of the surgery planning is confirmed by the observation that only 1.5% of the collected units were disposed of because outdated before patient's surgery.

To optimize the cost-effectiveness of perioperative blood salvage, beside the adoption of the "stand-by procedures" it has been recommended to extend salvaging in the post-operative period whenever the intraoperative yield is equivalent to approssimately 1 unit of blood, or higher. Indeed as it can be seen from tab. 6 in the majority of the cases where both intraoperative and postoperative salvage has been performed, more than 1.5 units of blood have been collected and transfused.

Tab 6. Mean number of salvaged units harvested and % of cases in which more than 1.5 units of blood have been harvested in different orthopedic surgical procedure subdivided according to the type of salvaging performed.

Operation	n° of salvaged units					
	IOS		POS		IOS+POS	
	Mean	% 1.5	Mean	% 1.5	Mean	% 1.5
Total Hip Replacement (THR)	0.6	5.1	n.a.		1.5	52
Bilateral THR	n.a.		n.a.		2.6	93
THR Revision	1.6	43	n.a.		2.6	90
Revision of THR component	1.0	20	n.a.		2.6	78
Pelvis Osteotomy	0.5		n.a.		n.a.	
Total Knee Replacement	0.3	35	0.7	8	1.2	34
Vertebral Arthrodesis	0.9	6	n.a.		n.a.	
Osteosynthesis for femur fracture	0.6	0.5	n.a.		2.2	100
Partial Hip Prosthesis	0.5	0	n.a.		n.a.	

IOS = intraoperative salvage; POS= postoperative salvage; n.a.= not applicable because of the limited number of cases

Avoidance from the collection of unnecessary autologous units.

The most relevant cause of the higher cost of autologous units is the wastage of units that are collected and discarded because not transfused.

In our Institute to minimize the wastage rate of predeposited units, preoperative collection has been taken into account only for patients candidates for surgical procedures in which the probability of allogeneic blood transfusion is higher than 10%. Moreover the number of autologous units to be collected from patients who are appropriate candidates to the enrolment into the PABD program has been defined according to the SOPCAB (schedule of optimal preoperative collection of autologous blood) method suggested by Axelrod et al. According to SOPCAB the number of units of autologous units to be collected for any surgical procedures should be calculated in each hospital as the 70-80th percentile of the distribution of the number of units transfused during the whole hospital stay. The adoption of these systems resulted in an overall wastage rate of autologous units of 14%. The wastage rate in some of the orthopedic surgical procedures, compared with the % of patients completely avoiding allogeneic blood transfusion, is reported in tab 7.

Tab 7 Wastage of predeposited units and % of patients transfused exclusively with autologous blood in 1998 subdivided according to the surgical procedure

Operation	% of wasted predeposited units	% of Patients transfused only auto
Total Hip Replacement (THR)	Male 2; 1 Female 9	87
Bilateral THR	Male 0.4; Female 15	97
THR Revision	9	71
Revision of THR component	8	86
Pelvis Osteotomy	17	96
Total Knee Replacement	18	88
Vertebral Arthrodesis	14	100

The adoption of MSBOS and SOPCAB, although valuable to obtain a correct management of the inventory of allogeneic blood and acceptable results in containing the wastage of AB units, however, suffer from substantial limitations: these methods do not give any indication on the appropriateness of the transfusion indications and more important they do not take into account the different transfusion requirement of the single patients undergoing a specific surgical operation in that particular hospital.

In order to further optimize the utilization of all the alternative to allogeneic blood we are now experimenting with a new and more personalized approach to define both the perioperative blood requirement and the utilization the most appropriate methods to cover the calculated blood requirement. This new approach takes into account the predicted blood loss determined through a constantly update calculation of the real blood loss that occurred in each patient per surgical operation and the volume of the blood that the patient can tolerate to lose before necessitating a transfusion support.

Preliminary results seems to indicate that this method may effectively optimize the management of the transfusion strategy in the surgical patients.

Improvement of the safety of transfusion therapy

As a consequence of the adoption of a number of measures such as stricter criteria for blood donor selection and the introduction of sophisticated tests for infectious diseases markers, blood supply is safer now than any other time in the history of blood banking. However, the occurrence of acute hemolytic reactions, due to the transfusion of ABO incompatible blood, is still unacceptably relevant. Most incompatible transfusions are the results of clerical errors occurring during specimen collection, issue and transfusion of blood that lead to the transfusion of blood to a patient other than the intended recipient.

To reduce phlebotomy and bedside identification errors, a device, based on the forcing function concept, was proposed by Wenz et al (2). The system (Bloodloc Safety System, Novatek Medical Inc., Greenwich, USA) consists of a coded locking system so that a blood unit cannot be accessed without matching a three letters code that can be found only on the patient's wristband. Any error in patient or blood unit identification would make it impossible to open the lock, and consequently to transfuse the patient, Moreover, all the errors are automatically referred to the transfusion center; this makes possible the identification of all the errors occurring in the transfusion process and the concurrent implementation of a QA/QI program in the bedside transfusion practice.

