MANUAL FOR HOSPITAL
TRANSFUSION COMMITTEES
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ACRONYMS

BE     Blood Establishment
BTA    Blood Transfusion Authority
BTS    Blood Transfusion Services
CME    Continuous Medical Education
CTE    Continuous Technical Education
CUB    Clinical Use of Blood
DOH    Department of Health
EDO    Executive District Officer
HBB    Hospital Blood Bank
HOD    Head of Department
HTC    Hospital Transfusion Committee
ICU    Intensive Care Unit
ISO    International Organization for Standardization
IT     Information Technology
MBOS   Maximum Blood Order Schedule
PBM    Patient Blood Management
RBC    Regional Blood Centre
RCA    Root Cause Analysis
SOP    Standard Operating Procedure
TOR    Terms of Reference
TTI    Transfusion Transmissible Infection
VNRBD  Voluntary Non Remunerated Blood Donation
V2V    Vein to vein
WHO    World Health Organisation
PREFACE

In transfusion medicine, the key concept of blood safety encompasses the entire blood chain starting from the vein of the voluntary donor (blood collection) to the vein of the recipient (blood transfusion), covering quality assured component preparation and testing and management of both the donor and recipient for any adverse effect/event and reaction. Due to multistep involvement of multiple procedures and personnel, it is of paramount importance to ensure quality and safety of blood transfusion in the hospital as well, in addition to blood centres. To meet these requirements of high standards of patient care, hospitals have been forced to elaborate strategies and policies to oversee all aspects of blood transfusion within individual institution. According to the World Health Organization, "a transfusion committee should be established in each hospital to implement the national policy and guidelines and to monitor the use of blood and blood products at the local level."

A fundamental role of hospital transfusion committees is to ensure appropriate blood product use by developing local blood transfusion policies and protocols, educating clinicians, and auditing blood use. The hospital transfusion committee plays a pivotal role in promoting safety, efficacy, and efficiency of blood transfusion services. A hospital transfusion committee is a multi-disciplinary team and includes representatives from all departments in the hospital that are involved in providing, prescribing and transfusing blood and blood products.

The current manual developed with the support of the ‘GIZ Technical Cooperation Team’, is intended for the use by members of hospital transfusion committees and it provides guidance to new members explaining the functionality of the committee and how to conduct clinical audits in the hospital. The manual also includes necessary tools (such as standard blood request form and recipient adverse reaction notification form) required to monitor the transfusion activities. The clinical chain process protocols have recently been added in new version of SOPs for BTS.

Prof. Dr. Hasan Abbas Zaheer
National Coordinator
Safe Blood Transfusion Programme
Government of Pakistan
1. INTRODUCTION

Blood is an expensive and limited resource. To guide the blood user community towards its appropriate and judicious use, a governance body should exist in every hospital to ensure both that all alternatives to blood transfusion are explored and employed and that the limited blood resource collected from the donor community is used cautiously, appropriately and responsibly in all therapeutic processes.

A Hospital Transfusion Committee serves the purpose of such a “regulatory/governance” body within the hospital environment and is meant to promote the “transfusion of the right unit of blood to the right patient at the right time, and in the right condition and according to appropriate guidelines.”\(^1\) WHO recommends that “a transfusion committee should be established in each hospital to implement the national policy and guidelines and monitor the use of blood and blood products at local level.”\(^2\)

The main aim of a Hospital Transfusion Committee is to ensure optimal use of blood in every ward of the hospital. Therefore, every physician prescribing blood transfusion for the management of haematological or non-haematological pathologies should be well aware of the established guidelines and indications for the transfusion of blood and blood components. As blood transfusion may be associated with acute and delayed transfusion reactions and the transmission of TTI, blood must only be prescribed when appropriately indicated. The primary role of a Hospital Transfusion Committee therefore is to promote appropriate use of blood. In addition, a Hospital Transfusion Committee must also implement haemovigilance at the hospital level. A third function of the Committee is to promote safe blood practices at all levels in the hospital.

A Hospital Transfusion Committee can perform its functions by developing local policies, educating clinicians, and auditing blood use. The HTC must hold an authority within the hospital structure to determine hospital policies in relation to transfusion and resolve any problems identified. In turn, for the HTC to function effectively, it must take on board not only the hospital management, but also physicians involved in transfusion activities. This will include physicians from internal medicine, surgeons, gynaecologists, anaesthetists, nursing staff and haematologists.\(^3\) The HTC is a platform bringing together all the departments of a hospital involved in transfusion activities, governing every aspect of V2V transfusion chain.

The members jointly analyse issues and problems, assess compliance with prescribed guidelines and standards and formulate changes in policies/action plans to prevent the occurrence and recurrence of such transfusion related problems. The process also leads to the promotion of best practice by providing continuing professional education, as well as by monitoring the performance through clinical audits and peer review. Regularly notifying clinicians of their performance against established benchmarks is an additional strategy that may improve transfusion practice. It goes without saying that such benchmarks must be pre-established jointly by the members of the Hospital Transfusion Committee and communicated to the clinicians.

This manual is intended for members of Hospital Transfusion Committee, which includes personnel from the hospital administration, physicians, blood bank professional, nursing

\(^1\) Manual of Optimal Blood Use McClelland DBL, Pirie E, Franklin IM for the EU Optimal Use of Blood Project Partners

\(^2\) Developing a National Policy and Guidelines on the Clinical Use of Blood (WHO)

\(^3\) A more detailed description of the composition of the HTC is provided in chapter 2.
staff, and others. It provides guidance to new members explaining the "what, why and who" about the HTC of a Hospital Transfusion Committee - what a hospital transfusion committee is, what the purpose of establishing an HTC in a hospital is, and who should ideally be members of the HTC and why.

A detailed description of safe blood practices and clinical use of blood guidelines is beyond the scope of this manual, and the user is encouraged to visit the SBTP Programme website for these materials. This manual will focus on the status of the Hospital Transfusion Committee within the blood transfusion sector; its recommended composition; its main functions within a hospital setting; quality measures within a hospital transfusion committee; blood transfusion audits within a hospital; sensitization, training and education of hospital staff regarding safe blood practices and optimal utilization of blood; as well as advocacy and outreach.
2. STATUS OF A HOSPITAL TRANSFUSION COMMITTEE

Establishment of HTC is mandatory in every hospital. It forms an integral part of the regulatory framework of a Blood Transfusion System, as well as a hospital. In effect, a Hospital Transfusion Committee forms a liaison between the hospital staff and the health authorities, including the Blood Transfusion Authority and the Provincial Safe Blood Programme.

