PRACTICES OF PRESCRIBING AND PROVISIONING FOR TRANSFUSIONS: A STUDY OF DELHI

Thesis submitted to Jawaharlal Nehru University in fulfilment of the requirements for the award of the degree of

DOCTOR OF PHILOSOPHY

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DECLARATION

I hereby declare that this thesis entitled **"PRACTICES OF PRESCRIBING AND PROVISIONING FOR TRANSFUSIONS: A STUDY OF DELHI"**, submitted to Jawaharlal Nehru University for the award of Degree of Doctor of Philosophy, is my original work. This thesis has not been previously submitted for the award of any other degree of this or any other university.

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CERTIFICATE

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helping at home and managing her studies side by side. Now an MPH herself, helped me put together this thesis. It was not an ordinary journey it had become a way of life.

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Abbreviations

AABB-American Association of Blood Banks

AIDS-Acquired Immuno Deficiency Syndrome

BCSU-Blood Component Storage Unit

BMI-Body Mass Index

BP-Blood Pressure

BSCs-Blood Storage Centres

BTS-Blood Transfusion Services

CABG-Coronary Artery Bypass Surgery

CBHI-Central Bureau of Health Intelligence

CGMP-Current Good Manufacturing Practice

CHC-Community Health Centre

CJD- Creutzfeldt-Jakob Disease

CMAJ-Canadian Medical Association Journal

CME-Continuing Medical Education

CTVS-Cardio Thoracic and Vascular Surgery

CT RATIO-Cross Match Transfusion Ratio

DCGI-Drug Controller General Of India

DGHS-Director General of Health Services

DIC-Disseminated Intravascular Coagulation

DOTS-Directly Observed Treatment Short Course

Dr. RMLH- Dr. Ram Manohar Lohia Hospital

DSACS-Delhi State Aids Control Society

ENT-Ear Nose Throat

ELISA-Enzyme Sorbent Immunosorbent Assay

EBM-Evidence Based Medicine

FDA-Food and Drug Administration

FFP-Fresh Frozen Plasma

FGDs-Focus Group Discussions

FRU-First Referral Unit

GBSI-Global Blood Safety Initiative

GDP-Gross Domestic Product

GMP-Good Manufacturing Practices

GOI-Government of India

GVHD-Graft versus Host Disease

Hb-Haemoglobin

Hct-Hematocrit

HDI-Human Development Index

HIV- Human Immunodeficiency Virus

HLA-Human Leucocyte Antigen

HTA-Health Technology Assessment

ICER-Incremental Cost Effectiveness Ratio

ICMR-Indian Council of Medical Research

IEC-Information Education Communication

IEA-International Economic Association

INR-International Normalized Ratio

ISBT-International Society of Blood Transfusion

ITP-Idiopathic Thrombocytopenic Purpura

IV-Intra Venous

JACAHO-Joint Action Council of Accreditation of Hospitals

MCD-Municipal Corporation of Delhi

MCI-Medical Council of India

MOU-Memorandum of Understanding

MSOBS-Maximum Surgical Blood Order Schedule

MTS-Multitask Staff

NAT-Nucleic Acid Testing

NACP-National AIDS Control Program

NACO-National Aids Control Organisation

NBTC-National Blood Transfusion Council

NBP-National Blood Policy

NDMC-New Delhi Municipal Corporation

NFHS-National Family Health Survey

NFHTR-Non Febrile Haemolytic Transfusion Reaction

NGO-Non-Governmental Organization

NHMRC-National Health and Medical Research Council

NICD-National Institute of Communicable Diseases

NNMB-National Nutrition Monitoring Buereau

NPP-National Plasma Policy

NRHM-National Rural Health Mission

NSSO-National Sample Survey Organization

OPD-Out Patient Department

OT-Operation Theatre

PAM-Process Analysis and Management

PC-Packed Cells

PDMPs-Plasma Derived Medicinal Products

PHC-Primary Health Centre

PIL-Public Interest Litigation

PRP-Platelet Rich Plasma

PV-Plasma Volume

QA-Quality Assurance

QUALYS-Quality Adjusted Life Years

RBC-Red Blood Corpuscles

RBTC-Regional Blood Transfusion Centre

RCT-Randomized Control Trial

REDS STUDY-Retrovirus Epidemiology Study

RTA-Road Traffic Accidents

SAnGUIS STUDY- Safe And Good Use of Blood In Surgery

SBTC-State Blood Transfusion Council

SEAR-South East Asian Region

SHOT-Serious Hazards of Transfusion

SOP-Standard Operating Procedure

SRS-Sample Registration System

STD-Sexually Transmitted Diseases

TAH-Total Abdominal Hysterectomy

TB-Tuberculosis

THR-Total Hip Replacement

TI-Transfusion Index

TKR-Total Knee Replacement

TPC-Total Process Control

TQM-Total Quality Management

TRALI-Transfusion Related Acute Lung Injury

TTI-Transmission Transmissible Virus

TURP-Trans Urethral Resection of Prostrate

UDBT-Unbanked Directed Blood Transfusion

UK-United Kingdom

USD-United States of America Dollars

VCTC-Voluntary Counselling and Testing Centre

VIP-Very Important Person

VBB-Village Blood Banks

WB –Whole Blood

WHO-World Health Organization

ZBTC-Zonal Blood testing Centre

ABSTRACT

A systems approach was used to study the blood transfusion services in Delhi, the changes it underwent as part of the AIDS control efforts and to understand the factors that affect transfusion decision making specially the problems faced by the prescribers in conditions of resource constraint, to inform transfusion policy. Several studies from developed and developing countries had concluded that inadequate knowledge of transfusion guidelines was the primary reason for inappropriate transfusion practice. This finding led to introduction of interventions to educate clinicians on guidelines with the expectation that education would bring about a change in practice behavior. Most studies used quantitative methods, designed with an objective to measure change in practice, before and after application of an educational intervention. Some such interventions did not produce desired results indicating that certain 'other' factors in addition to inadequate knowledge of guidelines could be operating.

Conceptualization and Methodology

This study was conceptualized with the understanding that the approach to merely educate clinicians about transfusion guidelines was based on the premise that the guidelines were universally appropriate and only required to be put into practice. It was hypothesized that transfusion decision making is complex and depends upon several factors besides knowledge of guidelines, like those related to the settings in which the prescribers operate. To examine this hypothesis, and in an attempt to capture the factors related to the practice environment, a sequential mixed method design was adopted.

First a quantitative assessment of transfusion practices between the years 1997 to 2003, was made to get an overall picture of the status and trends in transfusion prescribing practice and identify its inadequacies. Then, awareness and perceptions of the prescribing clinicians were studied through Interviews with clinicians of five user departments, capturing information on their knowledge of guidelines, attitudes towards blood safety and the transfusion practice they followed. Next, eighty cases of blood and component use that were inappropriately transfused by WHO guidelines were analyzed, along with interviewing the prescribers to understand their rationale and also the problems they faced in translating the guidelines into actual practice. Lastly, a focus group discussion was carried out with the clinicians of each department to elicit

their opinion on the findings and interpretation from the previous steps of the study. Then, analysis was done by data triangulation to integrate the results from all the sources and get a holistic understanding of the issues. In addition, a comparative costing of ways in which the essential components could be supplied was done to justify, policy on setting up of component separation units for different levels of health care in the Indian context.

Finally, 2018 data was also incorporated, as there was a break in thesis. During this intervening period even though the nature of services had somewhat changed, the contextual issues still remained the same. Analyzing data over this period gave us a chance to see how technology had unfolded over time and how practices had changed.

Discussion and Conclusions

The study findings reinforce the fact that the understanding of such issues requires a more comprehensive health systems research framework i.e., a system-wide problem identification by application of the right methods for research. Use of survey methods alone does not allow an in-depth enquiry into the factors that could affect practice. Hence, qualitative methods should be used alongside to complement quantitative methods.

This study provides evidence that decision making for transfusion of blood and components is difficult and complex and is guided by several factors rooted in the practice environment. Hence the guidelines have to be adapted to include the social and the health service system factors as well, and should not be based on biomedical criteria alone. In fact, the deviation from standard guidelines is often for the benefit of the patients under the given social and institutional conditions.

The benefits of component separation must be acknowledged and ideally it must be universally available, but health system constraints hinder its universal adoption. Until such time that it becomes available in large enough scale, the value of local adaptation of guidelines must be appreciated and retained with the logic of the provider and in the interest of the patient. For the smaller essential requirement of components, other low cost methods can be employed.

Also, mere availability of a technology cannot be the sole basis for its universal adoption. Policy makers and administrators and must take into account the systemic issues, the epidemiological,

and the socioeconomic and health systems constraints and thereby assess its appropriateness in the diverse contexts prevailing in the country and across states and districts. This requires a decentralized, flexible approach to decision making and an orientation with capacities to do context specific health systems research and planning.

Introduction

Blood transfusion is an essential therapeutic modality in contemporary medical care. It is a precious and scarce resource, which saves lives but if used inappropriately there is a possibility of occurrence of serious hazards. If used correctly and appropriately the benefits outweigh the risks. Therefore, a safe supply and rational/appropriate transfusion practice becomes very important.

Hazards like transfusion transmissible infections- Syphilis and Hepatitis, circulatory overload and immune related problems have been recognized for quite some time. But after the discovery of transmission of HIV infection through blood and blood products in the 1980's, concern for safety of blood transfusion increased considerably. This led to the development of newer technology in the form of assays and equipment for testing and component separation. Keeping pace with this discovery there has been development of global policy recommendations and the formulation of guidelines for the testing of donated blood and its appropriate use.

Following on these lines, India too adopted policies for a safe blood supply. An ICMR task force on AIDS met in October 1985, with the objective to find out whether HIV infection had reached India and screening (sero-surveillance) of high risk groups was started, as a collaborative effort of ICMR, DGHS and state health Authorities. In 1986 the first evidence of HIV was found among female sex workers in Madras.

The National Aids Control Program of India was launched in the year 1987. A total of twenty-eight Zonal Blood Testing Centers (ZBTC's) were established in metropolitan cities, to which blood banks were linked to ensure testing of blood and blood products. In 1989, the medium-term plan for HIV /AIDS control was drawn up and a programme for prevention of infection via transfusion was started which made screening for syphilis, malaria, hepatitis B and HIV mandatory. Between April 1989 to March 1990, a total of 3, 52,470 samples were tested, at the ZBTC's, out of which 3613 tested positive by ELISA, a rate of 10.3 per 1000. This high sero-positivity rate among the donors prompted the government to screen all blood units for infection.

In 1992, the National AIDS Control Organization (NACO), the nodal body established for making of major policy and regulatory decisions for the NACP and blood safety was made an integral part of it. As part of these efforts, Zonal Blood Testing Centers (ZBTCs) were set up, linking few blood banks for the purpose of screening. Later, blood component separation units (BCSU), were set up and training in 'Rational use' of blood was initiated. The honorable Supreme Court of India in January 1996 issued directives to phase out unlicensed blood banks and professional/paid donors and also ordered mandatory testing of blood and blood products for transfusion of transmissible infections (Annexure-2).

Technological interventions had been developed, marketed and adopted to limit transfusion hazards by ensuring proper testing and processing of blood. The main focus was screening of blood for infections. Newer generation of kits and advanced screening technologies were introduced one after another in rapid succession designed to shorten the window period: Radioimmunoassay, ELISA, Western Blot, NAT, to name a few. As a new test becomes available it forms a 'layer' over the previous one, adding to blood safety and to the already existing financial costs. This indicates that testing methods are not fool proof and adding new tests reduces the risk, but 'Zero Risk' cannot be achieved. The latest available testing in India is Nucleic Acid test and is the most expensive of all. Screening of blood units is the basic necessity for a safe blood supply and decisions about testing as a public health policy have been influenced by rational need, associated societal pressures and cost effectiveness.

Separation of blood into components, also dependent on technology, facilitates the separation of one unit of blood into parts, for use in two or three patients depending upon the specific needs. It further helps in leukoreduction[1] and arresting the spread of infections like, cytomegalovirus, Epstein Barr virus and prions (the causative agent for bovine spongiform encephalopathy a fatal disease) which are harbored in the leukocytes. As blood banks are legally accountable to the practice of blood safety, in some countries all possible risks are avoided regardless of cost.

[1] Leukoreduction: Cases of bovine spongiform encephalopathy were detected in the UK that led to the decision for universal leukoreduction of all blood products in 1999. Although cases were reported in UK and France, leukoreduction was later adopted by many other western countries, adding exorbitantly to the cost of blood. The incremental cost of leukoreduction relative to no leukoreduction is approximately 25 pounds per unit (Cleemput et al., 2006). Leukoreduction also is beneficial in selected patient populations such as those of recurrent NHFTR, HLA isoimmunization and platelet refractoriness.

Nevertheless, choice of technology should be guided by a careful assessment of epidemiological, economic, clinical, sociological and ethical considerations. Epidemiology and cost effectiveness are an important guiding tool for the policy makers, to ensure sustainability and equitable use of the available resources, especially for the developing countries.

To ensure maximum safety, along with technological initiatives for testing, it is also important that the three elements of the blood banking system namely (a) sourcing of blood from voluntary non-remunerated donors (b) processing and (c) its appropriate/rational use should complement each other. Whereas processing of blood, done mainly for testing and component separation is dependent on technology and equipment, the other two elements of the safety chain are human behavioral factors, one of the donors and the other of the prescribing clinicians. Voluntary donors generate a safer supply and its appropriate use limits demands and risk, thus cutting costs and negative post transfusion events. Creating conditions that encourage people to donate blood voluntarily, is a function of the health system and therefore is a component of rational blood banking. Appropriate blood use involves not only the blood banking system and the transfusion specialists but also the prescribing clinicians. This study focusses on the importance of the last component of the chain, which is 'Rational'/ appropriate use of blood, by the clinicians.

Appropriate Prescribing Practices for Blood Transfusion

International guidelines for the prescribing and use of blood and blood products have been published by WHO from the 1980's (GBSI-Global Blood Safety Initiative). Since then many other institutions and countries have framed guidelines based on the WHO guidelines (Annexure-1); Canadian Medical Association Journal (CMAJ), Consensus Conferences, Guidelines of Anesthetists.

Evaluations and research have shown that worldwide, inadequacies and unsafe practices persist in spite of these efforts, and these are likely to be more pronounced in developing countries. In India, there is a low proportion of voluntary donation, proper testing facilities are restricted to large towns and big centres and irrational prescribing adds to these problems.

Blood transfusion practices not conforming to these international guidelines are common across diverse practice settings (Use of blood products for elective surgery in 43 European hospitals, 1994). Likewise, many studies on various other aspects of health care delivery show that in

actual clinical practice, evidence-based guidelines are not followed, resulting in wastage of resources. The examples of misuse of antibiotics, vitamins, diagnostic and curative technology in medical practice are well established (Kotwal et al., 2004) (Rajagopalan et al., 2008) (Bhardwaj et al., 2003) (Gilberg et al., 2003). Several reasons have been identified, the most important one being inadequate knowledge among clinicians of recent developments in medical science. It has been found that the clinicians do not keep themselves updated with available scientific knowledge and published recommendations but prefer to depend on reasoning, experience and conventional wisdom (Olatunbosun et al., 1998).

