Strengthening quality management system: An assessment of awareness and knowledge in trainees in blood bank

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Abstract:

OBJECTIVES: The objective of this study was to assess the changes in knowledge concerning quality management system (QMS) among the participants before and after attending a QMS training.

METHODS: After obtaining the ethical approval, a retrospective study was designed to evaluate the effectiveness of QMS. Fifty participants from district blood banks of three different states participated in the study organized at two different periods. After obtaining informed consent, the participants were subjected to a set of questionnaire containing 45 questions (35 multiple choice and 10 subjective questions) as pretest on quality standards and were again subjected to posttest questionnaire containing the same set of questions after 5 days of workshop. Twenty minutes were granted to solve the questions. Each question was given one mark. There was no negative marking. An assessment of knowledge gained during training was evaluated by comparing the scores of pre- and post-assessment.

RESULTS: Of the total 50 delegates, 29 were trained in the month of July (Training I) and 21 were trained in the month of November (Training II). There were 96% (n = 48) males and 4% (n = 2) females. In both the training sessions, that is, Training I and II, the mean scores of objective questions in pretest were 13.629 ± 6.58 and 9.34 ± 5.74, and after the training, the posttest scores increased significantly to 17.77 ± 7.05 and 14.34 ± 7.09, respectively. Paired Student's t-test was applied which showed statistically significant increment in knowledge (P = 0.001).

CONCLUSIONS: There was a significant positive change in the knowledge of the participants after attending QMS workshop.

Keywords: Blood banks, hemovigilance, quality management systems, transfusion medicine

Introduction

The blood transfusion services are an essential component of health-care system that works with a motive to ensure availability, accessibility, and adequacy to provide quality blood products. Transfusion of blood is a life-saving procedure. At every step from donor screening to transfusion of blood unit required a quality management system (QMS) and any lowering in quality would reflect adversely on the final product. Profound theoretical and practical knowledge is required to ensure the optimal clinical use of blood and blood products. Various studies have been conducted to assess knowledge and practice of blood transfusion among medical personnel and nursing staff suggesting that the lack of training in transfusion practices is detrimental to patient safety.

The competent performance in transfusion medicine becomes an essential requirement...
to prevent possible complications and transfusion reactions as lack of knowledge in this field can reduce transfusion safety and can cause significant harm to the patient.\cite{8} Based on the principle of delivering quality health-care services, the National Blood Transfusion Council (NBTC) and the National AIDS Control Organization (NACO) have conducted baseline assessment of NACO supported blood bank and concluded that many blood bank in the country are not aware of the standard quality management practices for various procedures that are performed in blood transfusion services.\cite{9,10} To achieve the quality in blood transfusion services, the NACO conducted training sessions on strengthening QMS at its recognized nodal training centers. Trainings are aimed first to enhance the knowledge of the individuals and later to monitor the improvement thereof in the service where the trainings have focused. The objective of this study was to assess the changes in knowledge concerning QMS among the participants before and after attending a QMS training.

Methods

After obtaining the ethical approval from the Institutional Ethical Committee, a retrospective study was designed to evaluate the effectiveness of QMS. Fifty participants from district blood banks of three different states Madhya Pradesh, Bihar, and Jharkhand participated in the National QMS workshop organized at two different periods of time at the Department of Transfusion Medicine, Bhopal Memorial Hospital and Research Center, Bhopal, which is a recognized nodal training center for NBTC and NACO, in the month of July 2017 and November 2017. For the convenience of analysis, the training in the month of July including the participants of Madhya Pradesh was named as Training I and training in the month of November including the participants of Jharkhand and Bihar was named as Training II. After taking informed consent from the participants, they were subjected to a predesigned questionnaire on quality standards containing questions on relevant topics of the workshop which were approved by the NACO and sent by the QMS training team of NACO.\cite{9} The workshops conducted were of 5 days, respectively, covering the basics of QMS in blood banks through lectures delivered by experts as well as group activities and interactive sessions. The participants were again subjected to posttest questionnaire containing the same set of questions. Twenty minutes were granted to solve the 45 questions containing 35 multiple choice questions (MCQ) and 10 subjective questions. Each question whether MCQ or subjective was given one mark. The MCQs were evaluated on the basis of choosing the correct choice of answer, whereas all the subjective questions were evaluated on the basis of standard answer sheet, and after summing up the scores, the subjective questions were graded on a three-level scale of minimum knowledge (0–5 marks), medium knowledge (5–10 marks), and adequate knowledge (10–15 marks). There was no negative marking. An assessment of knowledge gained during training was evaluated by comparing the scores of pre- and post-assessment.

