

Haemovigilance System Quality After Establishment of Patient's Safety Standards: Quality of Patient Identification, Blood Typing, and Transport and Conservation of Blood and Blood Components

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Abstract

Field: Patient safety friendly hospital initiative incorporates a set of patient safety standards such as the critical standard of safe blood and blood components in the group of safe clinical service standards based on evidence. Haemovigilance is a country-wide surveillance system for monitoring the health of blood and blood components in all the stages of blood transfusion from the donors to the recipients, the collection and analysis of the data related to the undesirable effects of blood transfusion, and issuing alarms in order to correct and take the necessary measures to prevent the repetition of such effects. The present study was an attempt to investigate the quality of patient identification, and transport and conservation of blood and blood components after the establishment of patient safety standards.

Materials and methods: The study was conducted in two consecutive steps on one group of patients in Baharloo Hospital of Tehran, Iran. The data collected in 2011 (the beginning of the establishment of patient safety standards) were compared with those collected in 2016 (5 years after the establishment of the standards). As many as 100 blood bags estimated by Cochrane's formula were collected using the collection checklist and were compared with the data belonging to the beginning of establishment of this system. Data analysis was conducted using descriptive statistics indices, paired t-test, and SPSS 22 software.

Findings: The finding of the present study revealed that the mean of indices evaluated after the establishment of patient safety standards was higher than that obtained at the beginning of the establishment of the

standards. Using paired t-test, this increase in mean was found to be statistically significant for each of the indices ($P < 0/01$).

Conclusion: The results demonstrated that the establishment of patient safety standards can exert a significant effect on the quality of patient identification, blood typing, and the implementation of tests for determining ABO compatibility and blood transport and conservation in the haemovigilance system.

Key words: Haemovigilance System, Patient Safety Standards, Patient Identification, Blood Typing, Transport and Conservation.

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Introduction

Blood health, as a global concern, particularly in developing countries, addresses all aspects of the transfusion chain. (1)

According to the International Haemovigilance Network, the definition of haemovigilance may be 'a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood components, and to prevent their occurrence or recurrence'. (2)

Haemovigilance in its broader sense encompasses other important aspects of transfusion safety; surveillance of donors to ascertain the residual risks of transfusion-transmitted infections, traceability of transfused blood components, monitoring of blood utilization, epidemiology of transfused patients, and monitoring of the hazards of blood conservation. Compilation of this information, together with clinical assessment of transfused patients, has the potential to provide much-needed evidence of the outcomes, risks and benefits of blood transfusion, and transfusion alternatives.(3)

Since establishment of the first national haemovigilance system in France in 1994, such systems have identified issues requiring attention and helped improve blood product safety and transfusion processes. (4)

Limited conservation time and processes such as blood health screening, determining the group and cross-matching which require costs for employing personnel and laboratory equipment, add to the importance of proper blood request and utilization (5). Cold chain in blood transfusion is a set of crucial and integrated activities in which equipment and manpower play a significant part, such that inefficiency in each section of the chain results in serious disorder in its performance (6). Hence, establishing a multiple surveillance system to re-investigate blood transfusion stages enhances the safety of this activity (7). Disorder in the cold chain may be due to various reasons such as lack of standard equipment such as standard transport boxes and fridges and freezers designed to conserve blood and blood components, and lack of practical standard instructions, lack of surveillance and monitoring over the process of transport and conservation of blood and blood products (8).

A Less common form of haemovigilance is the direct observation system, based on direct observation of transfusion by appropriately trained technical staff at the patients' bedside and verification of adherence to standard operating procedures.(9)

In the blood transfusion chain, there may be numerous errors in the stages of transportation, request, and transfusion of blood and blood components. Most of these

errors are non-technical. By rechecking and correcting operation methods in such processes, such errors can be prevented and the side effects of the transportation of blood and blood products can be reduced (10). The causes of the errors in the blood transfusion chain include: incorrect transfusion (the patient does not need blood or blood products but they are transfused to him/her); lack of identification of patient during sample collection or during the transfusion of blood and blood components into the patient; incorrect labeling; errors in the transport of blood from the blood bank to the hospital or hospital wards; errors in the transfusion of blood or blood components-not following blood conservation, storage and transport principles-; and technical errors (such as experiments conducted incorrectly) (11, 12).