The Blood Transfusion Safety Law enjoins the establishment of a Hospital Transfusion Committee in every hospital. It states that ‘the hospital administration will ensure rational clinical use of blood and blood components through their Hospital Transfusion Committees, in accordance with guidelines adopted and endorsed by the Blood Transfusion Authority.’ Ultimately, it is the responsibility of health authorities (Department of Health/Health Care Commission/Blood Transfusion Authority) to ensure that an HTC is established in every hospital. At the same time, the hospital administration must also ensure that the nomination of its Hospital Transfusion Committee is notified to the relevant Health Authority (Blood Transfusion Authority), including the names and designations of its members. In addition, a Blood Transfusion Authority must also be informed of the HTC’s functioning and progress in the form of regular reports, such as the minutes of meetings. Regardless of the injunctions of the law, however, the ethics of medical practice also dictate that blood and blood components transfused to patients must be safe and effective, a goal that mandates the formation and functioning of Hospital Transfusion Committees in every hospital.

The HTC is a link between the DOH, the Hospital and the BTA. Transfusion related data, especially the types and frequencies of transfusion reactions and events at the hospital level, are collected by the HTC and communicated to the health authorities (DOH/BTA). At the same time, Hospital Transfusion Committees must be abreast of the policy measures and regulations formulated by the health authorities to be implemented in the hospital.

While nominating members of a Hospital Transfusion Committee, commitment is a priority, as the work of an HTC involves a lot of extra time and effort that the members may have to take out apart from their other primary responsibilities as clinicians, nursing staff, hospital administrators, etc. Membership is honorary without financial rewards from this additional responsibility. Their efforts must be duly appreciated by the hospital administration, and ways to maintain their motivation and commitment must be continuously devised. Their efforts must be upheld by provision of all the necessary financial resources or other resources required for the implementation of recommendations.

The hospital administration is responsible for providing adequate resources to achieving and maintaining quality in transfusion practices - as quality does not come cheap; the greater financial reward of preventing morbidity is much higher than the initial high costs incurred to provide safe blood to patients. Moreover, the prevention of unnecessary transfusions through optimal blood utilization practices may reduce required funding. For a hospital, HTC

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4 The Punjab Blood Transfusion Safety Act 2015 (draft).
should not be established just to fulfil the obligations of the BTA and DOH. This HTC should be active and vigilant in its function. As mentioned in “Composition and Structure of the HTC” section of the manual, the hospital management forms an integral part of the HTC. The hospital management ensures that resources are made available to promote rational use of blood and blood components in the hospital and is according to the guidelines recommended by the BTA.

As Hospital Transfusion Committee is multidisciplinary and involves all departments in the hospital that are providing and prescribing blood and blood products, the HTC members. Physicians are held responsible and are answerable for providing data of any transfusion reaction occurring in their respective ward to the HTC. These are discussed in their regular HTC meetings. This will ensure that the primary purpose of an HTC is served, which is to ensure blood safety and accountability of BTS in the hospital which will, in principle, lead to a significant decrease in transfusion related morbidity and mortality.

Map of HTC established and trained in 2014-1
3. COMPOSITION

Blood safety is dependent on the entire transfusion chain, stretching from donor to recipient, covering blood collection, processing, testing, storage and clinical use. Any weakness in the chain will adversely affect the quality of blood – blood will be as safe as the weakest link in the chain. This also means that meticulous attention must be paid to each individual process of the chain, which requires the provision of adequate resources.

Hospital Transfusion Committees can only guide their systems towards the goal of blood safety and effectiveness if the processes involved are adequately resourced, which will require a structured communication between technical units and hospital administration. We can safely say, though, that not all initiatives of a Hospital Transfusion Committee require major financial resources. This applies to all ‘soft’ components, such as the formulation of policies and guidelines, motivation of clinicians to compile and report transfusion reactions, as well as adhere to indications and guidelines for blood transfusions etc.

The Hospital Transfusion Committee is a standing committee concerned with policies and practices related to clinical blood transfusion and involves all departments in the hospital that are involved in providing and prescribing blood and blood products. The role of the committee shall be to provide consultative and support services with relation to transfusion practices and activities. Its multidisciplinary composition reflects the key staff groups involved in transfusion, including the blood bank staff, prescribers, nursing staff, pharmacy and hospital administration. An HTC must include the representatives of departments which frequently use blood components, such as Haematology, Oncology, Surgery, Anaesthesiology, Ob-Gyn, Paediatrics, Neonatology, Emergency and ICU.

In addition, any other representative with stakes in the safety of blood and blood components, including decision making pertaining to the purchase of the right equipment, reagents, etc., should be included in the committee or be invited to join for specific sessions. It must be remembered that many variables affect the safety of blood directly or indirectly. While prescribers have a role in the transfusion of blood at the right time to the right patient, the hospital administration will be involved in making the right purchases of supplies and reagents for the blood bank, and the blood bank staff will ensure that blood bank standards are met. It is only through a collaborative effort of all stakeholders that the goal of blood safety and effectiveness in a hospital may be achieved.

3.1 STRUCTURE

As an advisory body, the HTC has to be a unit distinct from the transfusion services. The main purpose of establishing an HTC is to promote rational use of blood and blood safety in hospitals (cf. Annex 1 TOR of HTC). Having a ‘consumer’ of blood products serve as chair, however, is likely to enhance the credibility, visibility and effectiveness of the transfusion committee. The chairperson of the Committee may be someone from the hospital administration, the clinical staff, or the blood bank staff. It must be remembered, however,
that the chairperson must be someone with the requisite authority and standing to effect
decision making, and to oversee its implementation.

It is obvious that the organogram depicted above serves as a general recommendation for
the constitution of an HTC. This may vary with the needs and circumstances of each
hospital. There following considerations, then, must be kept in mind while constituting a
Hospital Transfusion Committee:

1. The committee must have a chairperson with authority and standing within the setting of
   the hospital
2. There must be representation of all stakeholders directly or indirectly involved with blood
   safety and its rational use.
3. The members must be carefully selected lest the committee becomes a dysfunctional
   bureaucracy over time as often happens. Members must be sufficiently motivated to
   undertake this additional responsibility without any financial reward.
4. The tendency to delegate representation to junior members of the staff may result in
   reduced analytical capacity and impact of decision making; quality choices beyond the
   overall representation of specialties have to be taken to come to the most dynamic ‘right
   mix’ possible.

3.2 CHAIRPERSON
The chairperson’s role in the HTC is:
1. to ensure that Terms of Reference are developed, approved and provided to all members;
2. to develop meetings based on clear agendas, which lend structure to meetings, decision making and reporting;
3. to ensure the committee can fulfils its mandate
4. to encourage all members to participate equally in discussions and provide their opinion;
5. to maintain awareness about the ethical aspects of decision making;
6. to encourage all members to declare conflicts of interest and maintain decorum;
7. to review the annual reports of transfusion medicine, assess quality assurance programmes;
8. to follow-up on decisions taken.

The Chairperson should not be permanently appointed. The rotation of the Chairmanship should not be less than two years and not more than four years.

3.3 SECRETARY

The Secretary’s role is:

1. to record meeting attendance;
2. to schedule meetings to ensure the Committee meets at least quarterly;
3. to ensure committee members are provided with and/or contribute the data and tools required to enable them to develop recommendations;
4. to arrange for minutes to be distributed and ensure action items are reviewed and completed;
5. to assist the members in understanding the concept of accountability within HTCs;
6. to assist the chairperson in setting agendas;
7. to follow up on quality assurance programmes;
8. to collect complaints or suggestions from staff or patients;
9. to ensure that action items, decisions and recommendations are documented within the minutes;
10. to distribute background documents for discussion to committee members as required;
11. to assist the Chairperson in scheduling meetings as required.