In the field of transfusion medicine too, evidence suggests that inadequate knowledge of transfusion guidelines among clinicians is the predominant factor that leads to irrational blood and product use (Lam et al., 1997) (Mahfooz & Akhtar, 2001) (Skodlar et al., 2005). Various methods to educate clinicians, have been tried but the results have been variable and success limited. Some methods like outreach 'face to face' visits (O'brien et al., 2000) and reminders to clinicians (Olatunbosun et al., 1998) (Rowe et al., 2000) have succeeded while others like feedback or audit (Toy, 1999) and use of local opinion leaders (O'brien et al., 2000) have produced variable results. The failure of some of these methods to bring about better adherence to established guidelines can be attributed to several barriers related to the practice environment. Therefore, as suggested by (Strauss, 2000) (Sackett et al., 2000) the following questions need to be answered: 'Are the patients' or community's beliefs, values and preferences compatible with the recommendations or guidelines? Are there other geographic, organizational, traditional, authoritarian, legal or behavioral barriers?' Also, are there valid reasons in the local context that makes violation of guidelines rational in that setting?

'Most guidelines are an amalgam of clinical experience, expert opinion, and research evidence that have to be adapted or modified according to local clinical needs and constraints' (Cook et al., 1997). WHO also recommends that the guidelines prescribed for blood and component transfusion should be adapted according to the local needs and constraints- "Nevertheless clinical transfusion practice should always be based on national guidelines where available. Users are therefore encouraged to adapt the information and guidance contained in the module and pocket handbook to conform to national guidelines and established procedures in their own countries"

(World Health Organization, 2001). Based on these guidelines NACO has also published guidelines for transfusion practice (NACO 1996).

In our opinion, for effective translation of the guidelines into practice, an understanding of the context is essential. Education of the guidelines alone without taking into consideration the complexities of the context in which they have to be applied, fails to produce the desired results. Moreover, since most guidelines are formulated in developed countries, with best available health facilities its implementation in resource constrained developing countries is sometimes difficult. To ensure that these guidelines work well in diverse environments they have to be adapted to the context in which they are proposed to be applied (Harrison et al., 2010). Therefore, there is need for health service research to identify and incorporate the organizational, structural and socioeconomic aspects of health care into the evidence, so that context specific guidelines can be generated (Tomlin et al., 1999) (Ely et al., 2002). Empirical studies that identify clear suggestions, on how to bridge barriers and improve the application of evidence-based medicine is essential (Olatunbosun et al., 1998) (Putnam et al., 2002). A 'top down' approach of health service research restricts the understanding of the complexities of practice. Therefore a 'bottom–up' approach incorporating the perspective of the clinician is necessary to complement the 'top-down' approach (Mcdonald, 2000).

In light of the above arguments, I propose the hypothesis that in addition to inadequate knowledge of transfusion guidelines, several factors associated with the practice environment, which I call *Non-Clinical Factors*, affect transfusion decision making. Even though the non-clinical factors may form a small part of the determinants, an understanding of these factors is crucial for redefining 'Rational transfusion practice' for the given practice context. This research has been conceptualized with the above issues in mind and the methodology adopted is directed towards developing a better understanding of the problems in implementing universal guidelines from the perspective of the clinicians. Further, an objective epidemiological assessment of available options and needs at each step of the transfusion chain has also been made. A health systems approach has been adopted.

This Study

This study attempts to examine the rationality of prescribing practices of clinicians within the context of the current trends in blood banking and the status of blood banking services in Delhi and explores specific issues of concern for making transfusions safe. The main focus of this study is on transfusion prescribing practices at a tertiary level public hospital in Delhi and the problems associated with adhering to international guidelines. Taking the opportunity provided by the rapidly changing scenario consequent to the HIV and AIDS pandemic, this study was initiated in the year 1997 to document the changes and assess the outcomes with focus on the prescribing behaviors of clinicians.

The research has been divided into five parts. The first part provides a profile of blood banking in Delhi and the study hospital, with an audit of the prescription practices over a seven-year period, from 1997 to 2003, essentially to capture the changes in prescribing practices in relation to blood economy after HIV/AIDS control measures were instituted, including the establishment of a component separation unit in the hospital blood bank. An estimate was also generated of the proportions of those transfusions that are inappropriate according to the WHO guidelines. The rest of the study then attempted to understand the reasons for the non-practice of WHO guidelines by prescribing clinicians.

The second part, by way of a KAP study, deals with knowledge of the prescribers about transfusion guidelines, their attitudes towards blood transfusion as a treatment option and also common practice patterns. A schedule-based interview with clinicians of various specialties was conducted for this purpose.

Next an in-depth study of a sample of cases, considered inappropriate by W.H.O. guidelines, was conducted to find out the rationale of the prescribing practices from the treating physician's point of view. This was to get an insight into the conditions under which these decisions were made.

After analyzing the findings of this part, the research was presented to the clinicians through 'focus group discussions' to elicit their feedback with deeper reflection.

Lastly, cost of supplying a unit of whole blood and components has been calculated to understand the economic rationale and its implications for policy in terms of appropriateness of setting up of fractionation units in the Indian Health services system at various levels, given the patient profile and the status of health service institutions. The study was interrupted and

restarted in 2018, thereby providing the opportunity to study trends over 10 years, which are captured as an update on the various dimensions that could be captured.

The findings lead to conclusions that corroborate some policy approaches and blood transfusion guidelines while providing directions for adaptations that could optimize health outcomes within the local resource constrained Indian context of a public hospital and the blood banking system.

CHAPTER -1

"From Blood Banking to Transfusion Medicine"-A Paradigm Shift

Literature on pattern of blood use, knowledge of guidelines, interventions to increase knowledge of guidelines, interventions that worked and those that did not and their possible reasons were reviewed. Factors that hinder the practice of evidence-based medicine, behavioral or those rooted in the practice environment- were reviewed to develop an understanding of the problems faced by the clinicians at the ground level. Red cell transfusion that forms the bulk of transfusions is given for anemia, hence literature on pathophysiology of anemia and its complexities were included. Finally, since testing for infections and component separation are costly procedures, determination of cost is important in order to improve efficiency and safety of services within the finances available and for a sustainable blood safety program. Relevant literature especially from developing countries was reviewed to get an insight into the economic aspect of blood safety.

The Changing Concept and Scope of "Quality" in Transfusion Medicine

The definition of 'Safe Blood' has undergone a drastic change since the discovery of the AIDS virus. From the first documented evidence of transfusions in the 17th century, to the discovery of blood groups by Karl Landsteiner in 1900, followed by the discovery of transmissible diseases like Syphilis, Hepatitis, Malaria and HIV in 1984, and tests to detect them in blood, its meaning changed from a *'vital force'* that saved lives, to one that could be potentially hazardous. The fact that HIV was transmissible through blood transfusions sparked a lot of interest in this field and helped in a better understanding of the science of transfusion. Although, transfusion transmitted Syphilis was known since the early 1940's, introduction of donor syphilis testing was completely 'devoid of the turmoil' that was associated with the introduction of testing for antibodies to HIV (Neil Blumberg, 1999a) (Barker, 1985).

With scientific advancements and better understanding of disease transmission and the 'window period', attitudes to the 'Quality' of safe blood have changed over the last two decades. The emphasis has switched from *detection* (of TTIs) to *prevention* (of transfusion hazards). This further led to the introduction of the concept of Total Quality Management (TQM) in blood banks (Benedictus, 1999). The scope of quality assurance in Hospital transfusion practice was

enlarged to include transfusion practice, with the aim of minimizing risk to the recipients and limiting exposure by optimizing its therapeutic use. Along with developments in quality assurance, and increase in complexities, the role of the blood bank specialist has also undergone a sea change. Being earlier confined to the blood bank and restricted only to testing and storage, it now extends to guiding clinical transfusion practice as well: to facilitate safe, effective and appropriate transfusions. Blood banking has thus transformed into 'Transfusion Medicine'- a paradigm shift from the limited responsibility of 'Good Manufacturing' to 'Rational Blood Use'. As rightly expressed, it has changed from a "cottage industry" with unpredictable outcomes to a "science that delivers components that are safe and efficacious and transfusion advice that is increasingly based on evidence rather than speculation" (AuBuchon, 1996).The emphasis now is on the ***use*** of the 'Right' component of the 'Right' quality at the 'Right' time.

Quality System in Blood Banking

Quality systems in blood banks were introduced on the pattern of scientific management of businesses by Frederick Taylor and manufacturers such as Ford and general Motors, with focus on the manufacturing side of blood banking (Callery et al., 1994). This resulted in the introduction of pharmaceutical type, Good Manufacturing Practices (GMP), with FDA issuing guidelines for the same (FDA 1993).

Quality Systems adopt a Systems approach with focus on the processes and not only the end product; therefore, quality assurance in each step of the process is important. To adopt GMP the tools used are, Total Process Control (TPC) which means that the manufacturing is performed in such a way that the product is of consistent quality (Callery et al., 1994). There is an inbuilt system of Process Analysis and Management (PAM) to evaluate practice by measurable indicators. Current GMP (CGMP) therefore ensures that Quality Assurance (QA) is a dynamic process, which must be constantly reviewed and updated. International organization (ISO) for standardization is one model for quality systems. From a systems perspective, with inputs, processes and outputs, the change must be in culture itself, not just the parts of the system. The nature of quality systems employed varies from country to country, depending upon available finance, skill, level of personnel, geographical location etc. (Makenzie, 1999) increasing cost considerably. However, some experts are of the opinion that from the mid 80's the revolution in blood banking wherein federal regulatory standards intended for manufacturing (e.g., good

manufacturing practices) and industrial management theory (e.g., total quality management) were instituted with little or no data to support their safety and efficacy, much less their cost-effectiveness. Same is being proposed in other areas of health care delivery which must be done cautiously drawing from the lessons learnt from this sector (Neil Blumberg, 1999a)

Various dimensions of Quality in healthcare have been identified in service/marketing literature- tangible, intangible and their interrelatedness. Tangible aspects include the physical characteristics of Quality, whereas intangible dimensions include functional quality, technical quality, interactive quality, corporate quality and accessibility in terms of social access (Patil et al., 1996) (Baru, 2003)

Going by a more comprehensive definition of quality for the blood banking system, quality must be ensured from 'Vein to Vein' i.e., in all steps right from recruitment of healthy donors to transfusion of patients.

'Blood Donors' the Source of Blood

There are three kinds of donors- Voluntary, Paid and Replacement donors. By definition 'Voluntary non remunerative donors are persons who give blood, plasma or other blood components, of their own free will, and receive no payment for it either in the form of cash or kind which could be considered a substitute for money. This includes time off work other than reasonably needed for donation or free travel. Small tokens, refreshments and reimbursements of direct travel costs are comparable with voluntary non-remunerated donations' (ISBT). 'Paid donors' on the other hand, donate in exchange for money. In fact, the concept of paid donation came from commercial plasma donors who catered to the plasma fractionation industry, which was common in the U.S. and also in the Nicaragua and Haiti in the 1960's and 70's.

Some like Prof. R.W. Beal differ with the laid down definition of voluntary donors. 'The matter of "safety" is the most important difference between the voluntary system and the paid system, as safety can be measured and documented. Voluntarism alone cannot be considered as the major difference between the two, as commercial donors also give voluntarily and not under coercion. 'Also, in an increasingly materialistic world, the elements of ethical, moral values associated with voluntarism are perceived benefits and subjective which cannot be measured' (Beal & Van

Aken, 1992) Several studies from the developing as well as developed countries establish the fact that blood sourced from voluntary donors has low rates of infectivity for T.T.I.'s (Patil et al., 1996) (Rock et al., 2007) (Arora et al., 2017) (Birhaneselassie, 2016).

A third category of donors are the 'Replacement donors'. Replacement donors are the major source supply of blood in India and other developing countries. They are relatives and friends of the patients' but are not voluntary donors in the true sense, as a "motive" behind this type of donation cannot be overlooked. Sometimes these donors are forced to replace blood for their ailing relative, and in the process hide facts about their health for fear of rejection. Hence, these donors are not considered as safe as voluntary donors in terms of safety.

Multiple Layers of Safety

In developed countries, the approach to Blood safety is multipronged and comprehensive, whereas in the developing countries the emphasis is primarily on testing for TTIs and even now often remains the only measure taken for the purpose. *"It is a seductive but dangerous fallacy, frequently espoused in developing economies, that near absolute safety (of the Blood Transfusion Services) can be ensured through technical / laboratory solutions alone, without regard for the other vital and complimentary elements which are essential to quality and safety" (Editorial, Transfusion Today, 2000; 1-3).* Whereas, developed countries have moved on to "other hazards", after having achieved the highest available levels of testing for TTIs, developing countries still struggle with control of Transfusion Transmissible Infection's within a very narrow and piecemeal 'HIV centric' approach. Data related to adverse incidents of transfusion support this view, as risk from TTI's is negligible in the developed countries when compared to the other transfusion hazards (Williamson et al., 1999).

Thus, for minimizing post transfusion adverse incidents an integrated approach is required, where the selection of low risk donors, proper control of laboratory processes, and the appropriate use of blood and components are all complementary to each other. There is no short cut to a multipronged strategy and emphasis on one or two areas alone does not result in the required quality outcomes (Lomas et al., 2005) (Benedictus , 1999).

In summary, to minimize transfusion risks "Multiple layers of safety" is required, which would include proper screening of donors, maintaining a list of deferred donors, testing, quarantine of

products and process controls, monitoring of blood establishments, investigation of adverse incidents and formulating regulations under CGMP (Current Good manufacturing Practice) as defined in the US code of federal regulations. (Valinsky, 2001)

Adverse Incidents of Transfusion

Despite ongoing efforts to make blood transfusion safe, the risk of adverse reactions of transfusions cannot be done away with completely. Transfusion related hazards may be characterized into two types-***infectious and non-infectious.*** In addition, there is the risk of inadvertent transfusion of ABO incompatible blood due to human errors.

Magnitude of the Problem

The actual magnitude of the problem is difficult to ascertain as the hazards are underreported mainly for two reasons. Firstly, some hazards often go unrecognized because it is difficult to diagnose them. Complications like Graft versus host disease (GVHD) develop days or weeks after a transfusion and it is difficult to link the complication with a transfusion received earlier after few days have elapsed. Secondly, there are poor documentation practices of transfusion related events (Rock et al., 2007)

Several estimates of these errors have been made in the past but in recent years there have been systematic efforts by some developed countries to compile hazard data. These Hemovigilance reports from countries like the UK (SHOT), Canada, France and South Africa throw some light on the magnitude and proportion of the various transfusion hazards. Hemovigilance data is however incomplete because adverse incidence reporting is a voluntary process with many centers electing not to take part. Analysis of the SHOT findings suggests that Transfusion transmitted viral infections, reported by SHOT are relatively rare compared to the proportion of other hazards (Olatunbosun et al., 1998) (Williamson et al., 1999) (Williamson et al., 1999). This finding is consistent with calculated low residual viral risk in the developed countries (Glynn et al., 2000). Of much more concern now among the transmissible infections is bacterial contamination by Platelet transfusion (Brecher & Hay, 2005).