Statistical analysis

Statistical analysis was done for calculations of means, percentages, and ranges. The comparison of means was done using paired sample Student’s t-test at 95% confidence interval, and \( P < 0.05 \) was considered statistically significant.

Results

Of the total 50 delegates, 29 delegates were trained in the month of July (Training I) and 21 delegates were trained in the month of November (Training II). There were 96% \((n = 48)\) males and 4% \((n = 2)\) females. All participants consented to fill the pretest and posttest questionnaire, and informed consent was obtained from the participants. Combining the participants of both the training sessions, there were total 48% \((n = 24)\) medical officers and 52% \((n = 26)\) laboratory technicians registered as participants [Table 1]. Figure 1 represents that, in both the trainings (Training I and II), the mean scores of objective questions in pretest were 13.629 ± 6.58

| Training Sessions | Features       | Number of participants (%) |
|-------------------|----------------|----------------------------|
| Training I        | Male           | 27 (93.10)                 |
|                   | Female         | 2 (6.89)                   |
|                   | Medical officers| 13 (44.82)                 |
|                   | Laboratory technicians | 16 (55.17) |
| Training II       | Male           | 21 (100)                   |
|                   | Female         | 0                          |
|                   | Medical officers| 11 (52.38)                 |
|                   | Laboratory technicians | 10 (47.61) |

Figure 1: Mean correct knowledge before and after test in July and November
and 9.34 ± 5.74, and after the training, the posttest scores increased to 17.77 ± 7.05 and 14.34 ± 7.09, respectively. The mean pretest scores of objective questions of laboratory technicians and medical officers were 13.92 ± 5.37 and 20.18 ± 4.60 and were increased to mean posttest scores of 21.9259 ± 4.62 and 23.0455 ± 4.64, respectively [Table 2]. The mean rise in the score of laboratory technicians and medical officers increased to 8.0% and 2.86%, respectively, with an overall rise in the scores of 4.6%. Paired Student’s t-test was applied to find the significant difference before and after test, and statistically significant increment was seen in knowledge (P = 0.001).

As evident from Table 3, the scores of subjective questions were also increased significantly in both the training sessions. In Training I, maximum participants 96.55% (n = 28) had a pretest score the sum between 0–5 while they reduced to 48.27% (n = 14) in posttest, whereas none of the participants scored the sum between 11–15 in pretest and the achievement of this increased up to 10.34% (n = 3) in posttest. Similarly, in Training II, 95.23% (n = 20) maximum number of participants scored the sum between 0–5 which reduced to such an extent that no participant scored the minimum score of 0–5 in posttest, whereas the maximum scores of sum between11and 15, of the participants, increased from none in pretest to 38.05% (n = 8) in posttest [Table 4]. Chi-square test was applied to find the significant difference before and after test. There was a statistically significant increment seen in knowledge (P = 0.001).

Table 5 suggests the comparison of the knowledge of subjective questions between medical officers and laboratory technicians in both the training sessions. The knowledge of subjective questions in medical officers was higher in Training I in pretest score and was found statistically significant whereas the posttest scores showed almost equal increment in the knowledge of both. However, in Training II, there was no significant difference between the knowledge of the medical officers and laboratory technicians in pretest as well as in posttest. While comparing both the scores of both the trainings, the participants in Training II showed a higher compatibility to the training as the rise in score is higher in Training II.