3.4 MEMBERS

As already pointed out, participation of all blood safety stakeholders is vital. It is only through an active contribution from all members that blood safety, effectiveness, and its rational use can be ensured.

The role of members includes:

1. to collect and compile data related to transfusion of blood and blood components in their respective wards including the number of transfusions per patient, the indication of transfusion for each patient, type and frequency of transfusion reactions, if any;
2. to present the data at the regular HTC meetings, so that these may be analysed for any deviations from normal e.g. unindicated transfusion of blood, unusually high or low number of blood transfusions per patient, etc.
3. to discuss possible solutions to transfusion related problems encountered in wards;
4. to implement the decisions taken at the HTC meetings in their respective wards;
5. to ensure that safety standards for blood transfusions, e.g. proper phlebotomy, correct storage and thawing of blood, etc., are followed in the respective wards.
4. FUNCTIONS

The key functions of Hospital Transfusion Committee, as already mentioned, include haemovigilance at the hospital level, and audits of the clinical use of blood. In addition, an HTC should also oversee that each process of the transfusion chain, starting from collection of blood from the donor to the transfusion of blood to the patient, is carried out in accordance with prescribed standards. In order to fulfil its functions effectively, an HTC not only coordinates with all the staff in the hospital, but will also have links to health authorities at their level, which could be the district or province level.

The HTC is collaborating with the following stakeholders:

- The Blood Transfusion Authority
- The Regional Blood Centre
- The Hospital Blood Bank
- Clinical and Nursing Staff
- Quality Managers
- Hospital Administration

An HTC must define (and communicate) its scope of responsibilities. The overall objective is to enhance competence in the hospital environment as concerns blood safety in transfusion and all supporting procedures. As an important clinical governance and quality assurance body, the HTC will have a guiding function for all those involved in transfusion.

The key functions of the HTC are:

1. To develop/adopt guidelines for rational clinical use of blood in their establishment;
2. To devise policies related to the blood transfusion at the hospital level;
3. To review blood utilization and wastage;
4. To analyse the type and frequency of adverse reactions to blood components;
5. To review errors/incidents related to blood transfusions;
6. To perform a Root Cause Analyses (RCA) in cases of severe transfusion reactions;
7. To review the quality of equipment and reagents purchased by the hospital;
8. To ensure that the standards for blood safety and quality are being followed by the blood bank.

4.1 DEVELOPMENT OF GUIDELINES

Transfusion practices can vary widely by facility and by physician. Guidelines can help support clinical decisions about appropriate transfusion and the use of blood components and products. Establishing facility guidelines for transfusion will help to reduce inappropriate transfusions and increase patient safety.

Local guidelines should be evidence based, appropriate for the facility, easy to comprehend, easy for clinicians to access and should be developed with both clinical and laboratory input.
As an alternate and perhaps more preferable course of action, a hospital may adopt established guidelines for clinical use of blood. A set of such guidelines developed by a national working group can be downloaded from the Safe Blood Transfusion Services Programme website (www.sbtp.org.pk).
4.2 TO DETERMINE POLICIES FOR BLOOD TRANSFUSION

The Members of the HTC should strive to develop policies pertaining to each step of the blood transfusion process. This would ensure consistency and avoid errors. It also ensures a transparent process for clinical areas, departments, administration and auditors. The HTC should be responsible to develop and review the donor policy, an informed consent form for transfusion. It also needs criteria for donor deferrals in case donors are bled in the hospital, which may happen rather in emergencies, and pre-transfusion testing orders: group and screen versus crossmatch. Policies should also be in place for blood ordering practices and patient blood management (PBM). In addition, guidelines for transfusion in adults, neonates and paediatric patients, massive haemorrhage protocols, adverse event identification, intervention, reporting and monitoring, non-conformance/error reporting, complaints, corrective and preventative measures should be developed and regularly reviewed by the HTC members.

4.3 BLOOD UTILIZATION AND WASTAGE REVIEW

The dual purpose of a blood utilization review is to minimize inappropriate use of blood components and to promote transfusion of the right component at the right time to the right patient. A blood utilization review touches all aspects of the transfusion process, including physician ordering, wastage rates and inventory levels, cases of over-transfusion or under-transfusion, reduction in unnecessary patient exposure to blood products and prevention of associated adverse events, indications for transfusion, transfusion thresholds, patient identification, blood administration, monitoring for adverse effects, error reporting and quality improvement through physician education. Review of blood ordering practice can be achieved by examining the appropriateness of orders, hence improving patient care and safety, to ensure efficient and effective use of the blood products in facility and reducing the cost to the healthcare system due to unnecessary transfusion.

4.4 REVIEW OF ADVERSE REACTIONS TO BLOOD COMPONENTS

Tracking the types of reactions and monitoring incidence rates helps the organization to identify appropriate treatment of reaction, investigate causes of reactions, review patient safety risks (e.g. haemolytic reactions due to patient identification errors), and prevention of reactions in future.

4.5 REVIEW OF AUDIT

One of the functions of the hospital HTC is to assess and review the results of audits of transfusion practices in the hospital. Auditing can improve an organization’s effectiveness and efficiency by leading to recommendations that promote continuous quality improvement.
of transfusion practice. As part of the audit process, it is essential that the findings of audits, including any corrective action implemented, are documented. The transfusion service must establish an internal audit programme to ensure quality of processes and procedures. Important audits that should be conducted and reviewed by HTC include the blood utilization review that can be used to identify the appropriate use of blood components and products. Moreover regular evaluations of blood ordering and transfusion practices should be conducted. The respective formats for audit/review processes must also be established by the institution.

4.6 REVIEW OF ERRORS/INCIDENTS RELATED TO BLOOD TRANSFUSION

Any incidents, such as errors, accidents and deviations from normal operating procedures should be identified, investigated and evaluated; corrective actions should be taken as required. The process for formulating corrective actions must include an investigation to determine the underlying root causes of the problem. Corrective action shall be appropriate to the magnitude of the problem and risks encountered.

Reporting Near Miss Events
Reporting of actual errors as well as “near miss" incidents should be encouraged in a blame free and non-punitive environment. The subsequent investigation and analysis should take a system based approach, focusing on all relevant contributing factors. Serious errors usually occur as a result of multiple contributing factors. Near miss events provide an opportunity for learning and formulation of preventative measures in the absence of serious harm. The investigation of serious errors will usually be performed by trained individuals.

Root Cause Analyses (RCA)
RCA is a quality improvement tool that helps individuals and organizations to determine the contributing factors that led to an incident. Recurrence can be prevented by finding the root cause that has led to an event. This brainstorming exercise will provide the group with a better understanding of the process. The group will have to describe the problem/issue, gather data and evidence, brainstorm all the possible causes of the problem, identify the most effective solutions, determine corrective actions and preventative measures, implement and verify the corrective and preventative actions and measures, monitor the process for compliance (did the preventative measures work?).