Comparison of the Reported Adverse Incidents in the UK

Incorrect blood and component use were the largest category at 22 percent and TTI was the least at 0.2 percent of all (Table 1.1).

Table 1.1 U.K. SHOT Summary-2008, 2009			
SN	**Category**	**2008 (%)**	**2009(%)**
1	IBCT	25	22
2	Autologous	3	1.1
3	TTI	0.6	0.2
4	TAD	0.1	0.3
5	TACO	2	2.7
6	TRALI	2	1.6
7	HTR	5	3.7
8	ATR	29	31.3
9	ANTI-D	13	14.5
10	HSE	13	15.3
11	I&U	7	7.2
12	PTP	0.1	X
13	TA-GvHD	X	X

[Key-IBCT-Incorrect blood and component transfusion, Autologous-related to Autologous transfusions, TTI-Transfusion transmissible infections, TAD-Transfusion associated Dyspnea, TACO-transfusion associated cardiac overload, TRALI-Transfusion associated acute lung injury, HTR-Hemolytic transfusion reactions, ATR-Acute transfusion reactions, Anti-D-Anti -D related events, HSE-Human spongiform Encephalopathy, I&U-Incorrect and unnecessary transfusion, PTP-Post transfusion purpura, TA-GvHD-Transfusion associated graft versus host disease].

The proportions of the different categories of adverse incidents vary from one country to another depending on the reporting pattern, the quality procedures in place and upon the degree of development of the health services. Variability of the findings is well illustrated in the reports from various countries like South Africa (2000) and France. In India a Hemovigilance program was launched in December 2012**,** with few enrolments, therefore the actual extent of transfusion hazards is difficult to ascertain but is likely to be higher than the developed countries. However, data from NACO gives some estimate of HIV related infectious complications in transfused patients. In 2006, transfusion associated AIDS contributed to approximately 2 percent of total AIDS cases (NACO 2006). Studies on the prevalence of TTI's in multiply transfused thalassemia patients (Sidhu et al., 2016) (Jain et al., 2012) and those on dialysis throw some light on the infectious complications of transfusion.

Requirement of Blood and Components

An assessment for the South East Asia region puts the requirement at 15 million units but only half of this is actually collected (WHO 2001). The number of units donated in the SEAR countries during 1998-99 was about 7 million. This showed an increase of 2.2 million since 1992 and accounted for only 50 percent of the total requirement with a shortfall of nearly 8 million units. Over all proportion of blood collected as voluntary donations in the region increased marginally from 54 percent in 1988, to 61 percent in 1999 (Bharucha, 2005).

Only 24 percent of blood is collected in low- and middle-income countries that comprise 48 percent of the global population. During humanitarian emergencies, availability and safety of blood transfusion is a major concern, as demand for blood and blood components increases and delivery often proves to be challenging (WHO 2019).

In U.K. and in all European countries the estimate is 12 units per bed per year. In USA and Australia 14 units per bed per year is considered as the norm. Blood donation rates are 52/1000 in industrialized countries, 10/1000 in middle-income countries, 1/1000 in low-income countries.

Requirement of blood and blood products in a country depends on the population, health care structure, prevalence of conditions requiring regular transfusions, such as hemophilia and thalassemia, availability of surgical centers using modern sophisticated techniques, and awareness amongst clinicians regarding judicious use of blood.

There are many different ways to estimate the total need for blood. The requirement of blood is assessed in relation to: Total population, acute hospital beds, medical facilities available in the area and annual blood usage (past, present and future).

According to W.H.O. ideally, if 2 percent of the population donates blood, it will be sufficient to meet the needs of the developing countries. Estimation of the requirement by this method ignores the disparity between the size of the population and hospital beds. The requirement of blood is usually calculated in terms of requirement of red cells, which very often falls short of the requirement of plasma for fractionation. The need for blood varies from 7-15 units per acute bed per year depending on the type of medical care available. In a primary health care unit, the need is estimated at 5-7 units/bed/year whereas in a specialized institution, dealing with hematological and oncological cases, as well as for specialized surgeries the need may be 25-30 units/bed/year (Assessing Needs and Setting Recruitment Goals, WHO).

Information received from various states and union territories in India indicates that total estimated requirement of blood is 15 million units per annum and the collection was 12 million units in 2018, a short fall of 3 million units (Unpublished data NACO).

In India cases requiring transfusions are referred to the district hospitals where facility for transfusion is available.

What are Guidelines?

“Most guidelines are an amalgam of clinical experience, expert opinion, and research evidence that have to be adapted or modified according to local clinical needs and constraints” (Cook et al., 1997). Ideally, practice guidelines provide a broad framework that are intended to assist

practitioners to make appropriate decisions and are not intended to provide a rigid prescription for care. Though the scientific rationale is the most dominant of all, consideration of the contextual issues is necessary while developing guidelines. Inclusion of these factors, which are generally missing from most existing guidelines, provides scope for adaptation and effective translation of guidelines into practice.

Guidelines and Evidence Based Medicine

Guidelines are framed to facilitate the practice of evidence-based medicine. Transfusion science is a fairly new branch of medicine and is not taught at the undergraduate level; hence knowledge is acquired mainly by experience. Guidelines for the appropriate use of blood have been formulated and disseminated among clinicians but, studies have shown that in actual practice, the results of efforts made to educate clinicians are far from satisfactory. Experience from other branches of medicine also has been similar, which point to the fact that there are several barriers that hinder the practice of evidence-based medicine (Bero et al., 1998) (Freemantle et al., 2000) have reviewed interventions to promote good clinical practice and found that some like educational outreach visits, reminders at the time of request/diagnosis/procedure/prescription, interactive workshops etc., are consistently successful. Whereas audit and feedback, influence of local opinion leaders, local consensus processes, and patient mediated interventions have shown variable, effectiveness. They also reported that, distribution of guidelines for clinical practice; didactic educational conferences and lectures do not have significant results.

Clinical practice based on 'Evidence Based Medicine' has been seen by some as "promoting what may become a dogmatic application of probability laws to the very improbable practice of medicine", or that "time honored procedures may be discouraged on statistical grounds if Randomized Controlled Trials' cannot be performed" Nevertheless, the fact that the practice has the ability to organize complex data sets for the ultimate benefit of patients is difficult to deny (Porta, 2004)

Barriers to the Practice of Evidence Based Medicine

Karin Hannes (2005) reviewed some of the barriers that hinder the practice of evidence-based medicine among general practitioners identified in various studies reported between 1998 and 2003. The factors identified give an idea of those operating in other areas of medical practice as

well. Among the most significant was access to information, limited applicability of evidence at individual level, influence of colleagues and commercial organizations on practice.

As the practice of Evidence based medicine and access to resources is time consuming, the busy clinicians find it difficult to update themselves with new knowledge (Olatunbosun et al., 1998) (Scott et al., 2000) (Young & Ward, 2001). The presence of contradictions in scientific evidence cannot be denied. In addition to this there is the problem of limited applicability to individual patients, and reliability of information at the individual level. As evidence does not take into account the complexity of the situation into practice, it makes it difficult to apply (Tomlin et al., 1999) (Mayer & Piterman, 1999). Influence of colleagues, patients and commercial organizations have been known to affect practice. Application of evidence based medicine does not take the experience of the clinicians into account and since it relies on objective evidence, it decreases the 'Art of medicine' (Olatunbosun et al., 1998).

Some authors like Tomlin 1999 and Ely 2002 have noted that there are few well controlled empirical studies identifying clear suggestions on how to bridge barriers for the practice of Evidence based medicine and to deal with organizational problems. Also, there is lack of logistic support for proper implementation of Evidence based medicine in terms of access to new information.

Although the factors identified are complex and varied, the suggestions to address them were limited to, different ways to improve access to scientific knowledge, information or evidence, or were limited to providing logistic support for access to information. Few studies dealt with the operational aspects as well. Hannes concludes that there are three levels of *factors* and *actors* that influence the practice of evidence based medicine. At the micro level, interventions related to individual problems of the general practitioners', meso level- problems related to organizations and institutes, and macro level-problems and interventions related to the broader social environment, (policy related, and media related).

For a better understanding of these factors the participation of prescribers is essential since a 'top down' approach of health service research restricts the understanding of the factors that operate at the micro level. Therefore, health service research needs to incorporate the socioeconomic context of the communities to be served, as well as the organizational and the structural aspects

of health care, so that issues can be identified and context specific guidelines can be generated. The study of appropriateness of interventions from the perspective of clinicians on the problems they face at the ground level becomes important. In other words, the 'bottom-up' approach should complement the 'top-down' approach (Mcdonald, 2000; Schmittdiel et al., 2010).

In view of the factors mentioned above it becomes necessary to adapt the guidelines to the local contextual issues for its effective implementation.

Guideline Adaptation

"Guideline adaptation is a systematic approach to considering the use and /or modification of a guideline(s) produced in one cultural and organizational setting for application in a different context." (ADAPTE collaboration[2], 2007)

Adaptation of guidelines has become necessary because health organizations have to work within limited resources. They are increasingly facing a need for standardizing health policies and practices to promote optimal, evidence based as well as equitable patient care with better management of finite resources. In addition, one of the crucial aspects of guideline adaptation is to improve knowledge transfer and uptake by the users and their effective implementation in practice. Insufficient attention to the implementation phase has hampered the effectiveness of Clinical Practice Guidelines to change practice significantly (Coffin et al., 1989) (ADAPTE collaboration,2007)

Transfusion Guidelines and Scientific Evidence

Transfusion guidelines for the use of different blood components, based on the available scientific evidence, have been framed by several international organizations like the WHO,

[2] ADAPTE an organization that works on guideline adaptation provides a systematic approach for the adaptation of guidelines produced in one setting to be used in a different cultural organizational context. It says that the 'adapted guideline should address specific clinical questions relevant to the context of use and is suited to the needs, priorities, legislation, policies and resources in the targeted setting' (ADAPTE collaboration, 2007).

(Canadian Medical Association Journal) CMAJ 1997 and the Association of Anesthetists, BCSH guidelines etc.

But consensus on appropriate transfusion practice is difficult to reach, due to lack of sufficient evidence and gaps in scientific knowledge. There is no clarity on factors such as the exact hematocrit or hemoglobin levels at which a transfusion should be ordered, the use of fresh frozen plasma in massive transfusion, the use of cryoprecipitate to reverse uremic platelet dysfunction, and the platelet count at which prophylactic transfusions become necessary. Moreover, concrete criteria are difficult to establish in transfusion medicine due to scarce evidence and conceptual controversies. Criteria developed by a local committee may not be conceptually perfect and may reflect compromises from groups with divergent opinions (Stehling et al., 1994) (Coffin et al., 1989).

Since complete scientific evidence about some of these issues is lacking, transfusion practice guidelines are not intended to serve as medical indications for transfusion. Rather they list clinical circumstances in which transfusions might be administered without additional justification. They include conditions for which transfusion is usually considered reasonable, but may not be mandatory. Not all patients who are considered eligible for transfusion by the guidelines will actually benefit from blood administration. On the contrary, transfusion may be indicated in clinical situations not falling within the guidelines (Stehling et al., 1994). In circumstances where scientific evidence is deficient, clinicians tend to depend more on conventional wisdom and personal experience.

Biomedical Criteria for Transfusion

Pathophysiology of Anemia

Transfusion requirement for a particular patient is based on the clinical situation whether elective, urgent or emergency treatment, disease for which patient is being transfused and whether transfusion is required before during or after surgery. In addition to these, the patients cerebrovascular, cardiovascular, hemodynamic, pulmonary and hematologic status are important factors that determine the need for transfusion.

Anemia results in improper oxygen delivery, problems with homeostasis, non-surgical blood loss, nitric oxide production and platelet dysfunction (Valeri et al., 1997). Factors such as myocardial depression and inadequate ventilation can also decrease oxygen delivery, but their occurrence cannot be reliably predicted, particularly in surgical patients. A margin of safety is therefore necessary to prevent inadequate oxygen delivery and potential morbidity and mortality in anemic patients. Acute blood loss is different from chronic anemia in terms of pathophysiology and treatment. A healthy patient can compensate for 20 percent of blood loss, but the patient with severe coronary artery disease may not be able to compensate (Stehling et al., 1994). Therefore, the requirement of transfusion varies between patients and the clinical condition.

The Patho physiology of anemia is ill understood and differs between acute and chronic anemia (hypovolemic, hypervolemic and normovolemic anemia). Physiologic changes such as increased cardiac output, decreased peripheral vascular resistance, and increased release of oxygen by R.B.C.'s, occur in response to anemia. The body has immense capacity to adapt to anemia in normal circumstances, but its critical limits are ill defined. Data regarding the level of anemia at which these physiologic changes occur are conflicting. Some studies suggest that cardiac output rises when the hemoglobin level is in the range of 9-10 gm per dl and others suggest that the hemoglobin level must be below 7 to 8 gm per dl for these changes to occur. It is likely that compensation begins at different hemoglobin levels depending on age, co morbidity, volume status and medications, but there is inadequate compensation at very low blood counts (Stehling et al., 1994) (Carson & Willett, 1993). Physiological adjustments to acute normovolemic anemia are influenced by factors associated with reduced cardiac output response, with decreased O_2 extractions response, altered gas exchange and factors associated with increased oxygen demand (Van der Linden P.2001).

The Decision to Transfuse: The Transfusion Trigger

All guidelines stress the fact that many patients are capable of tolerating Hb concentrations ranging from 70 – 100 g/l and that the decision to transfuse blood should depend on the clinical condition of the patient. In 1996 the American Society of Anesthesiologists Task Force on Blood Component Therapy concluded that 'transfusion is rarely indicated when the hemoglobin

concentration is greater than 100 g/l and is almost always indicated when it is less than 60 g/l, especially when the anemia is acute'[9].

As explained in the previous section, the need for RBC transfusion depends on the etiology and chronicity of anemia, the patient's ability to compensate for decreased oxygen carrying capacity and the anticipated clinical course. No appropriate transfusion trigger would be appropriate for all patients. The entire clinical picture not just the hemoglobin must be considered in each patient. But is has been observed in common practice that the 'trigger' takes precedence over other clinical information.

"No single measure can replace good clinical judgment as the basis for decisions regarding perioperative transfusion. However current experience would suggest that otherwise healthy patients with hemoglobin values of 10 gm/dl or greater rarely require perioperative transfusion whereas those with hemoglobin values of less than 7gm/dl will frequently require RBC transfusion (Stehling et al., 1994) (Goodnough & Audet, 1996).

Hemoglobin/Hematocrit as Indicators

The oxygen carrying capacity of blood is measured either indirectly by measurement of the red blood cell concentration-Hematocrit, or directly by determining the hemoglobin concentration. Although both measures are employed in practice, hemoglobin level is more commonly used for the assessment of anemia in clinical medicine.