As evident from Table 6, in Training sessions I and II, the pretest scores of Q13 and Q16 suggest that the delegates were well aware about the administrative part of the blood banks, including the knowledge of accessibility of standard operating protocol and quality of audit, whereas there was lack of knowledge in defining quality, implementation, intention, and direction of quality in blood banks. However, in posttest assessment, the knowledge about quality audit, blood storage, quality monitoring of blood components, documentation, stock control, and blood cold chain increased significantly as 82.75% delegates answered Q2, Q27, Q29, and 86.2% delegates answered Q16, Q24, Q25, Q30, and Q32 correctly in Training I, whereas in addition to some similar questions as in Training I knowledge about quality policy, document control, quality assurance, and assessment was significantly increased in Training II as 100% delegates answered Q8, Q15, Q21, Q22, Q23, Q25, Q27, and Q30 correctly.

**Discussion**

QMS is an integral part of blood banks as blood consists of living cells and is being used for pharmaceutical purposes and comes under the regulation of pharmaceutical production rules. The present study was aimed to assess the improvement in knowledge of the participants participated in QMS training. This training program in QMS was a predesigned activity-based training which incorporated the maximum involvement of the participants in the hands-on training, including group activities, homework assessments, interactive assessments, and laboratory demonstration including

| Table 2: Mean correct knowledge before and after test in Training I and Training II |
|---------------------------------|----------------|----------------|
|                                  | Mean±SD        | P              |
| Pretest                         | Posttest       |                |
| Training I                      | 13.629±6.58    | 17.77±7.05     | 0.001 (HS) |
| Training II                     | 9.343±5.74     | 14.934±7.09    | 0.001 (HS) |
| Total                           | 22.971±11.81   | 32.113±13.42   | 0.001 (HS) |
| Laboratory technicians          | 13.9259±5.37033| 21.9259±4.26006| 0.001 (HS) |
| Medical officers                | 20.1818±6.60   | 23.0455±4.64   | 0.05 (S)   |

SD=Standard deviation, S=Significant, HS=Highly significant

| Table 3: Pre- and post-subjective test scores (number range) |
|--------------------------------------------------------|
| Number range                                           |
| Training I (November n=21)                             |
| Training II (July n=29)                                |
| Pretest (%)    | Posttest (%)    | Pretest (%)    | Posttest (%)    |
| 0-5           | 20 (95.23)      | 0              | 28 (96.55)      | 14 (48.27)   |
| 6-10          | 1 (4.76)       | 13 (61.90)     | 1 (3.44)       | 11 (37.93)  |
| 11-15         | 0              | 8 (38.09)      | 0              | 3 (10.34)   |
| Significance  | 0.001 (HS)     | 0.001 (HS)     |                |             |

HS=Highly significant

| Table 4: Overall increase in knowledge in both the groups |
|---------------------------------------------------------|
| Paired sample (Post-Pre) (%)                            |
| Paired differences (%)                                  |
| t           | P             |
| Laboratory technicians (Group I)                       |
| 8.00000±8.0358 | 5.174        | 0.000 (HS)   |
| Medical officers (Group II)                            |
| 2.86364±6.50491 | 2.065       | 0.052 (HS)   |
| Overall training                                      |
| 4.60000±6.25652 | 6.142       | 0.000 (HS)   |

SD=Standard deviation, HS=Highly significant
As this is an era of evidence-based practice, regular workshops and their assessment become a mandatory to bring forth the ethics in clinical practices and ensure quality. Furthermore, various researches favor training and workshop and an important tool in medical education as well as for promoting ethical and evidence-based practice.[14][16] The pre- and post-assessment of the workshop is an effective method to find the effectiveness of the training program or workshop module and also helps in improving the instructor's ability.[14] However, to assess the QMS training prospective research studies needs to be planned to fulfill the research gap.

Various studies have been conducted to assess the knowledge of interns and nurses in working or involved in transfusion services.[5][6][7] Hijji et al. in their study reported a deficit of knowledge in the nurses working in blood transfusion services.[6] Similar results addressed in a survey conducted on Jordan nurses and were found detrimental to patient safety.[4] Further, a

### Table 5: Comparison of pre- and post-subjective test score in both the groups

| Training sessions | Groups                  | n   | Mean±SD          |
|-------------------|-------------------------|-----|------------------|
|                   | Presubjective test scores |     | Postsubjective test scores |
| Training I        | Laboratory technicians  | 16  | 1.44±1.263       |
|                   | Medical officers        | 13  | 2.92±1.801       |
|                   | Significance “F”        |     | 0.015 (S)        |
| Training II       | Laboratory technicians  | 11  | 2.91±1.136       |
|                   | Medical officers        | 10  | 2.70±1.337       |
|                   | Significance “F”        |     | 0.703 (NS)       |

S=Significant, NS=Not significant, SD=Standard deviation

The pre- and post-assessment of the training program or workshop module and also helps in improving the instructor’s ability.[14] However, to assess the QMS training prospective research studies needs to be planned to fulfill the research gap.