The patient safety friendly hospital initiative started in 2007 with the aim of tackling the major problem of unsafe care in this area. This project has been designed as a useful instrument for evaluating patient safety by considering different aspects of patient safety and drafting standards in each aspect. (13) A critical standard which falls into the category of evidence-based safe clinical service standards is in the field of safe blood and blood component transfusion. (14)

Based on numerous problems and errors in the blood transfusion chain, since the establishment of healthy blood and blood component transfusion safety standard in patient safety friendly hospitals in 2007 by the WHO Regional Office for the Eastern Mediterranean, no research has attempted to correctly implement this standard and correctly control the operation methods of this process in Iran.

In order to enhance the health of patients who undergo blood and blood component transfusion, and to reduce the undesirable events and reactions caused by the transfusion, it is essential that the activities of the blood bank including the processes, equipment and staff be monitored and standardized. (15)

This study was an attempt to help enhance patient health and safety and to assess one of the vital standards of patient safety at Baharloo hospital, Tehran, Iran, which is a patient safety friendly hospital which started to establish this system as a pilot investigation so as to monitor the implementation of methods pertaining to the stages of patient identification, blood typing, and blood and blood component transport and conservation in the haemovigilance system, to assess and monitor the enhancement of this system since the establishment of the system, to investigate the existing impediments, and to attempt to modify the processes according to the standards of WHO and Blood Transfusion Organization so as to create an index for measuring in other systems and to take appropriate measures nationally.

Materials and Methods

In order to do this research a One Group Pre-test / Post-test Design study was conducted to evaluate the quality of implementation of the haemovigilance system in Baharloo hospital in Tehran, Iran. For this purpose, the data of the year 2011 (the beginning of the execution of the standards) were compared to that from year 2016 (5 years after the implementation of the standards).

The statistical population contained all the blood bags used at the hospital since the execution of the patient safety standards at the Baharloo hospital up to the present (from year 2010 to 2016). Convenience sampling was used to select the samples. The data were collected during July through to November of the year 2016. The sample size was estimated using the Cochran formula.

The data were collected via a checklist which contained 3 dimensions and 27 items checking blood and blood's components safety. The items of the checklist were developed using different sources such as the Iranian Blood Transfusion Organization checklist for evaluation of haemovigilance system, the WHO's checklists, blood and component monitoring checklist used by several Iranian hospitals, interviewing the training supervisor and the blood transfusion experts of the hospital's blood bank, and Patient Safety assessment manual book(26). A three point Likert scale (i.e. 1= weak, 2= moderate, and 3= good) was used to score the items of the checklist. The experts' opinion was used to validate the checklist. The data were collected through direct observation which began since the announcement of the blood and blood component request until the completion of injections or the return of blood to the hospital's blood bank .The data were analyzed using paired t-test.

Findings

The findings revealed that the mean gained score for the quality of patient identification, quality of blood typing and the conduction of ABO compatibility test, quality of blood and blood component transport and conservation at the hospital after the establishment of patient safety standards (2016) was considerably higher than that at the beginning of the establishment of the standards (2011) (Table 1 and Diagram 1). In addition, according to the results of the paired t-test, this difference is statistically significant (Table 2).

In order to help better understand the results of the related indices in Table 1, the mean scores obtained at the beginning of and after the establishment of safety standards are presented in Diagram 1 (page 264).

Discussion

No study was found to share the focus of the present study in the literature. However, numerous studies have been conducted on the use of some strategies for healthy blood transfusion into patients, including studies conducted to 'determine the quality of patient identification during

sample collection, labeling blood bags, and blood and blood component transfusion'.

Use of machine-readable identity control technology, particularly based on a barcoding system, is an appropriate tool for patient bedside control. Experience at Juntendo university hospital has shown that barcode identity control system had a good performance at a hospital with 70,000 blood and blood component transfusions without even one case of error, and the system's compliance was 99 percent.