With the current practice of relying solely on measurements of peripheral hematocrit and hemoglobin to identify the RBC transfusion trigger many patients may be deprived of transfusion therapy that could help to reduce morbidity and mortality. It is important to understand that in case of acute blood loss, patients are hypovolemic and thus show a false increase in hematocrit and hemoglobin. Therefore, these measurements should not be the only considerations in defining the 'transfusion trigger'. Current practice guidelines suggest that, 'clinical judgment' and not the hematocrit should be the ultimate factor in determining the need for RBC transfusions. But despite the recognized problems caused by factors such as not knowing a patient's blood volume, measurement of hemoglobin or packed cell volume (also known as hematocrit) remain the only generally accepted and available objective indices influencing the decision to transfuse.

Ideally, transfusion triggers should be guided by the measured oxygen need of the patient. Accurate measurements are difficult to obtain in a routine clinical setting as 'Radioactive labelling' of RBC's is required. However, mixed venous oxygen saturation and oxygen extraction ratio require invasive monitoring and are therefore not applicable in most situations. On the other hand, there is insufficient evidence to justify the use of the hemoglobin concentration as the only transfusion trigger (Stehling et al., 1994) (Hébert et al., 1997)

Transfusion and Wound Healing

Red blood cells are frequently transfused to promote wound healing and "well-being". However, animal studies confirmed by observations in post-operative patients, indicate that normovolemic anemia is not detrimental to wound healing. The critical hematocrit at which anemia may influence tissue repair appears to be approximately 15 percent. The oxygen extraction ratio (ER)of healing tissue is only about 3 percent. The oxygen delivered in the plasma alone may be sufficient to meet the needs of healing tissue when the PaO2 approaches 300 mm Hg (Stehling et al., 1994) (Jonsson et al., 1991)

Some studies have reported that transfusion interferes with wound healing and actually led to delayed healing in a group of hip replacement surgery patients (Weber et al., 2005)

Immunomodulatory Effects of Transfusion

There is also evidence from a variety of sources indicating that allogenic blood transfusion can result in harmful immunomodulatory effects, also called transfusion associated immunomodulation TRIM (Neil Blumberg, 1999a) (N Blumberg & Heal, 1993) (Tartter et al., 1988). Some immunomodulatory effects that have been reported are, survival of renal allograft, increase in recurrence of resected malignancies, increased incidence of post-operative bacterial infection, reduction in the recurrence rate of Crohn's disease and activation of infection with CMV or HIV. However, a definitive evidence of existence of a deleterious immunomodulatory effect has not been presented (Vamvakas & Blajchman, 2001).

Why Evidence on the Effects of Transfusion in Humans is Scarce

Although, guidelines for red cell transfusions exist, none of them are based on randomized control trials or provide a detailed risk benefit analyses because of the associated risks. Several

studies on animals have been done; the results of which cannot be extrapolated to humans (Stehling et al., 1994). Few studies on Jehovah's witnesses who refuse blood transfusion provide indirect evidence. Data from Jehovah's witnesses indicate that morbidity and mortality rates increase when hemoglobin concentration decreases to less than 70 gm /l. Carson et al., (2002) studied postoperative hemoglobin levels, on adult Jehovah's witnesses and found that between a hemoglobin value of 7.1 to 8.0 gm percent there were no deaths and only 9.4 percent morbid events. The risk of mortality and /or morbidity rises and becomes extremely high below 5 to 6 gm per dl. The odds of death increase 2.5 times for each gm decrement in post-operative hemoglobin level.

Further, there is also little information on the risks associated with withholding transfusion. Some retrospective studies have been conducted which show that the use of a conservative transfusion trigger is safe and prudent practice, but retrospective studies are considered to be deficient in methodology. Moreover, these studies have taken mortality as the outcome indicator (VALERI et al., 1997) providing little information about morbidity avoidance with transfusion.

In view of the above facts, there is a clear need for epidemiological data on transfusion practice and outcomes. What is therefore needed is well designed, prospective randomized control trials, to evaluate the impact of transfusions or withholding them, on perioperative mortality, morbidity and non-surgical bleeding in subjects who are normal or in those with known diseases.

Composition and Indications for Blood Component Therapy

Constituents of blood include red cells, granulocytes, platelets, plasma, of which cellular components comprise 45 percent of the total blood volume and the remaining 55 percent is plasma. The granulocytes are part of the immune system, platelets help in blood clotting and red cells carry oxygen and carbon dioxide. Plasma consists of 7 percent proteins (55 percent is albumin-maintains volume,38 percent is globulins-immunoglobulins,7 percent is fibrinogen-a clotting factor) 91.5 percent of water, 1.5 percent of other substances like nutrients, electrolytes, hormones, vitamins, anticoagulants and other clotting factors.

Whole Blood

After availability of components, whole blood is only indicated in patients having severe sudden hemorrhage with acute hypovolemic shock and in exchange transfusions in neonates. The cause of hypovolemia may be either trauma, obstetric or operative, but management is the same i.e., restoration of the circulating blood volume as soon as possible. Circulating blood volume has to be maintained, oxygen carrying capacity improved upon, colloid osmotic pressure normalized and plasma biochemical factors balanced, before irreparable impairment of tissue perfusion takes place and predisposition to disseminated intravascular coagulation sets in.

In cases of 'massive blood transfusion', where the patients' total volume is replaced promptly within 24 hours, i.e., 8-10 units in an adult has been administered, platelet concentrates and fresh frozen plasma are also given. But this should not be transfused indiscriminately and continuously monitored for their hemostatic condition before administering further components.

But in most situations whole blood transfusion may be irrelevant and even fail to achieve its objective because there may be deficiency of labile clotting factor and platelets after massive transfusion. It may also lead to overloading of an already decompensated system or cause a transfusion reaction that could be avoided. This is so because at temperatures of 2-6 ^{0}C at which whole blood is stored, Platelets and some labile coagulation factors are destroyed. Transfusion of components which have been preserved at appropriate temperatures, on the other hand permits the delivery of an effective dose of the deficient component with a minimum risk of circulatory overload or adverse reactions to unnecessary blood components.

Concerns about safety and relative efficacy of whole blood versus component therapy have been argued against the use of whole blood in most settings.

Red Cells or Packed Cells

This is the component of choice to restore /maintain Oxygen carrying capacity with minimal expansion of blood volume. Plasma is removed by centrifugation from the red cells to form packed red cells.

There are two major advantages due to removal of plasma. It results in a decrease in the number of electrolytes and ammonia and is beneficial in patients with incipient congestive heart failure (due to Na^{+}), renal failure (due to K^{+} & acid) or hepatic failure (due to ammonia and citrate).

Further chances of allergic/anaphylactic reactions are minimized because of lesser granulocytes also known as leucoreduction (Forbes et al., 1991) (British Committee for Standards in Hematology et al., 2004).

Fresh Frozen Plasma

Fresh frozen plasma contains Factors II, V, VII, VIII, IX, XI and fibrinogen. Fresh frozen plasma is indicated to rectify absence of or low levels of coagulation factors which can be measured by determining the prothrombin time. A thrombin time of more than double the control indicates disseminated intravascular coagulation.

For most plasma factors it is recommended that they be given in doses calculated to achieve a minimum of 30 percent of normal concentration, (usually achieved with administration of 10-15ml of plasma/per kg body weight), except for urgent reversal of warfarin anticoagulation for which 5-8 ml/ kg would usually suffice.

However, these values were derived from synthesis of physiologic measurements of factor concentrates, homeostatic function and clinical observations of the effect of plasma administration on abnormal coagulation and not from systematic assessments of therapy. Ongoing clinical and laboratory assessments are necessary to determine subsequent action.

Platelets

Platelets are prepared for transfusion from whole blood donation or by Apheresis. Both methods use differential centrifugation of whole blood to prepare a concentrate of platelets suspended in the donor's plasma. platelets prepared from a unit of whole blood are designated a unit of platelet concentrate and generally contain $5.5\text{-}7.5 \times 10^{10}$ platelets in approximately 50 ml of donor plasma. Platelets prepared by pheresis technology contain approximately $30\text{-}50 \times 10^{10}$ platelets suspended in 200-400 ml of donor plasma.

Platelets can be stored for five days in plastic blood bags which are specially designed to facilitate gas exchange with the environment. Its viability and efficacy is best maintained by storage at 20-24^{o} C with agitation to facilitate gas exchange. There is a possibility of growth of contaminating bacteria if stored beyond five days at room temperature.

Platelet function defects can be caused by conditions such as uremia, severe liver disease, von Willebrand's disease and antiplatelet drugs such as aspirin, as well as by congenital and other platelet abnormalities.

Bleeding time is recognized as the only diagnostic test which directly measures the hemostatic effectiveness of platelets in vivo. Theoretically this test measures the combined effect of platelet number and function as well as vascular factors in hemostasis. However, the predictive value of the bleeding time in identifying patients at increased risk of bleeding is controversial.

Platelet transfusions are indicated, in patients with quantitative or qualitative platelet abnormalities. Platelet transfusion should only be used as a prelude to a more definitive correction of thrombocytopenia and should be reserved as intervention for significant or life-threatening bleeding or to treat major bleeding during a required major surgical procedure (BCSH, 1992)

In surgical bleeding it is necessary to rely on the characteristics of the bleeding. If the bleeding appears to be oozing from multiple surfaces, if there are no visible bleeders and if there are no documented coagulopathies, a trial of platelet transfusion is indicated.

Platelet transfusion is also indicated in cardiothoracic surgeries as Cardiopulmonary bypass induces both a qualitative and quantitative defect in platelets.

It is also indicated in hematology/oncology patients. To avert bleeding in patients with unstable thrombocytopenia following chemotherapy, the platelet count should be combined with clinical assessment of the patient (Kaufman et al., 2015).

Blood Transfusion Costs

Blood transfusion cost varies between one country to another, depending upon the type of services opted for. In countries where there is a mix of public and private providers, the cost varies between one blood center and another even among similar category of blood banks. A study in the US among 19 teaching hospitals attributed this variation to, geographic location of the blood supply source, type of red cell product transfused, prices charged by blood transfusion services and the frequency of laboratory tests. Acquisition cost, the price that the hospitals pay for blood was 37 percent of the total. The remaining 63 percent of the hospital cost included

costs for blood bank handling (13 percent), laboratory tests (43 percent) and blood administration (7 percent) (Forbes et al., 1991)

Market Reforms and Blood Banking

Reproduced/drawn from articles by Ann Oakley (1996), Catherine Waldby (2007), Philippe Steiner (2003)

The blood banks were first established for the army in the First World War, when blood donations were made by service men and were voluntary in nature. After commercialization took place and the plasma fractionation industries were set up, a system of payment for donated plasma was introduced. Two schools of thought subsequently emerged. Economists, Cooper and Culyer (1968), argued that blood be regarded as a marketable good and recommended commercialization of blood in Great Britain, an idea backed by those associated with the plasma industry (Beal R.W. 1992). The IEA argued that the British National Health Service and the National Blood Service would become efficient if market forces and market analysis were introduced. But at the same time, there were others who held opposite views. Richard Titmuss, in the year (1970) wrote that blood donation is an act of altruism, and equated the donation to a "gift". His work on blood donation, 'The Gift Relationship: From Human Blood to Social Policy' was a challenge to economists on this crucial point of the effects of commercializing blood collection. Titmuss was a strong proponent of an unpaid system and was against the classic free-market economy, which propagated replacement of this system with payment to the voluntary donors. Titmuss, was a great theorist and defender of Keynesian economics and believed in comprehensive welfare policies and the power of the welfare state to produce egalitarian and communitarian relations between citizens. His analysis remains relevant even today given that in contemporary societies, the human body is an increasingly valued "fictitious commodity". "Titmuss argued that blood must be 'given' rather than 'sold', because the circulation of gifts is crucial to the formation of collective social relations and mutuality among citizens. Giving and receiving blood creates a sense of impersonal mutuality and inclusion among fellow citizens, whereas to sell blood would create non-binding commodity relations between producers and consumers, whose relationship is strictly temporary, lasting only as long as the transaction."

According to Titmuss, the major contrast is between blood collected from unpaid volunteers versus paid blood donors. With the limited statistics available at his disposal, he compared the American system(paid) with the British system(unpaid) and showed that the latter was better in terms of quality and quantity. Using comparative statistics, he affirmed that the self-interested behaviour on which market relations are based was less efficient in allocating a scarce resource than unpaid donation by volunteers.

Another original feature of Titmuss' work is that he called this kind of giving altruistic, where the donor expects no reward in return either financial or moral. The unpaid donors are more likely to give correct information about their medical history as no self-interest was involved. Titmuss emphasized the need for careful selection of donors to avert hepatitis transmission, known at that time. Later selection of donors became much more difficult after the appearance of the AIDS virus. History taking meant divulging personal information like drug taking and sexual practices, which was considered to be touching upon the social identity of the donor rather than just taking medical history. This amounts to doubting the value of the gift and could lead to social discrimination. As the donor was at the centre of the system of collection from unpaid volunteers, questioning the donors' intentions would disrupt the very structure of the system. "According to Steiner P 2003, in underlining the fact that blood is collected, Titmuss indicated that it is not a produced good that is closely tied to what makes us human and that when commercialized, it falls into the category of "fictitious commodity" –like work, money and land." (Oakley, 1996) (Beal & Van Aken, 1992).

Mechanisms of Financing of the Blood Transfusion Services

Cost in a Centralized System versus Hospital Based System

There has been a debate on the financing mechanisms of blood transfusion services, its economic sustainability and desirability of different financing mechanisms, in the face of rising costs involved in running Blood transfusion services. The European Commission's Aids Task force recognizes four patterns of BTS. Pattern I- a centrally coordinated national blood program, Pattern II –hospital based blood banks, Pattern III- where relatives give blood in an emergency, Pattern IV-settings without organized transfusion practices (Beal & Van Aken, 1992). Each

pattern has its own advantages and disadvantages, in terms of screening, resource management, cost of logistics, training, supervision etc.

In most developing countries, blood services are run as vertical programs funded by the International donor community raising concerns for long term sustainability of such programs. A study in sub-Saharan Africa investigated the potential of 'user fees' as a means for sustainability, but found that there was a limited role of user fees in developing countries. Government and donor support have an important role to play as costs are high (Hensher & Jefferys, 2000).

Economies of scale is often argued in favor of blood-bank consolidation into large regional centers, and many studies have shown that the cost of a unit of blood is less when there is a system of centralized collection and processing (Bray et al., 2002). However, a study by Pereira (2006), aimed at testing the economies of scale hypothesis, was conducted in a sample of blood centers in the USA. The study included 71 blood centers and the scale of operations ranged from collection of 7270 to 275500 RBC units per year. It found that within the size range of blood centers included in this study, expanding the level of operations beyond a certain point led to decreased return to scale (DRS) as was found in 36 percent of the blood centers.