### Table 6: Question-wise scores of the participants in pre- and post-test assessment

| Questions | Training I pretest (%) | Training I posttest (%) | Training II pretest (%) | Training II posttest (%) |
|-----------|------------------------|-------------------------|-------------------------|-------------------------|
| Q1        | 6 (20.68)              | 20 (68.96)              | 6 (28.57)               | 0                       |
| Q2        | 23 (79.31)             | 24 (82.75)              | 16 (76.19)              | 14 (66.7)               |
| Q3        | 5 (17.24)              | 1 (3.44)                | 0                       | 15 (71.4)               |
| Q4        | 7 (24.13)              | 19 (65.51)              | 5 (23.8)                | 13 (61.9)               |
| Q5        | 7 (24.13)              | 20 (68.96)              | 9 (42.85)               | 0                       |
| Q6        | 14 (48.27)             | 16 (55.17)              | 6 (28.57)               | 13 (61.9)               |
| Q7        | 1 (3.44)               | 5 (17.24)               | 4 (19.04)               | 10 (47.6)               |
| Q8        | 10 (34.48)             | 12 (41.37)              | 10 (47.61)              | 21 (100)                |
| Q9        | 3 (10.34)              | 18 (62.06)              | 2 (9.52)                | 3 (14.3)                |
| Q10       | 18 (62.06)             | 23 (79.31)              | 14 (66.67)              | 3 (14.3)                |
| Q11       | 9 (31.03)              | 4 (13.79)               | 8 (38.09)               | 20 (95.3)               |
| Q12       | 8 (27.58)              | 5 (17.24)               | 0                       | 20 (95.3)               |
| Q13       | 25 (86.2)              | 23 (79.31)              | 18 (85.71)              | 18 (85.7)               |
| Q14       | 17 (58.62)             | 19 (65.51)              | 17 (80.95)              | 21 (100)                |
| Q15       | 17 (58.62)             | 7 (24.13)               | 8 (38.09)               | 21 (100)                |
| Q16       | 24 (82.75)             | 25 (86.2)               | 19 (90.47)              | 18 (85.7)               |
| Q17       | 16 (55.17)             | 23 (79.31)              | 8 (38.09)               | 7 (33.3)                |
| Q18       | 14 (48.27)             | 17 (58.62)              | 5 (23.8)                | 14 (66.7)               |
| Q19       | 6 (20.68)              | 12 (41.37)              | 2 (9.52)                | 6 (28.6)                |
| Q20       | 11 (37.93)             | 20 (68.96)              | 4 (19.04)               | 13 (61.9)               |
| Q21       | 12 (41.37)             | 12 (41.37)              | 5 (23.8)                | 21 (100)                |
| Q22       | 6 (20.68)              | 10 (34.48)              | 5 (23.8)                | 21 (100)                |
| Q23       | 18 (62.06)             | 22 (75.86)              | 19 (90.47)              | 21 (100)                |
| Q24       | 19 (65.51)             | 25 (86.2)               | 15 (71.42)              | 14 (66.7)               |
| Q25       | 21 (72.41)             | 25 (86.2)               | 16 (76.19)              | 21 (100)                |
| Q26       | 18 (62.06)             | 23 (79.31)              | 9 (42.85)               | 13 (61.9)               |
| Q17       | 19 (65.51)             | 24 (82.75)              | 16 (76.19)              | 21 (100)                |
| Q28       | 17 (58.62)             | 19 (65.51)              | 6 (28.57)               | 17 (81)                 |
| Q29       | 17 (58.62)             | 24 (82.75)              | 12 (56.14)              | 17 (81)                 |
| Q30       | 19 (65.51)             | 25 (86.2)               | 11 (52.38)              | 21 (100)                |
| Q31       | 16 (55.17)             | 17 (58.62)              | 9 (42.85)               | 20 (95.3)               |
| Q32       | 22 (75.86)             | 25 (86.2)               | 17 (80.95)              | 19 (90.5)               |
| Q33       | 16 (55.17)             | 23 (79.31)              | 11 (52.38)              | 1 (4.76)                |
| Q34       | 20 (68.96)             | 23 (79.31)              | 7 (33.33)               | 19 (90.5)               |
| Q35       | 6 (20.68)              | 12 (41.37)              | 1 (4.76)                | 1 (4.76)                |