4.7 APPROVING NEW BLOOD COMPONENTS OR PRODUCTS

The HTC at each hospital shall be responsible to determine if the new blood component or product will be used at their facility centred on evidence based clinical guidelines for use of the product. After approving any new blood product, the HTC should develop in house administrative protocols, policies and procedures and should educate staff (medical and nursing) about the new product and its appropriate use. Another role for the HTC is to review
audits on the use of the product once it has been implemented to ensure it is being ordered and used appropriately.

4.8 ROLE OF HTC DURING BLOOD SHORTAGE

The HTC should develop their own plan to address the specific needs of the hospital, should a blood shortage occur, in order to ensure that the hospital takes a consistent approach. The HTC members should be familiar with the hospital plans that relate to the management of blood resources in a disaster or critical shortage situation. It is in the best interest of the HTC to be familiar with and review the hospital emergency blood management plan. Emergency situations such as fire, flood or earthquake can result in a reduction of blood supply services. Similarly any local disaster such as multi-vehicle accident, airplane or train accident can result in overwhelming request for provision of blood and/or blood products.

5 HTCs established in hospitals supplied by the new Regional Blood Centres would need to develop a joint strategy with the RBC a representative of which should be regularly invited to HTC meetings. The RBC Management Information System would provide updates on the blood inventories of their region several times a day. An improvement stock management would reduce the occurrence of shortages.
5. QUALITY MEASURES IN A HOSPITAL TRANSFUSION COMMITTEE

The purpose of the HTC manual is to promote improvement in the quality of existing clinical blood transfusion practices and rational use of blood and blood products. Various queries and doubts exist in the minds of patients and donors regarding repercussions of blood transfusion on their health. The Hospital Transfusion Committee can address these concerns through a Quality Management System for transfusion activity, which should be an integral part of a hospital’s Quality Management System.

Quality management tools involved in transfusion services follow two separate paths of work flow:

1. Blood Component Inventory Management Path. This covers ordering, reception, managing, and disposing of the component inventory.

2. Patient Testing Path. This covers activities from the time a lab test is ordered on the medical record through the following sample collection, reception, processing, testing, review and reporting of results, billing and provision of follow-up consultations.

The HTC is widely held to be essential for the improvement of clinical transfusion practices and is responsible for setting up grounds for quality management systems in clinical blood transfusion. It should implement a framework of accountability, under which quality of clinical service is assured and all the systems and processes by which the hospital achieves its organizational blood safety objectives.

Certain quality measures or indicators need to be established by the HTC to achieve the above mentioned target. Quality system essentials which form the backbone of a hospital blood banking standards and form integral part of function and composition of an HTC are the following:

- a) Organization
- b) Resources
- c) Equipment
- d) Donor and Recipient Issues
- e) Process Control
- f) Documents and Records
- g) Deviations, Non-conformance’s, and Adverse Events
- h) Assessments: Internal and External
- i) Process Improvement through Corrective and Preventive Action
- j) Facilities and Safety

All these quality system essentials are described under one or more of the key elements of quality systems elaborated below.

a) Organizational Management

First and foremost, the HTCs to be formed in every hospital need to be both active and effective in their functions. Terms of Reference need to be laid down and Standards and Guidelines on Clinical Use of Blood (CUB) need to be formulated. Its core function should be the promotion of rational clinical use of blood (cf. section of “Composition of an HTC” for
i **Structure:** The members of an HTC should include representation from the hospital administration, clinicians (especially those dealing with significant blood transfusion activities, like surgeons, oncologists, haematologists, gynaecologists and obstetricians), blood bank in-charges, nurses, and pharmacists. The Blood Transfusion Authority should be notified of the formation of the HTC and its members. As the BTA would require regular updates of the HTC activities, this would force the hospital HTC to carry out its functions efficiently and on regular basis.

ii **Functions of an HTC:** This section is covered in detail in section “Functions of an HTC”. It deserves to be mentioned here, however, as a quality indicator in BTS of the hospital. The HTC must outline its strategies in implementing and maintaining quality management systems in transfusion and monitoring blood use in its respective hospital. Representation from hospital management is mandatory, as they are expected to demonstrate commitment to quality management in transfusion practice and accept responsibility to implement and sustain it. The management should also ensure that resources are available to maintain quality systems in transfusion process.

One of the most fundamental activities of an HTC in terms of quality management is conducting regular audits of the blood bank and wards. Audits are valuable if conducted with the intent to review thoroughly all the crucial systems within the hospital blood banks. They convey whether the hospital blood bank and wards are performing in accordance to blood policy formed by the HTC and are performing blood bank procedures and activities appropriately and timely. They also serve as a means of continuous assessment and therefore improvement in quality management of blood transfusion services and the promotion of rational use of blood.

Participation in regular meetings by each member of the HTC is mandatory to address the deficiencies observed in blood transfusion processes in the hospital and adverse reactions observed in recipients and donors. There should be active participation of the clinicians in these meetings. Reasons are sought by the members for any problems arising as a result of blood transfusion and measures are suggested and implemented to overcome the deficiencies and avoid recurrence of such problems. Minutes of these meetings should be recorded as a means of future reference and copy should be provided to the BTA, so that the Authority is aware of the activity of the Hospital Transfusion Committee and it’s commitment in constantly improving and sustaining quality in blood transfusion practice in the hospital.
b) Standards

Strategies to ensure safe and rational blood transfusion in a hospital include formulation of an effective hospital blood policy and SOPs based on Standards and Guidelines provided by the BTA. The Hospital Transfusion Committee of every hospital could have its own Blood Transfusion Policy, the aim of which is broadly to ensure that the correct blood is given and that any adverse reactions are dealt with promptly and efficiently. All staff involved in the process must be appropriately trained and aware of their responsibilities in relation to handling blood components and performing transfusion related tasks within their own competence and in accordance with procedures which are in place to reduce the risks to patients. The policy should state standards, manage risk and improve the quality of care to patients in relation to the transfusion of blood and blood products. While devising a blood transfusion policy, it should be borne in mind that the general public is now well aware of the pros and cons of blood transfusion. With increased awareness of transfusion transmitted infections, blood transfusion therapy has become an issue of increasing concern to both the general public and to health practitioners. Several measures should be taken by the HTC to reduce the risk of transfusion-related infections. These might include improved screening procedures, early detection of infectious donors by serological methods, institution of confidential donor self-deferral, and inactivation of viruses in some blood products with solvents and detergents.