In developing countries while it is costly to establish the infrastructure, the major costs are operational. Some studies have found that a centralized system of blood services may not be cost efficient in developing countries. A study from Malawi found that despite potential economies of scale, a unit of blood from the centralized system costs three times more than from the hospital-based replacement system. Though the factors affecting the relative cost are complex, it can be partly attributed to the cost of donor recruitment. In a hospital-based replacement donation system, this is borne by the families of the patient (Lara et al., 2007). In Tanzania it was found that the cost of safe blood in a vertically run program was USD 25-40 per unit, which was more than that in a hospital-based program that was USD 12.5. It was argued that a hospital-based blood bank functioning at a basic level was sufficient for low income African countries. A safe blood transfusion practice could be assured at an annual cost of USD 0.07 per capita. The authors recommended a hospital-based blood bank as a more cost-effective option in such situations (Jacobs & Mercer, 1999).

Rising Cost of Maintaining a Safe Blood Supply

To minimize the risk of adverse reactions associated with transfusion of blood and components several precautions are taken, the most important of all are the laboratory tests. These tests are expensive and as costs are rising steeply, long term sustainability of blood safety program especially in the developing countries is being questioned. Data from the developed countries show that from the mid 90's to the mid 2000's, there has been a steady rise in cost of blood ranging between 26 percent and 170 percent in Canada, United States and the United Kingdom (Custer & Hoch, 2009). An estimate from the US, puts the cost of packed red cells at 154 USD, Apheresis platelets at 461 USD, Whole Blood derived Platelets at 52 USD, Fresh Frozen Plasma at 51 USD and Pathogen inactivation costs100 USD. The cost of only disease marker testing in the US is at least USD 35 per donation (Custer & Hoch, 2009). Similarly, in U.K. in the year 1998 a unit of red cell cost 47pounds, a unit of platelet cost 90 pounds and a unit of fresh frozen plasma 13 pounds. These have risen to 198, 130 and 91 pounds respectively, owing mainly to newer antimicrobial tests and processes some of which increase safety only marginally (SHOT Annual Report 2003).According to a projection, as precaution for Prions, the organism responsible for causing CJD, complete or universal leucodepletion would cost the UK 70 million pounds annually, a sum enough to fund blood supplies of several African countries (Williamson et al., 1999) (Stainsby et al., 2004) which led to debate on universal versus selective leucodepletion. Universal leucodepletion of blood was subsequently adopted in the U.K.

Justifying the cost related to screening for transmissible diseases (Neil Blumberg, 1999) was critical about the cost involved in the management of the Blood Centers in the USA. The FDA introduced the principles of GMP in the blood banks, in line with Drug manufacturing practices and industrial management theories, to increase safety in the blood banks. These were purely administrative and organizational in nature, involving Quality managers and the like with a focus exclusively on process, record keeping etc. and did not address the issues of efficacy, safety and cost effectiveness. Blumberg has shown from data from the period between 1980 and 1997 that this administrative component was the major contributor to rising cost of blood in the U.S., a decision that was neither based on data to support their safety and efficacy, nor their cost effectiveness. This has resulted in the shift in focus and "physicians, technologists and scientists have been driven out of positions of leadership and have been replaced by lawyers, business administrators, bureaucrats and public relations experts".

The Indian Scenario

Sources of funding of blood banks in India are multiple; hence cost of blood and components in India varies widely among private blood banks and is largely unregulated with no government control whatsoever. The government funded blood banks mostly provide blood and components free of cost or at a nominal cost. However NACO has fixed processing charges which have been revised periodically.

Concerns have been raised by the private providers in India that government pricing is unrealistic and that if implemented would lead to a compromise in quality (Choudhury, 2008)

N. Choudhary (2008) has summarized the Indian government's pricing policy, since the inception of NACO. In the year 1992, a NACO circular stated that service charge for government hospital would be INR 250 and that for private hospital would be INR 500 after which there was no revision of pricing for the next fifteen years. Then on NACO recommendation of 2004 (Table-1.2,1.3), the rates were fixed at Rs 655 for whole blood /red cells and allowed those who conducted extra tests, like anti hepatitis B core antigen (anti HBc), alanine amino transferase (ALT) to add extra charges over this charge. But this recommendation was never implemented. The breakup of the costing was as follows:

Table 1.2 NACO Estimates Action Plan 2003

SN	**Item**	**Charges (Rs)**
1	Donor recruitment and retention	30
2	Blood collection/mobiles/refreshment	20
3	Multiple blood bag	550
4	**Mandatory Tests**	
	Hb	5

	Grouping/Crossmatching	50
	TTI testing (HBV/HCV/HIV/VDRL/MP)	100
	Qc/ discards/ wastage	150
5	Consumables/disposables	150
6	Staff /equipment maintenance	300
7	Blood to emergency and poor patients	100
8	Establishment cost	100
	Total	1555
	Service Charge for Components	
1	Red cells	650
2	Platelets	500
	FFP/Cryoprecipitate/Cryopoor plasma	400

Table 1.3 NACO Recommendations 2004		
	Cost of One Unit of Whole Blood	
SN	**Item**	**Charges (Rs)**
1	Donor recruitment /retention	30
2	Blood collection /mobiles/ refreshment	20

3	Single blood bag	50
4	Mandatory tests	
	Hb	5
	Grouping/crossmatching	50
	TTI testing (HBV/HCV/HIV/VDRL/MP)	100
5	Qc/discards/ wastage	50
6	Consumables/disposables	100
7	Staff equipment maintenance	200
8	Blood to emergency and poor patients	50
9	Establishment cost	50
	Total	655

In the 17th meeting of NBTC in 2006, rates fixed by NACO were, whole blood-Rs 550, packed red cells-Rs 400, plasma-Rs 200, platelet random Rs 200 and cryo precipitate-Rs 100.

Subsequently, the rates were again revised on Nov 7th 2007 by the NBTC and were increased to, whole blood- Rs 850, FFP-Rs 400, platelet-Rs 400 and cryo precipitate-Rs 200.

The directives on rates fixed by government are followed by few blood banks only. The private sector charges vary widely. DCGI has no control over price regulation.

A study of 35 blood banks in India showed a wide variation in the charges. The cost of RBC units ranged between Rs350 and Rs1350 (mean Rs705.32), FFP ranged between Rs 250 and Rs

900 (mean Rs 539.38), cryo precipitate ranged between Rs 25 to Rs 900(mean Rs 526.73)**,** random donor platelets were at Rs 400-900(mean Rs 497.32)**,** single donor platelets were sold at Rs14, 000 and the cost of a unit of NAT tested RBC was Rs 4000 (Choudhary, 2008).

Health Technology Assessment and Blood Safety: Balancing Evidence and Public Opinion

Health technology assessment analysis has an important role in blood safety given the steeply rising risk of hazards and costs due to the addition of newer technologies. It takes into account certain key parameters such as safety, efficacy, clinical effectiveness and cost effectiveness within the context of social, economic, legal, political and cultural effects. Technology assessment attempts to provide policy-makers with a rational basis for their decisions. It points out areas where specialists are in general agreement, where controversy exists, what assumptions or fears lie behind the differences of opinion and presents alternative decision-oriented options. Economic Evaluation is one of the key components of HTA. It involves undertaking cost-effectiveness analysis of health technologies, i.e., how much value is achieved by a form of care and at what cost, relative to alternatives. Treolar CJ 2001, studied factors that influence the uptake of technology to minimize perioperative allogenic blood use and found that funding mechanisms and presence of 'enthusiast' were the main factors. Critical review for the evidence of effectiveness or cost effectiveness of these technologies was not taken into consideration as blood safety has been viewed differently and that a lot of opportunities exist in this area.

In the case of universal leukoreduction of blood to prevent C-JD, the core problem was legal, as blood banks are legally accountable for blood safety. Therefore, regardless of the cost involved, universal leukoreduction was introduced in the UK in 1999. This costly policy was followed by many other countries, in the absence of much evidence of an actual health problem or of a more than presumed effectiveness of leukoreduction in preventing prion transmission. I. Cleemput 2006 et al, are of the opinion that such strategy leads to inefficiencies in health care as blood safety management is guided by available rather than cost effective technology. They suggest that a rational safety policy taking into account the costs and the effects of the safety procedure is necessary. This issue would need a discussion with a well-informed public about the real risks

and a clear and unambiguous definition of proportionality in the precautionary principle, based on the European law.

B.R. Jackson in 2003, estimated cost effectiveness of Nucleic Acid Testing (NAT) in the US. He found that to avert 4 to 7 HIV infections and 56 to 59 HCV infections, testing for HIV and HCV by mini pool NAT would cost $155 million and $428 million for single donation NAT. Similarly, for averting 9 to 37 HBV infections, an additional amount of $39 million and $130 million would have to be spent. Overall expenditure on NAT would be between $4.7 million and $11.2 million per quality-adjusted life-year saved. The cost-effectiveness of NAT for HIV, HCV and HBV in whole-blood donations

They concluded that the overall cost effectiveness of NAT is poor and that testing costs need to be decreased significantly in line with other health care practices.

Studies have demonstrated that increasing blood product safety through additional types of tests entails diminishing returns from additional investments of resources. But these decisions for blood safety are made to instill public confidence and are political where cost is not of primary concern. A study from US reviewed cost effectiveness of a wide range of health technologies, including NAT screening of all blood donations for HIV and HCV and noted that, using NAT would result in an incremental cost effectiveness ratio (ICERs) of more than 5 million dollars per Quality adjusted life years (QALY).

“According to observers, which services get funded is often more a matter of advocacy, colloquial evidence and politics than priority setting based on scientific evidence and resource constraints” (Lomas et al., 2005).

For better prioritization of public policy, multiple stakeholders should be involved e.g., “program officials, health care providers and private-sector payers, as well as evidence-based reviewers and economists”. Poor understanding of risks and benefits by stakeholders can lead to poor decisions at both the policy and individual levels.

Rational Use and Cost Effectiveness

The problem of unnecessary use is present in developed and developing countries alike. Unnecessary use of blood defeats the purpose of maximizing effectiveness per unit cost. 'It is paradoxical to finesse the safety when it is used unnecessarily' (McClelland & Contreras, 2005), instead, investment should be made in understanding in which situations, transfusion would be effective. About 2.5 million units are supplied annually in the UK out of which 40-50 percent is used in elective and emergency surgery and 5 percent in intensive care (Wells et al., 2002).

The hemovigilance system, a system of collecting data on Adverse incidents, can be used as a tool for technology assessment by enlarging its scope to include 1) the estimation of actual risks using notification and traceability data 2) an ongoing assessment of needs 3) the development of representative epidemiologic, economic or clinical studies (Mathoulin-Pélissier et al., 2000). SHOT report of UK collated for 1996-2003, during this period 26 million units of blood components were supplied, out of which, the incidence of serious adverse reactions (per 100,000 units of blood supplied) was death 0.2 and major morbidity 1.1(of which was transfusion related acute lung injury and 0.2 was infection -mostly bacterial).

In view of the high cost involved for ensuring blood safety, there is a need for blood and blood product transfusion audits. We review literature on this in the next chapter and thereby also develop the methodology for the present study.

CHAPTER -2

Conceptualizing a Blood Banking System and Methodology for Assessing Transfusion Prescribing Practices

In clinical practice 'Quality' of transfusion means safe, effective and appropriate transfusion. The ultimate aim of guidelines, recommendations and algorithms, is the appropriate, i.e. 'Rational' use of blood and components.
As has been explained in the previous chapter blood collected from low risk donors, proper testing and its appropriate use are all essential elements of the blood safety chain.

The problem of blood and component use not conforming to guidelines exists in both developed and developing countries, the extent varying according to the accepted definition of rationality and the differing conditions of their respective health services.

Transfusion Audit

Blood and component transfusion audit is done to assess the appropriateness or inappropriateness of a transfusion. Each episode of transfusion of blood or components is assessed against established international guidelines or those that have been agreed upon locally. In addition to deciding the appropriateness of a transfusion, an audit also helps to track the changing trends in transfusion practice.

Historical Background

The need to ensure appropriateness of transfusions was recognized as early as 1937 in the U.S. (Renner, 1998) but it was not until 1984 that a system of regular transfusion audits was initiated and made mandatory as part of the Joint Commission for the Accreditation of Health Care Organizations (JACAHO) requirement. The major driving factor was the rising cost of maintaining a safe blood supply after the discovery of the AIDS virus. This system first initiated in the US was later followed by many other developed countries. However, in India, blood and component transfusion audit is not a routine procedure and has not been made mandatory as yet.

Theoretically, blood bank or transfusion medicine audit includes all procedures from sourcing of blood to long term consequences of transfusion (Pinkerton, 1995). In practice however; transfusion audit usually refers only to the monitoring of transfusion prescribing practice of clinicians.

Two assumptions are central to the concept of auditing of transfusion practice:

A) There is over ordering and inappropriate use of blood

B) The primary reason for inappropriate use of blood and blood products is inadequate knowledge of transfusion guidelines

The Method and Procedure of Audit

In the US, the procedure of Audit is mostly *Retrospective* and is done quarterly at the institutional level (Toy, 1999). If there are more than 600 transfusions in a quarter than 5 percent sample or 30 total cases, whichever is larger are taken (Renner S. W. 1998). If no instance of inappropriateness of a transfusion is reported then it is presumed that the guidelines for review are liberal and need to be modified.

The other type is the *concurrent or prospective audit.* The advantage of this method is that it is more effective in influencing transfusion practice as it gives a clear picture of the situation with scope for immediate intervention, but it is generally difficult to do.

Audit is a three-step procedure. The first step is performed by quality management personnel or transfusion service technologists. This is a chart based initial screening review. The second consists of review of the shortlisted cases by the physician peers. Thirdly, it is ultimately the responsibility of the members of the hospital transfusion committee to judge the transfusion as appropriate or not. The committee comprises of representatives from the user departments, an Anesthetist and Transfusion medicine physicians. In India, National Aids Control Organization (NACO) has proposed that specialist clinicians be members and a transfusion specialist be the member secretary of a hospital transfusion committee.

The criteria for transfusion audits are normative, they reflect a consensus on what represents good or appropriate transfusion therapy. Ideally experts in transfusion medicine reach a consensus on what type of transfusions would produce the desired results in various types of patients and their consensus represents the essential criteria established (Toy, 1999) (Coffin et al., 1989).

Limitations of Transfusion Audit

Establishment of proper criteria for audit is very important as the amount of cases considered inappropriate will depend largely on this. If the criteria are stringent then the number of inappropriate cases will rise. Studies based in developed countries have reported peer reviewed audit findings and give an idea of the proportion of inappropriate transfusion depending upon the criteria used. With more implicit criterion, identification of inappropriate transfusions is likely to be low, while an explicit criterion would report more rates of inappropriateness (Hasley et al., 1994). In a review of studies on audit of transfusion practices based in US hospitals, Renner 1998, found that most audits reported a high level of appropriateness of transfusions, prompting some to suggest that the peer review process exists principally as a means to justify past transfusions (Goodnough & Audet, 1996). Nevertheless, the peer review process creates an environment for a dialogue between the transfusion medicine specialist and the clinicians. This helps in understanding the perceptions of the clinicians and the difficulties encountered in transfusion practice. If such a practice could be extended to multiple institutions, it would help in minimizing the effects of local practices and conventional beliefs and would provide comparisons for a better audit procedure (Toy, 1999).