Clark et al. reported an improvement in compliance with the national guidelines to over 95% in six out of seven of the recommendations on the best practice was seen 18 months after the initial intervention and suggested that education is the primary requisite of those who prescribe and administer transfusions.[13]

the quality issues related to blood banking. The training of clinical staff in blood banks is a national mandate and is being regularly conducted throughout the country. As there is paucity of studies related to the assessment of knowledge of the all clinical staff working in blood transfusion whereas no study has been published in India or abroad to find the effectiveness of these QMS training programs; however, the World Health Organization (WHO) reported a workshop conducted in Pakistan, 2014 on the WHO training on quality management and revealed an increment in knowledge of the delegates after an uniform workshop being organized at four different places of the country. The participants scored between 70%-80% in the postcourse assessment as compared with the scores 40%-50% in the precourse assessment.[11] The present study also revealed that there was a significant increase in knowledge among the delegates participated in both the training of QMSs as the scores increased from 46.99% to 61.82% in Training I and from 49.25% to 68.29% in Training II. Similarly, Kaur et al. in their study also reported the rise in the mean score of postraining assessment to 85.4% from 51% in the pretraining, which was statistically significant while training the clinicians for transfusion practices.[12]
The Pyramid Model was also described as a tool to manage the quality systems, which include a four-level model including the quality policy, annual plans, job descriptions, standard operating procedures (SOPs) and emergency operating procedures description, and record maintenance. The present study also included the questions related to quality policy, SOPs, documentations, and job responsibilities, and it was found that the participants were well compatible in maintaining documents, following SOP, and audits as between approximately 75% of participants answered the questions related to these topics correctly whereas they lacked in practical quality management. Furthermore, the participants lack information about the implementation, intention, and direction and overall organization in relation to quality as <41% of the participants answered the questions related to these topics. It is an essential requirement for quality, safety, and efficacy of blood and blood products to ensure well-equipped blood centers with adequate infrastructure and trained workforce. To ensure uniformly ethical practice, good quality practice, and effective clinical use of blood in blood banks, it is necessary to train clinical staff. While moving toward total quality management to attain maximum safety, the requirements of good manufacturing practices and implementation of the quality system have offered challenges to the organization and management of blood transfusion service. This study also included the questions related to quality monitoring of processed blood component and safety issues such as maintaining blood cold chain, identification of patients, and about the storage area for blood and blood components, and it was found that the participants were well aware of these questions and majority approximately 60% and above answered the questions correctly in pretest assessment in both the trainings; however, the scores increased further after the training. Unlike this study, Hijji et al. in their study reported the lack of knowledge related to the appropriate identification of patients.

The training in QMS along with the other quality issues and protocols also addresses the concept of hemovigilance. It is a continuous need to aware the transfusion team about hemovigilance to avoid undesired transfusion reaction and to keep the laws and tools in place. The present study also addressed the concept of hemovigilance in training and <51% of participants answered the question correctly in pretest assessment while it improved to 84% after training.

Transfusion services in developed world such as the USA are highly costly and efficient; however, in the developing world like ours, transfusion therapy is facing the continuous concern related to blood safety issues. The WHO has identified blood safety as a health issue requiring high priority and has developed a comprehensive program and guidelines to ensure the quality management in blood banks and also considered it important to provide comprehensive, appropriate, and effective training is for all blood transfusion service staff and other health-care professionals involved in blood transfusion which also includes the distance learning modules.