Although these measures have improved the quality of the blood supply, several important issues, such as other medical complications of blood transfusions, the conservation of limited resources, and cost, remain. Consequently, the HTC have been widely used as one mechanism of monitoring blood use through peer review and monitoring of transfusion activity. The HTC should ensure that the hospital staff (wards and blood banks) strictly adhere to the standards and the SOPs formulated by the clinicians and the haematologists, as any deviations may compromise quality and have grave consequences for the health of the donor and the recipient.
c) Documentation

Documentation of every activity of the HTC, blood bank and the clinical wards is essential. This includes action plans and new steps decided by the HTC to be implemented in blood transfusion practice. Some important documents which every HTC should design and use are a Standard Blood Request Form (cf. Annex 2), Blood Ordering Schedule, Recipient Adverse Reaction form (cf. Annex 3) and SOPs for all stages of clinical transfusion process. Their use should be endorsed by the HTC to improve blood transfusion practice and prevent occurrence and recurrence of reported adverse reactions in donor or recipient of blood. There should be a complete record of the transfusion session and management of adverse reactions in wards. Thorough investigation should be conducted to identify the cause and bring it to the knowledge of an HTC.

The members of an HTC will then come up with measures to prevent recurrence of a similar situation or suggest changes in current transfusion practice. These activities should be documented, and the records will prove fruitful as future reference and also serve as a proof of an active and effective Hospital Transfusion Committee. The BTA maintains a file of every hospital’s transfusion committee, and this file includes minutes of every HTC meeting provided by the hospital management. The hospitals are expected to send their data in a data collection form to the BTA (cf. Annex 4, Global DataBase for Blood Safety Indicators).

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6 In the “reformed blood transfusion system”, HTCs would not normally enter into direct contact with the donor, as donor management is one of the functions of the new Regional Blood Centres.
d) Training and Sensitization

The staff involved in blood transfusion processes including doctor in charge of the blood bank, lab technologist/technician in blood banks, clinicians and ward nurses should receive continuous training in blood transfusion processes and bedside transfusion protocols. Emphasis should be placed on internal quality control measures. Participation in external quality control programmes of blood banks should be arranged by the HTC as well. The training programmes, which can include after duty classes, seminars or workshops, should be devised according to local protocols and reviewed regularly for continuous improvement in blood transfusion practice. The staff should be updated with recent advancements in blood transfusion practices, especially in terms of quality assurance. The staff should be made aware of the importance of this continuous training and able to apply acquired knowledge in their daily practice, which eventually requires modifications at the working place. HTCs could contribute to convert their hospitals into ‘learning institutions’ and introduce a culture of learning from errors and acting on lessons learnt.

e) Monitoring and evaluation of outcomes

The most important quality measure to assess effectiveness and proper functioning of a Hospital Transfusion Committee is regular monitoring and evaluation. Assessment of the staff competency and skills is mandatory. The HTC should schedule regular assessments and formulate pre and post workshop/educational session evaluation schemes in the form of questionnaires for the clinician and staff, so that effectiveness of HTC training programmes can be judged and reformed according to staff performance. Decisions and future plans of the HTC should be based on reports of the HTC, analysis and use of data obtained from hospital blood bank and clinical wards all aiding towards practice of haemovigilance in the hospital.

Outcomes of an HTC can be analysed by collecting data of acute and delayed transfusion reactions observed in donor and recipients, indication of blood transfusions, amount of blood transfused in each ward, maximum blood ordering schedule and reported transfusion transmitted infections in the hospitals. If the HTC blood policy, guidelines and SOPs are effective and implemented properly in the hospital setting, favourable outcomes like minimum transfusion reactions, fall in demand of blood transfusion and proper observation of maximum blood ordering schedule (MBOS), effective blood stock management, fall in reported transfusion transmitted infections are the likely results.

Continuous quality improvement takes quality management system in blood transfusion a step further. It is based on the principle that despite utmost care processes and systems cannot be designed to be perfect. It is therefore necessary to implement an evolutionary refining process to detect deviations and to put in place appropriate corrective actions. The HTC should have a system in place for thoroughly searching for signs of deviations in processes. These deviations become apparent during validation of a new process, during quality control and quality assurance audits or through occurrences such as errors, accidents, complaints and transfusion reactions. These deviations should be investigated and root cause analysed so that appropriate corrective measures can be implemented. The staff and the patients must be encouraged to report deviations and they should be
encouraged to search actively for mistakes without fear of retribution. Errors or deviations are viewed as opportunities to improve and provide better transfusion services. Well-designed processes performed by well-trained staff should ideally not allow any deviations. When they do occur, it is critical to thoroughly evaluate the problem and the involved processes to ensure systemic quality improvement.
6. AUDITS

Audits are a must for the inspection and examination of a process or quality system to ensure compliance with requirements for an organization, function, process, product or step. A function of the hospital HTC is to assess and review the results of audits of transfusion practice at the hospital. Auditing can improve an organization’s effectiveness and efficiency by leading to recommendations that promote continuous quality improvement of transfusion practice. As part of the audit process, it is essential that the findings of audits, including any corrective action implemented, be documented.

Audits should be performed annually, at a minimum, to verify the continuing effectiveness of the quality system. The transfusion service must establish an internal audit programme to ensure quality of processes and procedures. Audit in Transfusion Medicine involves compliance with good clinical practices with the aim to improve transfusion services and to reduce accidents and errors based on evidence. Audits are a cost effective manner to induce modifications in physicians’ attitudes and behaviour towards patient transfusion needs.

6.1 TYPES OF AUDITS

Audits, when properly used, may be an important support tool to identify and analyse problems around blood transfusion which have to be addressed and solved systematically.

<table>
<thead>
<tr>
<th>Types of Audits</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Inspection Audit</td>
<td>The blood bank staff within a specified area carries out the procedure, e.g. staff involved in component preparation demonstrates their capacity to adhere to SOP.</td>
</tr>
<tr>
<td>2 Routine Audit</td>
<td>Based on the needs of BTS; monthly, quarterly, half-yearly or annually.</td>
</tr>
<tr>
<td>3 Emergency Audit</td>
<td>Conducted if some error or incidence comes to notice and has to be reported; for correction and formal/informal communication with concerned staff.</td>
</tr>
<tr>
<td>4 Internal Audit</td>
<td>Carried out by staff that does not bear direct responsibility to the area being audited. All parts BTS are covered in such audits and form a baseline for the future practices.</td>
</tr>
<tr>
<td>5 External Audit</td>
<td>Carried out by trained auditors outside the organization. Mandatory (e.g. Drug inspectors for issuing /renewal of blood bank licenses). A failure in such audit may lead to grave consequences like delicensing of the premise. Voluntary (on request by the BTS; usually restricted to some particular area of BTS e.g. by ISO, International Haemovigilance and College of American Pathologists) are also recommended.</td>
</tr>
<tr>
<td>6 Vendor Audit</td>
<td>Carried out by organizations to ensure safe and reliable supply of proper reagents or raw material e.g. purchase of kits, reagents, blood collection containers. Blood utilization review is an example of an audit that is used to identify the appropriate use of blood components and products at your facility.</td>
</tr>
</tbody>
</table>
Regular evaluations of blood ordering and transfusion practices have to be conducted. Specific areas that are important to address are: ordering, distribution, handling, dispensing, and administration of blood components and blood products.