It appears from the reported studies that while reviewing transfusions, biomedical aspects are examined and the contextual issues are not taken into account.

There are many studies on audit of transfusion practice from India that have looked into the various dimensions of audit however, none have reported on the audit of transfusion practice based on peer reviewed procedures. They have all relied primarily on the international guidelines for appropriate transfusion practice to identify ‘Correct’ and ‘Incorrect’ prescribing practices.

Appropriate Transfusion Practice

WHO defines ‘appropriate’ use of blood and components as, ‘The transfusion of safe blood products to treat a condition leading to significant morbidity and mortality that cannot be prevented or managed effectively by other means’ (W.H.O.1999, Guidelines for clinical use of blood).

According to International Guidelines, transfusion of whole blood should be avoided where possible instead use of components should be encouraged. Component therapy not only allows achievement of a more effective therapeutic level of the needed blood fraction, but components

made from each unit of whole blood can meet the needs of multiple recipients, thus enabling its judicious use. Whole blood may be appropriate in specific situations. The advantage being that it helps reduce donor exposure.

Single Unit Transfusions

In recent years, single unit whole blood and red cell transfusions have been at the center of clinical debate. The transfusion of single unit red cells was considered irrational in the1960s and 1970s when factors associated with the risks and benefits of transfusion were perceived differently. It was believed that transfusion of single units of red cells was not "clinically effective" and that for correction of anemia at least two units would be required (Pinkerton, 1995) (Napier et al., 1985) The BMJ series, on the ABC of transfusion, states "transfusion of less than two units is bad practice."

However, from the 1980s, with the discovery of the AIDS virus and a more serious review of transfusion practices thereafter, an alternative view has emerged. In the present context of the threat of transmission of infection a more conservative approach is advocated and single unit transfusions have come to be viewed as 'restrictive' practice, and as helping to reduce the number of transfusion exposures. Wood field (1999) writes, "Single unit transfusions could be useful if they bring a patient from an unsafe situation to a safer state."

The WHO guidelines for the clinical use of blood formulated in the nineties (WHO, 1999) also do not recognize single unit transfusions as irrational leaving it to clinicians to decide its use on the merits of the case. "Do not transfuse more than necessary. If one unit of red cells is enough to correct symptoms then do not give two units" (WHO 1999).

"Administration of one unit of blood more often effects appropriate use of blood than misuse. Emphasis on the scrutiny of single unit transfusions may result in poor transfusion practice. This screening procedure should be eliminated because it focuses arbitrarily and inappropriately on a subset of patients who have received transfusions" (Grindon et al., 1985).

Several descriptive studies, from India, have assessed the proportion of single unit transfusions, as an indicator of inappropriate transfusion practice (Makroo, 1992) (Saxena & Banerjee, 1999). Two studies, from Delhi and Haryana found the proportion of single unit transfusions to be quite

high. Saxena (1999) at the district hospital in Haryana found 87 percent, 87 percent and 90 percent single unit transfusions respectively in a three-year study. Makroo, (1992) categorized transfusions into four groups-conservative, reasonable, questionable and unnecessary, depending upon the preoperative hemoglobin levels (Hb less than 10 gm percent, between 10-10.5gm percent and more than10 gm percent) and found that only 32 percent were reasonable.

A study by Gupte S. 2007, found 40 percent of Packed Red Cell and 78 percent whole blood transfusions were single unit transfusions in cases of elective surgery and found them to be avoidable. Many studies still continue to label single unit transfusions as inappropriate based on the earlier school of thought.

Review of Studies on Transfusion Practice

Most of the studies on transfusion audit reviewed were categorized into the following types:

A. *Processes at the Blood Bank*:

B. *Descriptive Studies on Transfusion Practice*

C. *Studies on Intervention to improve Transfusion Practice*

D. *Non clinical factors affecting Practice identified by studies*

The studies reviewed have looked into various aspects of transfusion practice like, pattern of utilization, changes in transfusion practice after intervention, use by specialty and disease categories and trends in transfusion.

These studies assess transfusion practice against guidelines or set criteria, chiefly with the objective to study the pattern of utilization of a single component or all and also in one or several clinical conditions. These studies have focused in particular on, demographic patterns of transfusion, the Maximum Surgical Blood Ordering Schedule (MSOBS), distribution by clinical specialty and by diagnosis category. Some of them have identified other factors affecting transfusion practice, and suggested ways for improvement. The studies reviewed were from both developed and developing countries based in different categories of hospitals, using different study designs and definitions of appropriateness.

A. Processes at the Blood Bank

A number of indicators at the blood bank level can be used for better resource management and these indicators also give an insight into the transfusion practice followed at the hospital

(Pinkerton, 1995). They include, the return of unused blood, wastage rates, discard rates due to TTI'S, proportion of collection made into components, Cross Match to Transfusion Ratio (CTR), Transfusion Index (Ti)-which is the average number of units transfused for a given procedure (Napier et al., 1985)[3].

It has been found that procedures with a Ti of <0.5 merit only grouping and screening and not cross matching. However, though the CTR gives an estimate of the work load at the blood bank, it may not necessarily be an accurate assessment of the efficiency of blood usage. A low CTR may represent a low cross match incidence or alternatively a high transfusion incidence, but does not tell us whether or not they were appropriate. Only by determining pre- and post-operative hemoglobin values can the appropriateness of the transfusion be assessed. Conversely, a high CTR may represent a high cross match incidence or low transfusion incidence and considering the prevalence of widely differing transfusion practices, inappropriate cross matches and transfusions may well play a significant role in determining CTR's. It would be inadvisable to attempt to attain a CTR of 1. A safety factor must always be provided for, but a CTR of 2.5 should not be regarded as ideal, since this means that for each 10 units of blood ordered only 4 would be transfused (Rund et al., 1992). A high CTR is a common cause of wastage leading to shortages and sometimes leads to underutilization in subsequent patients (Napier et al., 1985).

Kumar A. (2014), reviewed practices in obstetrics and gynecology cases found that 75 percent of requests need not be cross matched since only 2 percent actually required transfusion, resulting in a high CTR. Therefore, to conserve resources, a group and screen procedure was appropriate. The Maximum Surgical Blood order Schedule (MSOBS) could be altered on this basis. Most studies show that the MSOBS is different for different hospitals resulting from divergent practice environments (Rund et al., 1992). The guidelines for CTR must be worked out according to the context of the practice setting, and would not be uniform even within the same country (Napier et al., 1985).

[3] CTR, Transfusion Index; Estimate of the number of units demanded and the number of units issued, helps in better inventory management, checks over ordering and wastage of resources. This a part of blood bank 'Process Audit'. If cross match to transfusion ratio exceeds >2.5 it indicates that there is over prescribing and requires better inventory management. This tool is of special significance in those situations where there is a system of centralized collection and testing. The user hospitals procure blood and components and maintain local stocks according to their requirements.

A study from the UK showed that Trans Urethral Resection would merit only a group and screen in Southampton, while in Wales it would be two units and in Dundee three units. These differences are a reflection of differing surgical and anesthetic policy in different hospitals and to apply a uniform policy to all hospitals could be dangerous (Jaffray et al., 1991). Napier (1985) explains that, 'The overall level of blood use probably reflects both availability and perceptions on the indications, risks and benefits, of transfusion. These beliefs which have a profound effect on the amount of blood transfusion activity are rarely challenged.' In conclusion, Cross Match Transfusion Ratio and Transfusion Index are indicators of transfusion activity in a particular setting and would vary from one to another. It helps in better inventory management, but it does not tell us whether the transfusions were appropriate.

B. **Descriptive Studies on Appropriateness of Transfusion Practice**

(i) Studies on Transfusion Practice from India

A prospective transfusion audit based in Bombay, designed to evaluate utilization patterns, reviewed a total of 3500 transfusion demands in a tertiary hospital, over a three month period in 1997.The study found that 19 percent of all patients admitted required transfusions and that Pediatric age group was the most frequently transfused. A blood component order form with indications based on international guidelines was used to assess the appropriateness of Red cell, fresh frozen plasma and Platelet transfusions. 42.65 percent of patients mostly having had single unit transfusions had questionable indications. In 30.39 percent of the cases of fresh frozen plasma transfusion, the indications were questionable and 20 percent of the plasma transfusions were questionable (Vishwanathan et al., 1999).Another, study from a tertiary care hospital in Delhi studied the pattern of blood utilization among specialties and found that the department of Burns and Plastic Surgery utilized the highest proportion of transfusions (29.8 percent), followed by General Surgery (25.70 percent). The main demand was for whole blood at 89.8 percent, followed by fresh frozen plasma at 8.8 percent. Patients receiving single unit transfusions were 80.18 percent. Vibhute M. (2000), found the rate of utilization of red cells to be 28 percent in elective surgery.

Fresh Frozen Plasma Audits

Along with Red cell concentrates, component misuse was also found to be on the rise. Many studies have highlighted the inappropriate usage of Fresh Frozen Plasma. Chaudhary R. 2005, in a study found 70.5 percent inappropriate use and only 29.5 percent of fresh frozen plasma transfusions were appropriate. A study by Makroo R.N. 2009 found that 69.8 percent were transfused appropriately and 30.2 percent were inappropriate transfusion as assessed by guidelines. Some other studies showed variable rates of usage: Kakkar (2003) found that 23 percent were inappropriate fresh frozen plasma requests, Chatterjee M and Bharucha Z. N (1998) found 39 percent were inappropriate issues among surgical oncology patients.

Platelet Audits

Studies on Platelet audits from northern India have also reported inappropriate use. Makroo R.N. (2007) found that 32 percent of platelet transfusions were inappropriate according to Delhi Health Service (DHS) guidelines, while Saluja (2007) found 12 percent of platelet transfusions to be inappropriate assessed by British Council (BCSH) guidelines. In a study from Delhi reviewing platelet usage during the Dengue epidemic, Kumar (2000) reported a high proportion of inappropriate transfusions. 35 percent received unnecessary prophylactic transfusions, and 89 percent were in inappropriate doses.

(ii)Studies on Transfusion Practice from Other Countries

On evaluation by using transfusion guidelines and pre-set criteria for red cell transfusion, (Ghali et al., 1994) found out that 55.3 percent of transfusion of packed red cell transfusion was unnecessary. A nationwide multicenter survey in Finland investigated blood loss and median transfusion thresholds resulting from common elective surgical procedures like Total Hip Replacement (THR), Total Knee Replacement (TKR) and Trans Urethral Resection (TUR). A total of 764 patients of THR, 397 of TKR and 343 patients of TUR were studied. It was found that the thresholds used for transfusion were liberal compared to international recommendations and that there was a need for rationalizing the transfusion policy (Capraro et al., 2000).

In a prospective observational study of red cell transfusions over a period of 28 days in Northern England, Wells 2002 found that more than half (51.6percent) of red cell units were transfused for medical indications; next were surgical patients with 40percent transfusions. This result was at variance with other studies that have shown that maximum transfusions were administered to

surgical patients. The author attributed this change in pattern of utilization to increased red cell use in an ageing population. It was also projected that by the year 2008, red cell use would increase by 4.9 percent.

In a retrospective review in a Belgian hospital, to study prevailing practices based on existing criteria, Schots J (1994) found that there was inappropriate use of packed cells in 15 percent of the cases and that fresh frozen plasma was not indicated in 67 percent of the cases. They however found that transfusion of platelets was always appropriate, concluding that inappropriate use was due to lack of consensus on guidelines.

In an audit of fresh frozen plasma and platelets in five London hospitals, Thomson (1991) reported that in 61.5 percent of cases the reason for component use was not stated. There was inadequate documentation in 66 percent of cases, whereas an accepted indication was found in only 36 percent of cases. Easy availability was the likely reason for high percentage of fresh frozen plasma use and suggested that many aspects of transfusion practice had to be improved.
Another audit of the usage of fresh frozen plasma, platelets and cryo precipitate, assessed against NHMRC/ASBT 2002 guidelines in New South Wales public hospitals found proportion of inappropriate transfusions to be 33 percent for platelet, 37 percent for fresh frozen plasma and 62 percent for cryoprecipitate (Schofield et al., 2003).

Etchells M. 2003, evaluated appropriateness of platelet transfusion in ten hospitals in Ontario and found that there exist significant variations between institutions in classifying appropriateness. In this study, 78 percent of transfusions were adjudicated as appropriate.

The SAnGUIS Study (The SAnGUIS study group 1994) was a landmark multi institutional study of transfusion practices in elective surgical procedures, across 43 European teaching hospitals. Wide variation was found between different hospitals, both in the proportion of patients transfused and the amount of products used for the same patient category, even for the same procedures. The wide differences were due to a variety of causes of which only some could be explained by the clinical factors taken into account. After adjustment for variables like age, gender, preoperative Hematocrit and blood loss, the differences still persisted, that appeared to be dependent on the individual clinician ordering the transfusion. The study concluded that there

was little consensus on the guidelines and currently available guidelines had little impact on transfusion practice.

Another eighteen-institution study on patients undergoing Coronary Artery Bypass Graft (CABG) surgery was conducted with the objective of describing variability and to determine factors that account for this variability. After controlling for patient and surgical practice variables, transfusion practice factors still accounted for variation in red blood cell transfusions. It concluded that practice differs widely among institutions, in part because of unnecessary transfusions (Rogers & Johnstone, 2006). Studies on plasma use have found similar results. It was shown that Plasma transfusions were used prophylactically and were unnecessary, concluding that the consensus statements need to be effectively applied

An example of unnecessary use due to availability of components was seen in a study conducted in Rhode Island between 1978 and 1985 which observed changes in practice in response to withdrawal of whole blood. The study showed that greater availability of components i.e. fresh frozen plasma and platelets led to their increased use among clinicians previously unaccustomed to using them. The primary reason was reconstitution of whole blood. Inappropriate use declined after 1983, with the dissemination of guidelines from consensus conferences (Crowley et al., 1987).

Studies reviewed in this section on transfusion practice have looked at the proportion of transfusions utilized by the various specialties, others have classified them as appropriate or inappropriate based on accepted guidelines. Some studies also give reasons for inappropriateness which is chiefly inadequate knowledge of transfusion guidelines.

Studies on erythrocyte transfusion rates for different procedures compiled by Goodnough L.T. 1999, showed wide variation in practice (Table-2.1).