In India, in spite of good training programs for QMSs in blood banks by NACO, the effectiveness of these QMS training programs has not been assessed and provides a research gap.

Conclusions

There was a significant positive change in the knowledge of the participants after attending QMS workshop. This study will help to develop the roadmap to the implementation of QMS in blood banks to improve consistency in all its activities and aware the participants for the enhancement of quality of the blood banks. A prospective study can be planned and also a standardized questionnaire can be developed to implement similar assessment throughout the country. Thus, it would be helpful to facilitate to focus the course on areas of particular need.

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Conflicts of interest
There are no conflicts of interest.

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QMT 1.5 PRE--COURSE ASSESSMENT QUESTIONS

Name: ____________________________________________________________

Total Questions: 45 Time: 20 minutes

Mark the correct answer to each question

1 The quality of a product or a service denotes:
   a High cost
   b Fitness for the purpose
   c Quick results and efficacious products
   d Sophistication and complexity of the process

2 ISO is:
   a Internal Services Office
   b International Organisation for Standardisation
   c International Safety Organization
   d Instant Solutions Offer

3 The relationship between the results achieved and the resources used is:
   a Efficiency
   b Effectiveness
   c Precision
   d Verification

4 The initial draft of a standard operating procedure should be written by:
   a Person performing the procedure
   b Quality manager
   c Technical head of the blood bank
   d An expert committee

5 A system of activities that uses resources to transform inputs into outputs
   is defined as:
   a Procedure
   b Process
   c Plan
   d Performance

6 The fulfilment of a requirement is defined as:
   a Conformity
   b Characteristic
   c SOP
   d Audit
7 The implementation of quality in blood banks is the responsibility of:
   a The quality manager only
   b The technical head of the blood bank only
   c External auditors
   d All staff members of the blood bank

8 A quality policy is officially endorsed and approved by the:
   a Top management of the blood bank
   b Quality Manager
   c Customer
   d Technical professionals of the blood bank

9 The overall intentions and direction of an organization in relation to quality, as formally expressed by top management is:
   a Quality objective
   b Quality policy
   c Quality management system
   d Quality planning

10 A document stating the quality policy and describing the quality system of an organization is called:
   a Quality manual
   b Guidelines
   c Specifications
   d Quality plan

11 A job description includes all of the following except:
   a Key tasks to be performed
   b Minimum qualifications and experience
   c Position in the organization’s organogram
   d Career advancement prospects

12 Standard operating procedures (SOPs):
   a Are guidelines for screening of transfusion-transmissible infections
   b May be used by some staff members sometimes
   c Are designed to help newly recruited and inexperienced technical staff to develop confidence and acquire skills
   d Must be followed strictly by all staff members at all times

13 SOPs should be accessible to:
   a Senior staff only
   b All relevant staff all the time
   c Staff when they encounter problems in performing procedure
   d All staff only on demand
14 The following documents need to be controlled:
   a Quality manual  
   b Standard operating procedures  
   c Donor records  
   d List of approved suppliers  
   e All of the above

15 The part of quality assurance that ensures that products are consistently produced and controlled to quality standards appropriate to their intended use is called:
   a Good Manufacturing Practice (GMP)  
   b Good Laboratory Practice (GLP)  
   c Good Clinical Practice (GCP)  
   d Internal quality control

16 A quality audit is:
   a A systematic, independent and documented examination to determine whether quality activities comply with planned arrangements  
   b An evaluation of conformity by observation and judgement  
   c An activity that ensures correct financial procedures

17 Competency assessment of staff includes all the following except:
   a Written evaluation  
   b Review of work records  
   c Testing of unknown samples  
   d Gross salary received  
   e Problem solving skills

18 A stock card is characterized by the following except:
   a A simple and efficient stock control system  
   b A record of the order, delivery and use of each item  
   c Decides next order and quantity to order  
   d Ensures excessive stocks are always available  
   e Helps at each time of issue, order or delivery of stock

19 The following essential information should be retained for stock control except:
   a Minimum stock level  
   b Minimum order  
   c Code number of consumables  
   d Test in which consumable is to be used