Additional auditing categories may include: policies and procedures, facility management, training/personnel qualifications and competency, quality assurance, complaints/deviations, error/accident trends, adverse events, testing and lookback/trace back. The format of any audit/review process must be established by each individual institution. A blood utilization review must include the criteria for appropriate blood utilization. Reviews can be conducted either prospectively or retrospectively and data collection can be performed manually or by accessing hospital or laboratory information system.

6.2 AUDIT AREAS OF BTS

Audits are conducted in the following areas of the Hospital and Blood Banks:

- Donor recruitment and blood collection policies;
- Percentage of voluntary donation;
- Antiseptics for arm preparation, donor reactions;
- Component preparation;
- Universal leukoreduction;
- Multicomponent collection and its cost-effectiveness;
- Infection screening – e.g. for new and emerging diseases like West Nile virus;
- Release of blood components for transfusion and disposal of biohazardous by-products;
- Adherence to MBOS and consent of recipients prior to transfusion;
- Immuno-haematological follow-up of post-transfusion complications;
- Causes of transfusion reactions;
- Blood group discrepancy workup;
- Research methodology;
- Evaluation and policy Issues – e.g. audit during research to justify the utility, efficacy and safety of such projects.
7. SENSITIZATION, TRAINING, EDUCATION

Blood transfusion involves personnel from diverse backgrounds with different levels of knowledge and understanding. In order to ensure compliance with the prescribed set of standards/guidelines, hospital staff dealing with blood or blood components must be appropriately trained. In order to properly and safely accomplish their roles in transfusion, training must be provided to each individual of them. The hospital and blood transfusion service shall ensure that there is ongoing training for staff involved in blood component/product administration.

Generally speaking, clinicians, during their time at medical school, receive little or no formal training on the clinical indications for blood transfusion. The HTC can promote best practice by providing continuous professional education and monitoring performance by clinical audit and peer review. Regularly notifying clinicians of their performance is an additional strategy that may improve transfusion practice.

A formal programme to assess skills in transfusion-related activities shall be developed and maintained in conjunction with all healthcare professionals and staff involved in any transfusion medicine related activities. Seminars and workshops shall be devised according to local protocols and reviewed regularly for continuous improvement in blood transfusion practice. Staff should be up to date with recent advancements in blood transfusion practices. Eventually, blood transfusion issues have to be inserted into the governmental CME curricula. A parallel training programme for technical staff still has to be established. This programme could be dubbed CTE, Continuous Technical Education. There would be no harm, though, in starting this work through pioneering activities at any of the hospitals right away.

Transfusion Medicine is always evolving and practices are continually improving. Appropriate knowledge of the indications for blood product transfusion and safety should be the main drivers of educational interventions directed at prescribers. Education and training are of key importance for safe and effective blood transfusion practice. Education in blood transfusion must be included in the curriculum for all clinical staff involved in prescribing and administering blood.

Adequate resources are needed to ensure that all staff involved in the transfusion chain in hospitals receive appropriate training, which must be documented.

The concept of Haemovigilance is novel for many people working in hospitals in Pakistan. Most staff is not familiar with standards for blood transfusion and the guidelines for clinical use of blood either. HTCs are encouraged to organize regular training courses for all staff involved in blood transfusion therapy (physicians and nurses of clinical units and staff of HBB). The training programmes should be designed to enhance levels of knowledge on the recommendations formulated in three publications of the Safe Blood Transfusion Programme related to the practice of blood transfusion at the hospital: (1) Standards and Guidelines for Blood Banks, (2) Standard Operating Procedures for Blood Banks and Transfusion Services and (3) Guidelines for the Appropriate Clinical Use of Blood. Training
programmes and training tools developed at national level are also expected to be implemented at hospital level by HTCs.

A training programme must include:

- For clinical wards: Ordering, issuance and use of blood and blood components at the hospital level (transport and storage before transfusion, control at bedside and for infusion, management of transfused patient).

- For HBBs: Management of procurement, reception and storage of blood and blood components distributed by RBCs, pre-transfusion compatibility testing, selection of blood and blood components, issuance of blood and blood components. Training tools shall be PowerPoint presentations, printed posters, printed documents and international publications. Other regular trainings will focus on continuous professional education and will include:
  - Presentation and discussion at staff meetings about adverse events and corrective actions undertaken;
  - Regular workshops for reporting haemovigilance data. Assessment of training effectiveness through clinical audits. Peer reviews including pre and post-training assessments of participants should also be conducted.

The Committee should be monitoring and reviewing their current practices based on:

- New evidence (i.e. Restrictive Transfusion Strategies).
- Increased use of alternatives to transfusion in the management of anaemia, i.e. Erythrocyte Stimulating Agents (ESAs).

Appropriate use of blood components must be strenuously promoted and evaluated. This must include monitoring for serious adverse effects of alternatives to transfusion. Further national initiatives are needed to drive forward blood safety issues in hospital transfusion laboratories. Information technology as an aid to transfusion safety should be assessed and developed at National Level. A coordinated approach is essential.

All newly qualified doctors must receive education in blood transfusion. Pending the availability of effective IT solutions, hospitals should take steps to ensure that the patients’ transfusion histories, including special requirements, are kept up to date and accessible to the transfusion laboratory at all times. Training and education in blood sampling, including the practical aspects of venepuncture and positive patient ID, should be included in the curriculum for medical and nursing students.

Consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being cross matched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.

A system of notifying clinicians of their performance should also set up, which involved sending a letter of reminder of the new guidelines when shared transfusion criteria were not
met. Blood utilization may be improved by combining evidence-based transfusion triggers with physician's education.

Possibly the major obstacle to making transfusion practices more consistent and bringing them in line with published guidelines and evidence-based medicine is the overall lack of knowledge regarding transfusion medicine shared by clinicians across specialties as evidenced by published data. This evidence would seem to indicate that medical education in transfusion medicine continues to lag behind. This must be addressed now, especially as a new national curriculum for the training in blood transfusion services has been developed.⁷

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⁷ The Curriculum is currently with the Higher Education Commission in Islamabad and will be put before the Technical Panel in February 2016.
8. **ADVOCACY AND OUTREACH**

Advocacy forms an essential strategy for the establishment and maintenance of an effective Hospital Transfusion Committee. To initiate the process, advocacy to the hospital administration is mandatory. An advocacy document which includes the rationale of an HTC, its enshrinement in the regulatory framework of the country, as well its paramount role in blood safety and clinical governance must be prepared at some level in the hospital.8

The establishment of a committee through notification does not yet guarantee its functioning. This necessitates that considerations to the functioning of the committee should be undertaken from the outset. As already pointed out, the foremost of these is sufficient authority to enable the committee to effect decisions, sufficient motivation of its members lest the committee degenerate into an ineffective bureaucracy, as well as participation of all stakeholders in a hospital. The process of advocacy is therefore an ongoing one.