Table 2.1 Erythrocyte Transfusion Rates (Allo and Auto) in Multicentric Studies					
Procedure	**Study**	**Year***	**P (n)**	**Hosp(n)**	**Range Pt/ Po (%)**
CABG	Goodnough	1987	540	18	30-100
	Surgenor	1988	216	3	42-95
	SAnGUIS	1991	1154	19	19-100
THR	Surgenor	1986	722	7	50-85
	Toy	1989	249	6	60-90
	SAnGUIS	1991	1582	25	25-100
	Biomed I	1996	901	46	15-100
	Biomed II **	1999	554	28	
Hemicolectomy	SAnGUIS	1991	995	28	7-78
	Biomed I	1996	382	20	10-79
	Biomed II **	1999	292	15	5-60

** Years refer to dates of data collection, not to dates of publication.*

*** Compare ad hoc report to the Federal Ministry of Health (Belgium) and to the participating clinicians.*

P = Patients, Pt = Patients transfused, Po = Patients operated upon, Hosp = Hospitals.

(iii) Studies on Intervention to Improve Transfusion Practice

As mentioned in the previous section the primary assumption about inappropriate use of blood and component transfusion is inadequate knowledge of guidelines. Therefore, interventions to improve knowledge of guidelines were used to study the impact on practice. These interventions were basically of two types-(a) to improve knowledge of guidelines by way of intensive training, use of printed material, personal visits to educate the clinicians, lectures, physician self-audits,

computerized audits, algorithms / criteria maps, or redesigned blood request forms (b) by way of policy decisions or institutional changes, for use of guidelines revised by consensus.

The studies that have used interventions assess their success by measuring various outcome indicators such as, decrease in the number of requests received, decrease in the Cross/Transfusion Ratio, or decrease in proportion of transfusion of various components, or fall in proportion of single unit transfusions.

Three studies from African countries (Solomon Islands, Zaire and Tanzania), found that education of guidelines was necessary for improvement in transfusion practice, but that for its sustainability, continuous medical education is necessary. In the study reported from Solomon Islands by Lucas (1997), the cutoff hemoglobin level for peri operative patients was reduced from 10 to 8 gm percent. This conservative strategy showed positive results with a reduction in the number of units cross matched from 29.7 percent to 30.1 percent units transfused per 100 operations. But the proportion of group and hold requests did not increase, indicating that most of the requested units were cross matched.

The study done by Lucas (1997), used revised guidelines, used a lower threshold indication of 6 gm percent hemoglobin and 20 percent hematocrit, along with clinical criteria --tachycardia, hypotension, dyspnea and impaired consciousness and found that there was a reduction in transfusions. It concluded that the development of guidelines and continuous education of health workers would lead to a reduction in unnecessary blood transfusions. The findings had significant implication because in Africa, blood transfusion was the third most common means of HIV transmission after heterosexual and peri natal transmission.

In the study from Tanzania, consensus guidelines were developed to educate clinicians but this exercise alone was not sufficient to change overall transfusion practices. The proportion of avoidable blood transfusions decreased only in hospitals, where compliance was maintained through regular clinical meetings and strict supervision by senior medical staff.

Mahfooz Ur Rahman (2001) found that education of practice guidelines gave positive results leading to an improvement in the blood ordering practices in a hospital in Malaysia. The number of requests received decreased by 38.5 percent and blood bank compliance increased by 12.7 percent. Proportion of blood utilization decreased and Cross Match Transfusion Ratio came down to 2:1.

Three studies by Hume 1997, Coffin 1989 and Finkle 1992, found that criteria maps and algorithms have positive effects on practice. Criteria maps help in educating the prescribers about transfusion guidelines. In an audit of pediatric transfusion practice using criteria maps, Hume (1990) found that 79.7 percent of red cells, 42.3 percent of fresh frozen plasma, and 64.7 percent of platelets were appropriate. Coffin 1989 also found a large proportion of transfusions to be appropriate; 96 percent red cells and, 69 percent of fresh frozen plasma were indicated but the author also acknowledges the existence of grey areas where decision making is difficult.

Tuckfield (1997) used a redesigned request form as an intervention which incorporated indications for transfusions and relevant clinical and laboratory data. As a result of this intervention inappropriate red cell utilization fell from16 percent to 3 percent and inappropriate platelet use fell from 13 percent to 2.5 percent. However, the intervention was only partially successful for fresh frozen plasma which fell from 31 percent to 15 percent. The author concluded that the findings reflected uncertainty of guidelines for its clinical use.

In a study based in Croatia, Skodlar in 2005 used the WHO transfusion Basic information Sheet (BIS) as a tool for data collection and assessment of transfusion practice. The intervention was successful but it was suggested that there was still a need to encourage clinicians to determine their transfusion targets before prescribing.

A prospective, one year study on the use of cross matched blood in cases of Total knee replacement (TKR) and Total hip replacement (THR) used intervention in accordance with published national guidelines. They were as follows:

1) Routine cross matching for THR was stopped and only group and save was done,

2) All patients would have full blood count check on the second day of surgery and

3) Patients above 65 years and with no significant co morbidity and with hemoglobin of 8 gm percent would be transfused.

It was observed that in the next 6 months the number of units cross matched but not transfused fell by 96 percent for THR and the CTR reduced from 3.21 to 1.62. Reductions were also observed in the TKR cohort. The study concluded that based on this study MSOBS could be changed in other hospitals too (Rogers & Johnstone, 2006).

In a case control study by Eindhoven 2005, in two different hospitals, guidelines were introduced in one hospital while the other served as a control. He found that intensive training led to reduction of blood and component use in the study hospital and not in the other. They used the

‘60-80-100-Flexinorm’ where they explicitly described the conditions that are relevant for the decision to transfuse, namely signs and symptoms caused by anemia, an increased need for oxygen and a decreased ability of the patient to compensate for anemia. The results of the study showed that the use of blood was reduced by 70 percent, the number of patients receiving transfusions decreased by 60 percent, with the reduction in blood use and hospital stay decreased significantly, despite a decrease in discharge hemoglobin to a mean of 13 gm percent.

Brandis K. 1994 used the transfusion policy framed by the hospital transfusion committee to reduce inappropriate transfusions. Transfusions six months prior and six months after the intervention were studied which showed positive results. The number of units transfused for 1000 patients fell by 28.8 percent, CTR reduced and G/S increased.

Mallet (2001) found a significant impact when hemoglobin was measured immediately before transfusion. Earlier, transfusions were given if the blood loss was more than 500 ml irrespective of the hemoglobin values. The total number of transfusions decreased by 43 percent between the years 1996 and 1998.

Greeno 2007, found that after reducing the cutoff for prophylactic platelet transfusions to 10x10(9) from 20x10(9), many prophylactic platelets were still given at a higher cutoff than the transfusion trigger and only a minor change in platelet usage was observed.

In a controlled intervention trial, Soumerai 1993 used three types of educational methods, lecture, brief graphic printed educational guidelines and thirty-minute visit with each physician. An audit of records 6 months before and 6 months after the intervention showed that transfusions that were not in compliance decreased significantly among surgeons. However, no effects were observed in the specialty of medicine, possibly because of low transfusion rates and lower pre transfusion hematocrits. It was concluded that brief, focused educational outreach visits would substantially improve appropriateness and cost effectiveness. More studies are required in order to measure the durability of changes and the possible economic benefits of such interventions.

Marconi’s (1996) intervention consisted of giving the privilege of non-urgent requests to a limited number of physicians and a computerized prospective audit of blood requests, patients’ laboratory data, clinical data and guidelines for proper use of blood. It found that 96.8 percent of requests for red cells and 98.1 percent of requests for platelets were appropriate. Also 27 percent of plasma did not comply with the guidelines, mainly because evidence of coagulopathy was

missing. However, the proportion of plasma used for reconstitution decreased in the study period. He concluded that the Prospective audit was a useful tool to educate the clinicians.

A preintervention and postintervention design with control was used to evaluate the effectiveness of a prospective physician self-audit transfusion monitoring system by Lam H.T.C. (1997). The objective was to study the effectiveness of issuing to physician a memo with transfusion guidelines. The process indicators measured were-(a) number of cross matches ordered per admission, (b) Transfusion to cross match ratio, (c) number of blood units returned after physician self-audit. The outcome indicators measured to assess overall blood utilization were, (a) percentage of patients who received red cells, (b) number of blood units transfused per recipient each month. Result indicated that the intervention had a significant effect on reducing transfusion of RBC's ($p=0.01$), FFP ($p=0.10$) and packed cell ($p=0.06$). After the intervention period however blood utilization returned to the same level as before the implementation of the prospective physician self-audit transfusion monitoring system. Similar changes in the blood utilization were not observed at the control hospital. The usage of RBC and fresh frozen plasma were not significantly decreased. On the contrary, the usage of packed cells significantly increased ($p=0.07$). However transient reduction was observed at the study hospital, which was hypothesized to be due to 'Hawthorne Effect'[4] , in which the observed behavior is affected by the subjects' awareness of the ongoing research. The author concluded that to achieve an acceptable standard of quality, a greater focus should be shifted to educating physicians.

A study on rational use, conducted at four cities in India, Delhi, Nashik, Bangalore, Imphal, which used a self-educating request form, as an intervention, showed inconsistent results across different hospitals studied (Bray et al., 2002). The objective of the study was 'to elucidate factors that influence blood use and appraise options for promoting good transfusion practice.' The methodology of the research was rigorous. The study involved a 'cluster-randomized trial', of an

[4] HAWTHORNE EFFECT- This term was coined after the classic illumination experiment conducted at the Hawthorne plant of the western electric company. In that experiment the researcher hypothesized that the worker productivity would increase if the illumination at the factory was improved. Unexpectedly the worker productivity increased regardless of whether the intensity of illumination was increased or decreased. The experimental data was interpreted to indicate that workers behaved positively when they were aware of being under special observation.

intervention to promote appropriate blood use, using a reminder at the time of the blood order (a new transfusion request form that listed indications for transfusion), at six matched study and six control hospitals across the four areas, over a four-month pre-intervention and a five-month post-intervention period.

The results showed a post intervention reduction in the median number of units transfused per admission from 0.18 to 0.15 (p=0.09), including a significant reduction (p=0.05), at two study hospitals. However, the intervention was not particularly effective and the results were inconsistent across different hospitals. Evaluation of transfusion practice revealed that inappropriate practice was common place, and that out of 1062 transfusion episodes analyzed, 60 were given for anemia, 42 percent for surgical cases, 26 percent for acute hemorrhage and16 percent for pregnant women. Out of a total of 87 percent of the transfusions given to adults, 74 percent were inappropriate.

The researcher attributed the findings to several interconnected influences and factors that moderate the impact of efforts to promote rational blood use. Possible common proximate causes for inappropriate transfusions include, unnecessary transfusion for iron deficiency anemia and transfusion as a first choice for volume replacement. The more distal inter-related influences could be traced through from the patient, through to the blood bank and the hospital and ultimately to the State. Lack of clinical training, the hospital environment and fragmented blood bank services influenced the way blood is used in India. The key non-clinical influences included the expectations of the patient and the patient's family, the desire for family donors, the cost of transfusion and blood screening, the position and influence of the blood bank, hospital policy and coordination, and city-wide and regional infrastructure of blood services. Bray acknowledged the role of initiatives in the field of education, policy and infrastructure as central to the promotion of good clinical practice. He prescribed intense efforts, one to one outreach and interactive educational workshops to raise awareness of transfusion guidelines, with a caveat that, "all this would be effective within the context of the larger framework of political commitment, administrative, organizational and financial support at the national level."

Bray (2002) prescribed intense efforts, one to one outreach and interactive educational workshops in order to raise awareness of transfusion guidelines among clinicians. But all this could be effective, only within the context of a larger framework of political commitment and

administrative, organizational and financial support at the national level. He also proposed consolidation of services and adoption of the national blood policy.

Both the studies by Lam in 1997 and Timothy Bray in 2002 are similar in the way that both are based on the assumption that education of transfusion guidelines would help improve transfusion practice and both use a physician self-audit procedure to educate the clinicians. However, the study by Bray is rigorous in its methodology in that it is a *Randomized Control Trial* whereas the one by Lam is a *Prospective study*. Lam concludes that greater emphasis should be laid on education of the physician whereas Bray goes a step further in saying that education would be effective within a larger framework of support and commitment at the regional and national level. Bray's study objective was limited to the study of effects of the intervention on transfusion practice so methodology appropriate for this was selected to achieve that end.

Since the general understanding developed by the various studies point to inadequate knowledge of transfusion guidelines as the chief reason for inappropriate practice, most studies reviewed in this section have assessed practice before and after an intervention to improve knowledge of transfusion guidelines. In some of those studies where the intervention failed, other factors that could have affected the results have been identified. Bray in his study has identified some these influences. But the methodology followed by Bray though rigorously designed does not facilitate the study of the immediate influences present within the practice environment. For such factors to be accounted for, the study design should incorporate qualitative methods as well.

(iv) Non clinical factors affecting practice identified by studies

Various factors, both 'clinical' (such as, differences in patient population, the patients' condition and surgical practice) and 'non clinical' have been identified as reasons for inappropriate blood and component use. Though the objectives of these studies were different, many studies have cited factors other than inadequate knowledge of guidelines to be affecting transfusion practice.

In their report on "The SAnGUIS Study", the authors explaining the reasons for wide variability in practice among European hospitals suggested that 'other factors seemed to be operative'. They also cited in their paper some factors contributing to major inter hospital variations, which were found by other studies that are enumerated here:

a) "*ill-defined criteria for transfusion due to incomplete scientific knowledge"* (Surgenor et al., 1991) (Carson & Willett, 1993)

b) *"Lack of effective methods for consistently translating available knowledge into clinical practice" (*Linton & Reachey1990; Berwick et al., 1992)

c) *"Differences in the application of the criteria for transfusion* (Carson & Willett, 1993; Surgenor et al., 1991) *differences in physicians' beliefs about the value of practices for meeting the patients' needs*"(Mulley &Eagle 1988); *"a negative association between knowledge and years of practice" (*Salem-Schatz et al., 1990),

d) *an 'institutional' effect in transfusion practice in CABG"* (Goodnough et al., 1991)

Several other studies have similarly reported wide and unexplained variability (Pinkerton, 1995; Thomson et al., 1991) (N Blumberg et al., 1986) (McCullough et al., 1988) (Brien et al., 1989). Clinicians' preferences and habits and institutional differences, which 'through reasons of training or hierarchy, become ingrained in hospitals' (Surgenor et al., 1991) have been found to affect 'Rational' transfusion practice.

A study from Rhode Island found that greater availability of components led to their increased use by clinicians previously unaccustomed to using them, after availability of centralized component separation facility (Crowley et al., 1987).

Problems of resource availability and factors related to health services have also been found to affect transfusion practice as reported in some studies from underdeveloped countries like Africa and India.

A study conducted in Ghana has found the influence of barriers like inadequate blood supply and an absence of laboratory facilities to affect transfusion practice adversely. An audit against present criteria undertaken in three hospitals in Ghana found that 1/5th (17 percent) of all transfusion episodes were avoidable. The proportion of avoidable transfusions in the surgical category was greater than in the medical category. In the absence of laboratory support (58 percent), most decisions were based on subjective clinical findings alone (pallor-64 percent, jaundice-18 percent, hemorrhage-7 percent, palpitations and weakness). Transfusions given to cases of asymptomatic anemia consisted of 21 percent of the total and the proportion of single

unit transfusions were 21 percent. The study concluded that a simple laboratory test could avert the need for transfusions (Addo-Yobo & Lovel, 1991).