20 The method most suitable for ordering consumables with a long expiry period if you have sufficient resources and storage space is:
   a Bulk order  
   b Standing order  
   c Order as required
21 Which of the following does not apply to an external quality assessment (EQA) scheme?
   a Organized by an external agency
   b Does not require follow up
   c Periodic
   d Compares performance at different sites

22 Material received by a participating blood bank for external quality assessment should be analyzed:
   a By the quality manager alone
   b By the most skilled worker
   c With specially procured and exclusive reagents
   d In the same manner as routine work

23 A unique number must be assigned to each donation of blood. To which of the following should this number be attached?
   a The primary collection bag only
   b The primary and all secondary collection bags only
   c The primary, all secondary collection bags and all specimen tubes used only
   d The primary, all secondary collection bags, all specimen tubes used and donation record

24 The following applies to storage areas for blood and blood components:
   a Quarantined components should be stored with non-conforming blood components
   b Tested (available) units should be stored separately from partially tested or untested (quarantined) blood components
   c Quarantined components should be stored with expired blood components

25 Quality monitoring of processed blood components is performed to:
   a Find reasons not to make blood components
   b Research new techniques for making blood components
   c Ensure that the final product meets specifications and that the process is "in control"
   d Keep the quality manager happy

26 The identification of a patient receiving transfusion should be carried out:
   a By the patient’s bedside immediately before transfusion
   b At the nurses’ station before transfusion
   c During the transfusion
   d After the transfusion
27 The documentation required in the preparation of blood components includes:
   a Approved SOPs and records of all key activities ranging from the receipt of whole blood to the distribution of released components to hospitals and blood banks for compatibility testing
   b Validation protocol for testing for transfusion-transmissible infections
   c Crossmatching results
   d Training records for staff working in the Quality Department

28 Documented procedures for the recall of blood components must enable:
   a Recall of all components/component pool related to the donation that caused an adverse reaction
   b Recall of the initial component that caused the adverse reaction
   c Awareness that the component caused an adverse reaction

29 Recall of a product should lead to:
   a Notification of the donor staff
   b No further action
   c An investigation, with corrective action to prevent recurrence
   d Notification of the components preparation staff

30 It is important to have a stock control system for reagents because:
   a It ensures that reagents are validated properly
   b It helps you in monitoring the rate of usage of items, and the reliability of your supplier which, in turn will help prevent an out-of-stock situation
   c It is an extra system to keep people busy
   d It is a new system that management wants implemented

31 Record-keeping in the laboratory is essential in meeting the requirements of:
   a Good laboratory practice
   b Good record-keeping practice
   c Good testing practice
   d Good housekeeping practice

32 A "blood cold chain" is:
   a A metal link that is kept in the refrigerator
   b The storage of products in a refrigerator and/or freezer
   c A system for storing and transporting blood and plasma in an appropriate way to maintain all its functions
   d A cold climate

33 The following are NOT essential parts of the blood cold chain:
   a Equipment for the storage and transportation of blood
   b People who manage the storage and transportation of blood
   c People and equipment, resulting in an adequate blood cold chain
   d Maintenance of blood storage equipment
   e Control of the stock of blood available for use
34 A Haemovigilance programme is concerned with:
   a Investigation of transfusion-related incidents
   b Haemoglobin level of a donor
   c Haemoglobin test
   d Efficiency of staff

35 The customers of the BTS at the clinical interface are:
   a Patients
   b Clinicians
   c Patients and clinicians
   d Donors

36 Write full form of the following
   a. NABH ..........................................................
   b. QCI ..........................................................
   c. MRM ..........................................................
   d. QMS ..........................................................

37 Name of Standards of Blood Bank and lay down by which organization?
   ........................................................................................................................................
   ........................................................................................................................................

38 Frequency of Internal Audit is
   ........................................................................................................................................

39 Write and describe type of Internal Audits
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................

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40 Activities includes in Process Control Clause of Blood Bank

41 Write the Clauses covered in Blood Bank Standards:

42 Write the steps when non conformity is detected

43 How can you improve performance of your Blood Bank?
44 Prepare an organogram of your Blood Bank

45 Write down hierarchy system of documents in QMS

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