It would be a mistake to assume that an HTC is a body with a role confined to the hospital. Instead, the Committee has links with a diverse group of stakeholders outside the hospital, and must be properly equipped with the right competence and knowledge to meaningfully interact with these stakeholders. On the one hand, an HTC provides an interface between the health authorities (BTA, Blood Programmes) and the hospital. At the same time, it also interacts with other related services (possibly the Regional Blood Centres), as well as suppliers of equipment and reagents. In short, the committee must be envisioned as a dynamic, committed, and action-driven organization.

Among the clinical laboratories, the Blood Transfusion Service (BTS) occupies a unique niche. These are activities devoted to collection and manufacturing (the Blood Donor Centre9 and Processing Laboratory), a component devoted to resource banking, allocation and diagnostics (the Transfusion Service), and a clinical and therapeutic component (the Transfusion/Infusion and Apheresis Unit).

The HTC shall systematically scrutinize the blood supply, blood safety, donor care, clinical use of blood products, and costs. It shall operate as a kind of blood transfusion service supervisory board. Clinicians and hospital administrations are directly involved in decision making and directing investigations to support potential changes and advances in the role and function of the blood transfusion service. The close relation with a major blood centre and HBB laboratory provides the impetus and support for research and investigations preliminary to decision making. Data collected and analysed can be reported in the international literature and contributed to disseminate progress made.

HTCs form part of a new governance structure, with Blood Transfusion Authorities as one of the change agents. The Blood Transfusion System Reform is based on some key elements:


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8 Annex 5 presents a ‘flyer’ for the presentation of a HTC in its internal environment. It could be uploaded on the Hospital’s intranet. This document could open up the dialogue. Later on, all new policies and strategies developed, changes introduced, etc., would form part of this structured dialogue.

9 In the reformed system, der Blood Donor Centre is located in the Regional Blood Centre, not in the hospital any more, in order to curb the practice of replacement donation.
- Introduction of VNRBD as principle and future unique source for blood donation.
- A clear separation between production of blood products at the level of ten new built RBC fully equipped, and use of blood in 64 sustained hospital through refurbished HBB with reduced functions, limited to storage, compatibility testing, and issuance, without any production activity.
- Development of human capacity at all levels, for which, a.o., a new training curriculum has been developed.
- Introduction of a rational use of blood and blood products.
- Introduction of audits and the concept of Haemovigilance.
- Introduction of HTCs, the blood transfusion governance body at hospital level.
- Management Information Systems to manage quality based on data and information.

The extension of the reform to the entire sector will need transition plans yet to be designed and a financial support from all required involved stakeholders.

Indeed, HTC is an operational and organizational concept which can be implemented, from now on, in any hospital, without any additional human or financial resources. Newly set up HTCs in 60 hospitals supplied through Regional Blood Centres should be a model to be implemented at national level.
Annex 1: Terms of Reference for HTC

1. To ensure safe procedures in V2V transfusion chain.
2. To develop policies for the use of blood and blood products.
3. To ensure the dissemination and implementation of national guidelines on Clinical Use of Blood to avoid unnecessary transfusion and rational use of blood.
4. To promote best practice through local protocols based on national guidelines.
5. To set up a surgical blood schedule (SBOS) and also regularly review it.
6. To ensure that adverse transfusion events/reactions are investigated and corrective actions are taken.
7. To ensure that adverse transfusion events/reactions are reported to the haemovigilance system.
8. To support training and education in Clinical Use of Blood.
9. To promote audits of the use of blood components.
10. To consider the legal implications of clinical transfusion practice.
11. To address issues relating to patients’ religious and cultural choices.
12. To be aware of factors which might affect short and long term demands for blood.
13. To promote techniques such as autologous transfusion for preventing the use of donor blood.
14. To support the blood bank to optimize stock management.
15. To communicate with internal and external quality assurance bodies.
Annex 2: Blood Request Form

Instructions:

- 5ml of patient’s clotted blood in red top tube (properly labelled) should accompany this requisition
- Form to be completed and signed by requesting physician

Patient’s Identification Data

<table>
<thead>
<tr>
<th>Patient’s Unique Hospital #</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>S/O,D/O</td>
</tr>
<tr>
<td>Age/DOB</td>
<td>Sex</td>
</tr>
</tbody>
</table>

Details of Blood Requisition

<table>
<thead>
<tr>
<th>Name</th>
<th>of Attending Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>of Requesting Physician</td>
</tr>
</tbody>
</table>

Required for

- Emergency
- Planned Surgery/Transfusion

Type and No. of Desired Blood Component (s) / Units:

<table>
<thead>
<tr>
<th>Type</th>
<th>Required No.</th>
<th>Date &amp; Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Whole Blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Red cell Concentrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Platelet Concentrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Fresh Frozen Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Cryoprecipitate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Un-crossmatch “O” Negative Blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Group Specific un-cross matched Blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Gamma Irradiated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical Diagnosis (Indication for Transfusion)

Baseline Investigations of Patient

| Haemoglobin | Platelet Count | Prothrombin Time | Partial Thromboplastin Time |
Past Transfusion History

Previously Identified Blood Group __________________________ Irregular
Antibodies ______________________________

Last Transfusion Date ________________________________

Previous Adverse Reaction Type __________________________ Date__________________

<table>
<thead>
<tr>
<th>Requesting Physician Name and Sign:</th>
<th>Receiving Technician Name and Sign:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/Time:</td>
<td>Date/Time:</td>
</tr>
</tbody>
</table>
### Annex 3: Recipient Adverse Reaction Reporting Form

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Sex: M □ F □ Age: ------- years File number/MR No.</th>
<th>Location (Ward/ICU/OT)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date of transfusion (dd/mm/yy): ………/……/………… Time of Transfusion: ____________

Date and Time of Appearance of Transfusion Reaction: ……min / ……hour(s) / ……day(s) / ……year(s)

(all other information is confidential and appears only on the hospital forms/patient record)

<table>
<thead>
<tr>
<th>Patient's Primary Diagnosis</th>
<th>Details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Surgical</td>
<td></td>
</tr>
<tr>
<td>□ Medical</td>
<td></td>
</tr>
<tr>
<td>□ Obstetric</td>
<td></td>
</tr>
<tr>
<td>□ Oncologic</td>
<td></td>
</tr>
<tr>
<td>□ Hematologic</td>
<td></td>
</tr>
<tr>
<td>□ Other:………………</td>
<td></td>
</tr>
</tbody>
</table>

Indication for Blood Transfusion: Specify:

Type of Blood Component (BC) Transfused:

- □ Whole Blood
- □ Red cells
- □ Platelets
- □ Plasma/FFP
- □ Other (specify):
- □ Leucocyte-poor
- □ Leucocyte-depleted/filtered
- □ CMV negative
- □ Irradiated
- □ Plasma-depleted/washed
- □ Other (specify):

Place of BC issuance:  
........................................
### Signs and Symptoms of Transfusion Reaction Observed