In our Institute the Bloodloc Safety System and the associated QA/QI program in transfusion practice were implemented in January 1993 with the aim of preventing bedside transfusion errors occurring outside the blood transfusion service.

Up to December 98, 30430 blood units (13749 predeposited autologous blood units

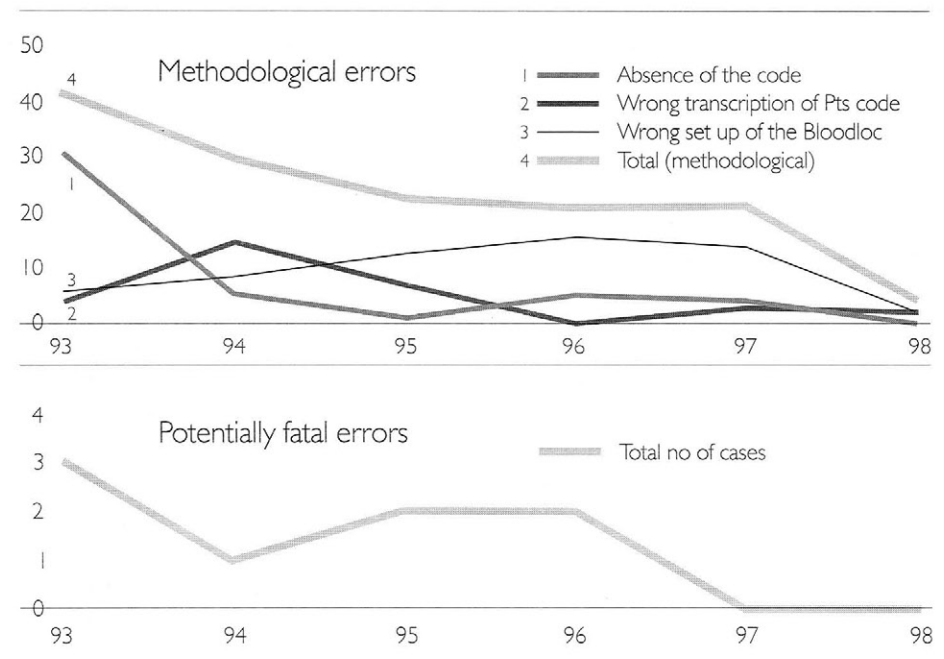
and 16668 allogeneic units) were transfused to 12.154 patients. A total of 143 methodological errors (absence of the three-letter code on the patient's specimen phlebotomist error in transcribing patient's code on the tubes, and improper encoding of the lock by the blood bank) were detected giving an incidence of 1 in every 212 units transfused.

In this period, 8 potentially fatal errors (1 in every 3803 units transfused) occurred, 6 of which were detected and prevented by the use of Bloodloc. The potentially fatal errors detected and prevented by the system included 2 cases of interchange of recipient sample tubes resulting in misgrouping of blood, 3 cases of patient misidentification and 1 case of blood unit misidentification.

Two errors have not been prevented: the first case was the transfusion of a unit of fresh frozen plasma (FFP) to the wrong patient (but in our Institute the Bloodloc is not utilized for FFP and other component because not associated with the risk of fatal hemolytic transfusion reaction); the other error was the transfusion of a compatible properly crossmatched allogeneic blood unit to a patient for whom autologous blood units were still available. The error was determined by omissions in the routine procedure for assignment and transfusion by the physician of transfusion service and the anesthesiologist in charge of the patient.

As it can be seen from Fig.3 the adoption of the Bloodloc system and the associated QA/QI program allowed to constantly reduce the incidence of errors in the transfusion practice in our hospital.

Fig.3 Methodological and potentially fatal errors through the years at the Gaetano Pini Orthopedic Institute



Conclusions

The results obtained through the years indicate that an integrated program of currently available autotransfusion techniques and proper use of blood is feasible and can significantly contribute to improve the quality of the transfusion practice given to the patients. Moreover, it can contribute to solve the problem of donor blood shortage that is becoming a more and more serious problem worldwide.

Critical parameters for the success of such a program are:

- The transfusion policy that must be discussed and developed by all hospital departments that are involved in the program and must give simple and unequivocal indication;
- The organization that must allow the patients to be referred, at least 10-15 days before hospital admission, to the preoperative autologous blood donation program, and the transfusion service must be provided of the logistical structures needed and of qualified physicians to bleed not only blood donors but also patients;
- Finally, it is essential that the results of the program should be monitored to ascertain the compliance. Both the results obtained and the measure eventually required to reach the target of the program should be discussed and analysed with the directors of the other departments involved.