Bernardello, et al (2009), introduced a secure blood system to guarantee the traceability of the transfusion. This system records the various stages of the transfusion process, the health care workers involved and any immediate transfusion reactions. The patients and staff are identified by fingerprinting or a bar code. The system was implemented within Ragusa hospital in 16 operative units (ordinary wards, day hospital, operating theatres). In the period from August 2007 to July 2008 blood components were transfused within the hospital, of which 5,606 (77%) used the secure blood system. Overall, 1,777 patients were transfused. In this year of experience, no transfusion errors were recorded and each blood component was transfused to the right patient. The secure blood system guarantees complete traceability of the transfusion and also the ability to identify the wrong patients or blood components. The use of fingerprinting to identify health care staff (nurses and doctors) and patients obliges the staff to carry out the identification procedures directly in the presence of the patient and guarantees the presence of the doctor at the start of the transfusion. (17)

Unfortunately according to the reports of the National Haemovigilance Office (2011) about some serious adverse events in the year 2011 (135 cases), 26 cases were due to transfusion of an incorrectly labeled component, 17 cases were due to incorrect component/ production transfused, 6 cases were due to transfusion of incorrectly stored component, 3 cases of incorrect ABO group transfused, 1 case of incorrect RhD group transfused and 20 cases of unnecessary transfusion.(18)

According to a report titled "transfusion of incorrectly labeled unit" by National haemovigilance office (2011), 4 cases of unit labeling errors on SD plasma, 6 cases of Data entry error on laboratory information systems, a case of laboratory information systems information technology error, no blood group on label in hospital's blood bank, and 4 cases of transcription error at sample collection and a case of transcription error at initial admission in clinical area have been the serious adverse events that have occurred.(18)

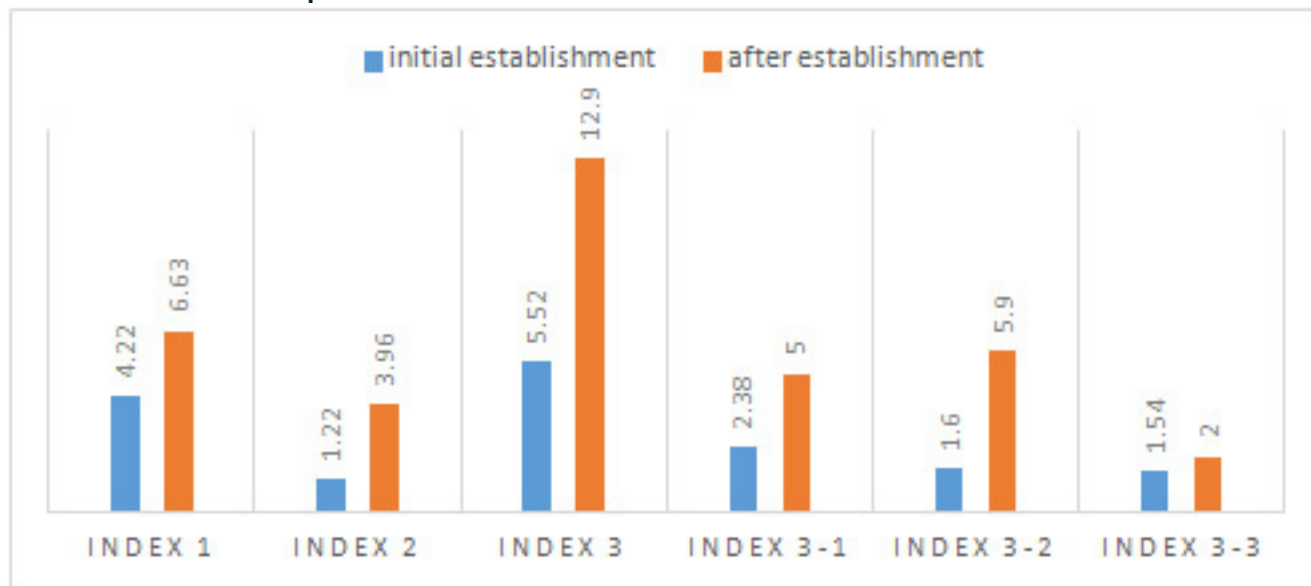
According to Escoval, et al's research (2014), in member countries of Europeancommunity, about the component label information, have shown that, in 100% EU and Non EU countries the following information is installed on the components: official name of the component, unique numeric or alphanumeric donation identification, name of

Table 1. Results of indices relating to the condition of establishment of patient safety standards in terms of blood and blood component transfusion