<table>
<thead>
<tr>
<th>Signs Before tx</th>
<th>After tx</th>
<th>Clinical Symptoms (1)</th>
<th>Clinical Symptoms (2)</th>
<th>Biological Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature (^\circ) C</td>
<td>...</td>
<td>- Discomfort</td>
<td>- Lower back pain</td>
<td>- Positive DAT / Direct Coombs</td>
</tr>
<tr>
<td>Blood pressure (systole/diastole)</td>
<td>.../...</td>
<td>- Chills</td>
<td>- Chest/abdominal pain</td>
<td>- Hyperbilirubinemia</td>
</tr>
<tr>
<td>In mm Hg</td>
<td>.../...</td>
<td>- Itching</td>
<td>- Nausea/vomiting</td>
<td>- ALT &gt; 2N</td>
</tr>
<tr>
<td>Pulse (beats/min.)</td>
<td>...</td>
<td>- Urticaria</td>
<td>- Dyspnea</td>
<td>- Transfusion refractoriness</td>
</tr>
<tr>
<td>Haemoglobinuria</td>
<td>□</td>
<td>- Redness</td>
<td>- Oliguria/Anuria</td>
<td></td>
</tr>
<tr>
<td>Cardiac arrhythmia</td>
<td>□</td>
<td>- Rash</td>
<td>- Shock</td>
<td></td>
</tr>
<tr>
<td>Others:</td>
<td></td>
<td>- Jaundice</td>
<td>- Loss of consciousness</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigations Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Test</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>12</td>
</tr>
</tbody>
</table>
Conclusions on RECIPIENT AR (Adverse Reaction to Transfusion) (only one for each report):

**Immunological**
- Haemolysis due to ABO incompatibility
- Haemolysis due to irregular antibody

Specify: ...............................................

- Immunisation to:
  - Red cells
  - Platelets
  - HLA
  - IgA
- PTP (post-transfusion purpura)
- Allergic reaction (mild)
- Anaphylactic reaction (severe)
- TRALI (tx related acute lung injury)
- TACO (tx associated circulatory overload)

**Infectious**

- Blood component with bacterial contamination

Microorganism(s): .........................

- HIV
- HBV
- HCV
- CMV
- Malaria
- Other infectious agent: ......................

**Others**

- NHFTR (Non haemolytic febrile transfusion reaction)
- TA-GVHD (tx associated graft versus host disease)
- Pulmonary oedema (due to cardiac failure, circulatory overload)
- Haemosiderosis
- Unspecified: .................................................................

**Severity**

- 0. no effect
- 1. immediate, no vital
- 2. immediate, vital
- 3. long term morbidity
- 4. death

**Imputability**

- 0. excluded
- 1. possible, dubious
- 2. likely, probable
- 3. certain, proven

**Other relevant clinical information on the transfused patient:**
(e.g. prior condition of the recipient, medication, ....)

**Transfusion process**

<table>
<thead>
<tr>
<th>Location:</th>
<th>Operation Theatre</th>
<th>Intensive Care Unit</th>
<th>Medical</th>
<th>Paediatric</th>
<th>Outpatient Clinic</th>
<th>Other unit/ward:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time:</td>
<td>Working hours</td>
<td>Night shift</td>
<td>Weekend</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Incorrect blood component transfused (IBCT):

Yes ☐ No ☐

Where in the process did the error occur?

Producing blood centre ☐ Hospital blood bank ☐
☐ clinical unit/ward
☐ other: ..............................................................
☐ at production of blood component ☐ at cross-matching
☐ at distribution/issuing ☐ at transfusion (administration of BC to patient)
☐ other:...............................................................................................

Describe the error:
...............................................................................................
Annex 4: Global Database for Blood Safety Indicators

<table>
<thead>
<tr>
<th>WHO Blood Safety Indicators Questionnaire for GDBS 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Number and type of blood banks/blood centres covered for this Report</strong></td>
</tr>
<tr>
<td>a. Stand-alone blood centres</td>
</tr>
<tr>
<td>b. Hospital blood bank (public)</td>
</tr>
<tr>
<td>c. Hospital blood bank (private)</td>
</tr>
<tr>
<td>d. Transfusion Centres (Thalassemia)</td>
</tr>
<tr>
<td>e. Total</td>
</tr>
</tbody>
</table>

| **2. Number of whole blood donations collected by types of donations** |
| a. Voluntary non-remunerated donations |
| b. Family/replacement donations |
| c. Paid donations |
| d. Total number of donations |

| **3. Number of blood centres that perform screening of blood donations for TTIs** |
| a. HBV |
| b. HCV |
| c. HIV |
| d. Syphilis |
| e. Malaria |

| **4. Number and % of donations that were screened for the TTIs (HBV, HCV, HIV, Syphilis and Malaria)** |
| a. HBV |
| b. HCV |
| c. HIV |
| d. Syphilis |
| e. Malaria |

<table>
<thead>
<tr>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
</table>
5. **Number and % of blood donations reactive for the TTIs marker**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>HBV</td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>HCV</td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td>HIV</td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Syphilis</td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>Malaria</td>
<td></td>
</tr>
</tbody>
</table>

6. **Number of blood Centres preparing blood components**

7. **Number and % of whole blood donations separated into components (RCC, FFP, Platelets)**

8. **Number of units of blood components prepared from whole blood Donations**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
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<td>a.</td>
<td>Red cell concentrates</td>
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<td>b.</td>
<td>Platelets concentrates</td>
</tr>
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<td>c.</td>
<td>Fresh frozen plasma</td>
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<td>d.</td>
<td>Cryoprecipitate</td>
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9. **Number of units of blood components prepared through aphaeresis procedures**

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<td>a.</td>
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<td>Apheresis platelets</td>
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<td>c.</td>
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10. **Number of units of whole blood/ red cell components discarded by cause**

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<td>a.</td>
<td>Incomplete blood donation</td>
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<td>Reactive for TTIs</td>
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<td>c.</td>
<td>Passed the expiry date</td>
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<td>d.</td>
<td>Storage problems</td>
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<tr>
<td>e.</td>
<td>Transportation problems</td>
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<td>f.</td>
<td>Processing problems</td>
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### 11. Number of hospitals that perform blood transfusion

### 12. Number and % of hospitals performing blood transfusion that have, or participate in:

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- a. Hospital Transfusion Committees.
- b. Clinical audit
- c. System for reporting adverse transfusion incidents and reactions

### 13. Number of units (whole blood, RCC, FFP, Platelets) issued/ transfused

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- a. Whole blood
- b. Red cells
- c. Platelets, whole blood derived
- d. Fresh frozen plasma
- e. Cryoprecipitate

### 14. Number of serious adverse transfusion reactions reported
Annex 5: Flyer for Hospital Transfusion Committee

Background

Hospital Transfusion Committee (HTC)
### Annex 6: Category of Trainees for WS on Clinical Governance and Haemovigilance

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Safe Blood Transfusion Programme Pakistan
Ministry of National Health Services, Regulation & Coordination, Government of Pakistan
NISTE Building, Hostel ‘A’, H-8/1, Islamabad, Pakistan
Tel: +92 (51) 9250307, Fax: +92 (51) 9250309
E-Mail: info@sbtp.gov.pk, Website: www.sbtp.gov.pk