Evaluated indices	At the beginning of establishment		After establishment	
	Mean	Standard deviation	Mean	Standard deviation
1. Quality of patient identification during sample collection, labeling blood bags, and transfusion of blood and blood components	4.22	1.087	6.63	0.794
2. Quality of blood typing and implementing ABO compatibility test	1.22	1.010	3.96	0.196
3. Quality of transport and conservation of blood and blood components at the hospital	5.52	1.049	12.90	0.301
3.1. Quality of conservation of blood and blood components in the blood bank fridge and controlling the fridge temperature	2.38	0.599	5.00	0.000
3.2. Quality of blood transport from the blood bank to the ward	1.60	0.568	5.90	0.301
3.3. Quality of conservation of blood and blood components at the ward	1.54	0.539	2.00	0.000

Table 2. Paired t-test results

Investigated indices	Results of paired t-test prior to and after establishment		
	Test result	Degree of freedom (pdf)	t
1. Quality of patient identification during sample collection, labeling on blood bags, and transfusion of blood and blood components	0.000	99	17.45
2. Quality of blood typing and implementation of tests to determine ABO compatibility	0.000	99	26.83
3. Quality of transport and conservation of blood and blood components at the hospital	0.000	99	65.53
3.1. Quality of the process of conservation of blood and blood components in blood bank fridges and adjustment of the fridge temperature	0.000	99	46.71
3.2. Quality of blood transfer from the blood bank to the ward	0.000	99	65.24
3.3. Quality of conservation of blood and blood components in the ward	0.000	99	8.52

Diagram 1. Results of indices relating to the condition of establishment of patient safety standards in terms of blood and blood component transfusion

producing establishment, ABO group, Rh D group, date or time of expiry. Volume, weight or number of cells in the component observed 89.5 % in EU and 90.9 % in Non EU countries. Storage temperature has been observed 89.5 % in EU and 81.8 % in Non EU countries. Name, composition and volume of anticoagulant and/or additive solution have been stated 100 % in EU and 72.7 % in Non EU countries. 70% (73.3% in the EU) use a single national coding system for blood components and 50% (57.9% in the EU) apply International Society of Blood Transfusion (ISBT) 128. (19).

According to the study by Robillard (2011), in Canada's haemovigilance system, there has been 29.3%, 7.9%, 1.4%, and 1.6% of error in sample collection, use of samples, characteristics of the donors, and request for blood and blood components, respectively. Of all the errors and mistakes reported, 6% have occurred in registration and labeling the products and 4.3% have been related to the reception of the wrong samples. (20)

Results of the study by Moshi et al.'s (2006) in the South African national blood service has shown that, 2 cases were reported from misidentification at collection and 10 from misidentification at transfusion. Also 2 cases from issuing the wrong blood for the wrong patient were reported. (21) Serious Transfusion Incident report (2010) reported 11 cases of near miss events (out of 26 cases) in labeling and documentation. (27)

Callum et al. (2011) stated that 15.5% of 122 hospitals noted at least annual occurrence of incorrect registration. In a report from a hospital that requires ABO-confirmation on all new patients, a 10 % AB-mismatch was observed when compared to the historic group related to patient registration errors. In a report of the details of 118 ABO-discrepancies at 35 hospitals in France, 5% were attributable to registration errors.(22)

Bolton-Maggs and Cohen (2013), showed in their research that where audits have been repeated, progressive improvements in standards can be shown. For example the 2011 re-audit of bedside administration showed an improvement in the numbers of patients wearing wristband at the time of transfusion, and better monitoring. Overall, the percentage of patients wearing a wristband had increased from 86% in 2003 to 99.5% in a 2011 audit. The recent audit shows that there were still problems, particularly in pediatrics where children and neonates were less likely to be wearing wristbands (absent in 9.5% and 12.9% respectively) than adults (absent in 1.8 %).(23)

Koh (2011), too, recommends the using of robots, barcodes, identification based on radio frequency, computer-assisted transfusion management system, and computer assisted system for blood utilization to determine the identity of patients in whole blood transfusion processes and thus reduce possible errors. (24)

Therefore, pre-transfusion bedside control of the patient is the most vital step in predicting the wrong transfusion. Human errors are the most common cause of bedside identity control errors, which can be reduced using optimal strategies. (16)

Investigation of the literature shows that no study has been conducted on the 'quality of blood typing and ABO compatibility tests'. However, numerous studies have investigated the reports of errors in blood typing and tests. Those studies show that transfusion of incompatible blood leads to the most acute transfusion reactions.

In addition, according to a global database on blood safety for 2011 from 148 countries, WHO (2013) stated that the reasons for discarding donated blood included expiry (33.4%), incomplete whole blood collections (21%), processing problems (13.6%) and problems during storage (3.1%) (25).

In their study on acute blood transfusion reactions, Teimoori Naghdeh et al. (2007) maintained that the ABO compatibility has been 0.03% which is higher than the global statistics (0.004%). (26)

According to National Haemovigilance Office Report (2011), near miss events which occurred at the hospital blood bank in 2011 were 44 cases. In the report of cases of near miss and mandatory serious adverse events reported in 2011 (60 cases), there were 9 cases of errors in testing donations, 11 errors in processing, 1 case of error in storage and 22 cases in distribution. Also, in the report of serious adverse events (135 cases), there were 5 cases of transfusion of other antigen incompatible RCC, 3 cases of transfusion of expired component, and, in the report of "transfusion of incorrectly labeled unit", there were 10 cases of transposition of labels in a single crossmatch and 1 case of no blood group on label in hospital's blood bank. (18)

According to the Serious Transfusion Incident report (2010), from 26 reports of near miss events, 5 reports were declared related to the laboratory. (Failure to have blood available resulting in delay of transfusion and transcription error in laboratory system)(27)

According to the study by Escoval, et al. (2014), in the EU countries, in all European and non-European countries, blood type and Rh group were mentioned as the information of blood component labeling.

In their study on the serious risks of blood transfusion in England, Taylor et al. (2009) reported that in 2009 the total numbers of reports were 1,279 cases which had undergone an increase of 23% as compared to the year 2008 (1,040 reports). Of these errors, 230 cases were related to the initial measures taken by the laboratories' blood banks at the hospitals, which also accounted for 18% of the reports in 2008. Besides, the number of laboratory errors (accounting for 149 out of the 282 cases of wrong blood transfusion which accounted for 53% of the reports in 2009) had increased in comparison to the 50% in 2008. (28)

Robillard (2011), in his research stated that in the period between 2003 and 2005, all Quebec hospitals were progressively computerized with the same blood bank software. Thus, each hospital can query the blood bank database of all other hospitals to see if the patient is present and information such as blood group, previous transfusions, previous transfusion reactions, and special requirements will appear on screen. Also according to the type of errors reported, laboratory errors and mistakes are as follows: sample reception (4.3%), sample testing (12.6%), unit selection (0.3%), unit manipulation (2%) and unit storage (5%).(20)

Results of the study by Moshi et al. (2006) in the South African national blood service have shown that 53.57% reports were due to laboratory errors, and a significant increase in failure to identify antibodies was observed in comparison to the data obtained in 2005. (21)

Callum et al (2011) in a blood research reported that 28 cases of ABO typing errors had been observed by the identification information systems in 26 hospitals in the Pittsburgh area over a 2 year period. The yield was impressive; they detected 28 major ABO typing errors at 16 hospitals served by their information system. In 8 cases, the sample collection error could have led to an ABO-incompatible transfusion reaction, had the error not been detected. A similar system has been implemented in the Province of Quebec, Canada, and has been associated with a decrease in the incidence of acute and delayed haemolytic transfusion reactions. (22)

Also, in another study on the role of follow-up in the blood bank activities by auditing and training the blood bank staff of the hospitals, Sharifi et al. maintained that standard blood typing, cross match test, and quality control between the two inspections had an increase of 19, 21 and 10 percent in state hospitals and 12, 17, and 5 percent in the private hospitals, respectively. (15)

With respect to 'quality of transport and conservation of blood and blood components at the hospital', the findings of the present study revealed that the establishment of safety standards has a considerable impact on this aspect.

Investigation of the literature showed that no study has shared the focus of the present study. However, numerous reports have been issued regarding the quality of transport and conservation. For instance, according to the global database on blood safety for 2011 from 148 countries, WHO (2013) indicates that 3.5 million blood donations were discarded out of the 67.3 million whole blood donations reported, and that 0.9% of it was caused by error in transportation.(25)

In their study, Asadi Fakhr et al. (2012) demonstrated that only a small number of the employees (3.3%) are sufficiently aware of the procedure and condition of conservation of blood and blood components, and 96.7% of them make performance errors. (29)

In their study, Teimoori Naghdeh et al. (2010) showed that 34 percent of hospital blood banks lack standard conditions, which can be due to lack of special blood bank freezers; and, that only 66 percent of the hospitals enjoyed defined standard conditions. This has led to inconvenience and low quality of conservation of blood and blood components at the blood bank. (30) Sharifi et al. in their study reported that the indices related to the 'establishment and utilization of special blood bank equipment such as fridges, freezers, platelet shaker incubators' improved in the interval between the two inspections by 42%, 32%, and 9% at state hospitals and by 28%, 17% and 8% at private hospitals. Besides, they maintained that periodic audits together with training and informing the blood bank staff of the use of standard methods and renewing blood bank equipment have played a significant role in this regard. (15)

According to the Annual Reporting of Serious Adverse events and reactions (SARE) 2013, in the 26 member states in 2011, 2,953 adverse events were reported in

total, of which 200 events (6.77%) were due to processing, 336 events (11.38%) were due to storage, 320 events (10.84%) were due to distribution, 76 events (2.57%) were due to materials, and 764 events (25.87%) were due to compatibility testing, transport, information technology, system errors and bacterial contamination.(31)

Also, Taylor et al. (2009) in their study of England's blood transfusion serious risks program reported that the number of storage errors was 196 cases in 2009, which had increased by 41% in comparison with that in 2008. Of course those errors have not caused death or disease, and no deviation before transfusion had been recorded. (28)

According to the National Haemovigilance Office Report regarding mandatory serious adverse events reporting (2011), 57 cases of adverse events had occurred at the blood banks of hospitals involved in transfusion of blood units, of which 6 cases of errors had occurred during the storage in Red Blood Cell Components. Also, of the mandatory near miss events accepted from hospitals' blood banks in 2011 (44 cases), 7 cases were due to errors in storage (3 cases due to human error and 4 cases for unknown reasons) and one case was due to errors in distribution (human error). (18)

Robillard (2011) also stated that 5% of errors reported in the laboratory were caused by errors in storage and 1% were caused by errors in distribution.(20)

According to the Serious Transfusion Incident report (2010), of 26 near miss events, 2 were due to error in storage and handling and 1 was due to inappropriate blood component distribution.(27)

The reports indicate that most errors and mistakes are due to the shortage of equipment, inefficient training and supervision by the authorities. Periodic audits, training and providing information as well as application of standard methods can play a significant role in correcting these errors. (15)

Considering the above discussion, it can be argued that blood safety officers and other similar roles serve as the key module of the haemovigilance team in many countries. Sufficient laboratory and medical support is essential for all hospital activities. (22)

There is also the need for a clear and concise informed consent process, and an established guideline for the appropriate infusion rate, with adequate monitoring of vital signs. The process of blood transfusion into a patient includes numerous steps, and if individuals do not remember each and every step, failures in the host will always be inevitable. (22).

Effective patient blood management means optimal use of blood and blood components through appropriately set standards and guidelines that produce the right unit of blood for the right patient at the right time and under the right conditions. Sadly, low policy implementation rates, inadequate financial resources and the lack of

trained human resources in many countries are barriers to appropriate Patient Blood Management. (32)

The transfusion community has a proven track record in facilitating the huge progress in blood safety and it is time that we re-focus our process improvement projects closer to the bedside. (22)

In this line, hospital transfusion committees should oversee haemovigilance activities and reporting, and ensure that hospital senior management is aware of, and responds to, serious reactions and events, especially where systems issues are contributory. (33)

Kasraian (2014) demonstrated that physicians and nurses have insufficient information about blood transfusion medicine, and training can increase their information in this respect. (34)

Research of Siddiqui et al (2012), show that the PSFHI provides compelling evidence that assessment of patient safety standards in hospitals is feasible and applicable even in resource-poor settings. Implementation of the patient safety standards has increased the level of awareness of participating hospitals as well as patients. Most of the safe and evidence-based critical standards of the domain of clinical services (mean 63%, range 14-86%) are met by many hospitals and need more improvements in their levels. (35)

Conclusion

Establishment of patient safety standards can exert a considerable effect on the quality of patient identification, blood typing, implementation of ABO compatibility test, and the transport and conservation of blood and blood components in the haemovigilance system. Therefore, it is recommended that patient safety standards be appropriately established for blood and blood components at other similar hospitals, as well.

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