Another retrospective study conducted by Emeribe (1993) in Nigeria between 1984 and1988 studied patterns of donations and blood use. Economic hardships leading to low nutrition levels among the general population, was an important factor contributing to low donation levels. Another contributing factor was fear of testing positive for HIV. This study found that shortages of blood even led to death.

A study in a district children's hospital in Kenya, found that shortages of blood packs, tubing, needle and donors affected practice. It was the responsibility of family members to provide donors and also to procure supplies, thus leading to delays in the administration of blood (Lackritz et al., 1993).

Often clinicians are under constant pressure to deliver because they are answerable to patients' families. In such situations they prefer to transfuse and err on the side of over transfusion than take the risk of withholding transfusion (Gupte & Shaw, 2007) in a review of single unit transfusions in surgical cases in India, observed that some surgeons transfused single unit red cells that could have been avoided, 'to please the patients', or could not keep blood units reserved for patients because of 'non availability' of refrigerators.

In a tertiary care private sector hospital during the dengue epidemic inappropriate platelet transfusions were given because of 'intense social pressure and pressure from the relatives' (Makroo et al., 2007), an observation pointing to the fact that these influences are seen across all categories of hospitals, both public and private.

Bray in his study has acknowledged the presence of several interconnected influences and factors that moderate the impact of efforts to promote rational blood use. These influences could be traced from the patient, through to the blood bank and the hospital and ultimately to the more distal influence- the state. The chief non-clinical influences included the expectations of the patient and the patient's family, the desire for family donors, the influence of factors like organization of the blood services, their coordination, policy and regulations related to the cost of transfusion and blood screening (Table-2.2).

Table 2.2 Summary of Non-clinical Factors Affecting Transfusion Decisions Identified by Various Studies

SN	Title	Author/Year	Place of Study	Reasons Identified for Inappropriate Transfusion Practice
1.	Transfusion medicine in India: A survey of current practice	Bray T.J.(2001)	India	Interconnected influences- traced from patient to blood bank to hospital to the state.
2.	Role of Platelet Transfusion in the Management of Dengue Patients in a Tertiary Care Hospital	Makroo R.N.(2007)	India	'Intense social pressure and pressure from the relatives' in Dengue, because of fear of deaths
3.	Evaluation of single unit red cell transfusions given to adults during surgery	Gupte S.(2007)	India	Surgeons transfuse 'to please the patients', Could not reserve blood units in advance because of 'non availability' of refrigerators in the hospitals.
4.	Blood transfusion practices and blood-banking services in a Kenyan hospital	Eve M. Lackritz (1992)	Kenya	Reasons for delay in blood administration- shortages of blood packs, tubing, needle and donors. Responsibility of family members to provide donors & also procure supplies.

5.	Blood donation and patterns of use in southeastern Nigeria	Emeribe (1993)	Nigeria	Economic hardships leading to low nutrition levels - important factor contributing to low donation levels. Another contributing factor was fear of testing positive for HIV.
6.	How well are hospitals preventing iatrogenic HIV? A study of the appropriateness of blood transfusions in three hospitals in the Ashanti region, Ghana	E O Addo-Yobo (1991)	Ghana	In absence of laboratory support - most transfusion decisions were based on subjective clinical findings alone.
7.	Changes in hospital component therapy in response to reduced availability of whole blood	Crowley J.P. (1987)	Rhode Island	Greater availability of components led to their increased use among clinicians previously unaccustomed to using them
8.	The specific hospital significantly affects red cell and component transfusion practice in coronary artery bypass graft surgery: a study of five hospitals	Surgenor D.M. (2002)	U.S.	Institutional differences, which 'through reasons of training or hierarchy, become ingrained in hospitals'

9.	Influence of knowledge and attitudes on the quality of physicians' transfusion Practice.	Salem – Schatz (1993)	U.S.	A negative association between knowledge and years of practice

(*v) Studies on Trends in Transfusion Practice*

Analysis of aggregate data at the national level shows that changing perceptions of clinicians about blood safety after the discovery of HIV resulted in changes in transfusion practices. It was found that the Surgeons rationed transfusions due to the perceived health risks, as a result of which transfusion in the US showed a downward trend (Atlas et al., 1994). Inappropriateness on both sides, i.e., over transfusion and under transfusion implies risk for patients and a waste of resources (Sazama, 2003).

Two studies show a change in pattern of transfusion practices with the discovery of AIDS virus (Atlas et al., 1994; Surgenor et al., 1988).

A study in four sets of US hospitals between 1980 and1985, showed an increase in total RBC use between 1980 and 1982, but that it remained constant between1982 and1985.In addition to these changes there was an increase in Autologous[5] blood use. This trend could be due to a response to the HIV epidemic, though such a conclusion to be definitive would require further support by larger national studies. These findings do however prove that new factors did enter transfusion practice at the time (Surgenor et al., 1988).

Another study conducted around the same period (1977-1989) documented blood use in elective surgery. It was found that total blood use decreased significantly while autologous blood use increased. A possible reason was that public anxiety about blood safety led to less demand from

[5] Autologous Transfusion: Autologous donations are made by individuals for their own use usually before a surgery. Blood is withdrawn and stored for transfusion back to the donor at a later date.

surgeons. It also showed that surgeons do alter practice in response to perceived health risks (Atlas et al., 1994).

Two other studies have described changing trends in transfusion practice in England for the same period (Ballard et al., 2007; Wallis et al., 2006). Though there were slight differences in the geographical area and methodology of the study (North of England and Oxford), the results were similar. Both studies found an increase in component use by medical specialties and a decrease in use by surgical specialties. The reason cited was an increase in the ageing population. They found that surgical use fell by 27.4 percent while medical use increased by 11.7 percent.

Shehata in 2014, conducted a study on changing trends in blood transfusion and found that there has been an increase in proportion of patients receiving RBCs and platelets while there has been a decrease in proportion of patients receiving plasma. The mean number of units transfused per admissions also decreased. Study also analyzed medical and surgical indications requiring blood transfusion and found that critical care and cardiology services accounted for highest mean number of RBC units utilized. None of the specialty showed a downward trend except internal medicine which showed a constant trend. Cardiac and vascular surgery showed more striking fluctuations with gradual rise of number of RBCs units transfused, whereas urology showed constant rates.

Singh R.K (2018) in a study on trends in transfusion practices in gynecology patients and found a decreasing trend of blood transfusion. He attributed this change to fear of transfusion related complications, better medical interventions and cost issues.

Conceptualization and Methodology

Study Rationale

Given that human blood is in limited supply and its use carries inherent risks to the recipient's health there is an urgent need to find a practical solution for the problem of irrational prescription of blood and blood products.

However, this problem should not be seen in isolation but should be seen within the context in which the prescribers operate. Transfusion decision making is a complex procedure. It is the

result of combined effects of, knowledge of transfusion guidelines among the prescribers, availability of facilities, availability of infrastructure, organizational factors, development of health services and the blood banking services, cultural-religious beliefs of the blood donors and socioeconomic context in which these services operate, to name some of them. Under these circumstances, what is 'rational' then depends upon the context of the prevailing conditions of the health services, the degree of health service development, the available resources, the epidemiology of blood borne diseases and the social context of the patients. Further these factors would be different for different settings, even when the evidence base is the same. For a better understanding, participation of end users i.e., the prescribers is essential as they are aware of the specific contextual issues.

This study has been conceptualized with an understanding that, transfusion decision making is complex and is dependent upon several factors. Just low knowledge levels among practitioners may not be the only reason that acts as a deterrent to adhering to guidelines. This study has attempted to situate the problem of blood and component prescription within the larger socioeconomic and cultural context, and conditions of resource constraints in which the clinician's practice in low-income countries. The overall aim of the study is to understand the factors that influence transfusion decision making under conditions of resource constraints, concerns for blood safety in this setting and initiate a discussion on what can be accepted as 'Rational' under these circumstances.

Study Objectives

a) To study the prevailing transfusion prescriptions practices and identify gaps therein,

b) To identify factors that influence transfusion decision-making in the context of low-income countries in a public hospital

c) To explore possibilities for promoting evidence based, 'Rational' blood use in the given circumstances.

d) To understand the Rationality of blood banking technology and resulting Policy implications.

It was decided to conduct the research in Delhi, in a public tertiary hospital which was purposively chosen for convenience because the researcher was employed in the same blood bank.

Blood Banks in Delhi

Delhi, being a metropolis and capital city of the country, has better facilities for treatment and has several tertiary care hospitals which cater to patients referred from other states as well. As these tertiary centres perform specialized surgeries and treat complicated cases blood transfusion is required on a large scale. There is a total of fifty-five blood banks in Delhi out of which sixteen percent are under central government, thirteen percent are under Delhi government, two percent under MCD, seven percent owned by NGO/trusts, fifty-six percent are private hospital based, five percent are private blood banks. Twenty blood banks are NACO supported (2015). The government or private blood banks are attached to hospitals and mostly supply blood and components to their respective hospitals. In addition to this there are Blood storage centres, at hospitals identified as the First Referral Units (FRUs) for Delhi state, the supply of which comes from the Regional centres to which they are attached. Ninety percent blood banks have component separation units and component preparation was approximately seventy four percent in Delhi (2015). It is mandatory to screen for five transfusion transmissible infections namely, HIV 1 and 2, Hepatitis B, Hepatitis C, Malaria and Syphilis. HIV seroprevalence in 2015 was 0.21 percent, HCV was 0.59 percent, HBV was 1.24 percent and syphilis was 0.23 percent among donors. (Preliminary report of assessment of NACO supported blood banks 2016)

Blood is sourced mostly from Replacement donors. Voluntary donors are gradually increasing. In the year 2015 voluntary collection was 53.2 percent of the total collection which was 308042 units.

The private hospital based blood banks and the NGO blood banks charge for blood and components which varies widely from one blood bank to the other over which there is no regulatory control of the government. The minimum price has been defined by the government but there is no upper ceiling. So the private blood banks charge exorbitantly in the name of quality. Supply of blood by the government blood banks to their patients is free of cost.

The World Bank aid to the government for AIDS control led to the setting up of NACO at the center, in the year 1992.The blood banking system received a major boost after a landmark judgment on 4th Jan 1997 by the Supreme Court, in response to a PIL filed by NGO 'Common Cause' vs. government of India. An important part of the directive of the court was to phase out the paid donors by the year end, i.e., December 1997 and up gradation of the blood banks, the conditions of which were sub-standard. A series of decisions were taken at the policy level which helped in the modernization of blood banks.

The Research Questions:

1. How has the blood banking system changed in the wake of AIDS control efforts in the 90's in Delhi?

2. What are the issues in the rational prescription of blood and blood products after changes in policy and introduction of component separation for blood components?

3. How does the present blood banking policy relate to the problems and issues identified and what are the implications for making blood banking safe in the Indian context?

Study Design and Methods of Data Collection and Analysis

This is an observational multiple method study designed to understand the nature of structural, operational, professional and social constraints affecting clinical transfusion practice. Such constraints, which are complex in nature, demand in-depth, qualitative and quantitative investigation, for their appreciation. Moreover, for the effective translation of research into practice, and to operationalize the findings, it is essential to understand the factors that operate at the ground level for which a 'bottom- up approach' i.e., the perspective of the treating clinicians is necessary (Mc Donald I.G. 2000).

The organization of the blood banking system in India with a focus on the blood banking services of Delhi and changes in them over the 1990s provides the backdrop to this study. The

blood banking system has been divided into three parts, i.e., sourcing of blood, the blood banking processes and blood use. The main focus of the study was on rational use of blood and components in a tertiary level public hospital in Delhi.

Data on Blood Banking Practices

Sourcing and Processing

For an understanding of the process of sourcing of blood, the study looked at the types of donation, (voluntary, replacement, paid), total annual requirement and collection, social characteristics of the donors, processes of screening of donors, important causes of deferral of donors, myths and misconception about blood donation etc.

The method of donor recruitment followed in the blood bank was studied in detail. The role of various personnel like, doctors, staff nurse, counsellor and technician involved in screening of donors was examined. The interactions of the donors with the blood bank personnel helped develop an understanding the perception of the donors regarding blood donation, and problems faced by them in arranging for Replacement donation.

The blood bank and its processes were studied as the background context for prescribing blood and components, blood economy, as well as quality of blood bank services. This involved an enquiry into the design of the premise, training of staff, equipment, inventory control, the minimum requirements for licensing, technological choices for safety, component preparation and storage, testing for transfusion transmitted diseases, quality control and regulations. Related data was retrieved from the blood bank records and government documents.

Data on Prescribing Practices and Their Rationale

A multi method study design was adopted to meet the objectives of the study and answer the research questions. Five types of primary data were collected.

(A) Retrospective analysis of request forms received at the blood bank over periods before and after changes in the blood bank occurred as part of the AIDS control measures

(B) Schedule based interview with 104 prescribers, for awareness and perceptions regarding blood transfusion

(C) Retrospective study of 80 cases of 'inappropriate' blood use by WHO guidelines

(D) Group discussion with the prescribers

(E) Cost of Blood Components

(A) Retrospective Analysis of Request Forms Received at the Blood Bank

A retrospective analysis of a 50 percent sample of Requisition forms received at the blood bank for the years 1997, 2000 and 2003 was undertaken to:

1) Study transfusion prescription practices, of the various departments of the hospital and variations across units within departments

2) Identify probable cases of inappropriate blood and component use and types of problems in the blood requisitioning and processing system,

3) Analyze trends in component prescription.

Rationale for selecting the years

Since blood safety guidelines were laid down by NACO in 1992, the year1997 was taken as the baseline, assuming that a period of five years would be sufficient for information regarding the blood safety guidelines, to reach the provider level and for its effects to be observed. The year 1997, was also an important year for blood safety in India, because of the landmark Supreme Court judgment and the directives issued for blood safety. Component separation was started at the study hospital in the year 2001, as part of the requirements of the blood safety program and also to cater to the newly established department of cardiothoracic vascular surgery. Therefore, the year immediately before the component separation unit was installed, i.e., 2000 and the year 2003, two years after component separation started, were included in the sample, to study the pattern of demands before and after the availability of components, in the hospital. A major

limitation to the study was that approximately 18 percent of the request forms were incompletely filled up. Therefore some data was missing.

Information from the Requisition Forms

Blood request forms are sent to the blood bank at least 24 hours before an elective surgery, whereas for emergency cases, are sent at short notice. There are two parts to the request form. The first part is filled up by the ward doctor and the second is filled up by the blood bank technician after the tests have been done.

Details of the patient, the hospital registration number, name, age, sex, date of admission, doctor in charge of the unit, diagnosis, ward, bed no, hemoglobin level, history of previous transfusion, the type and quantity of component required, date of transfusion, is included in the first part.

The second part deals with grouping and compatibility testing done at the blood bank i.e., the blood group, number of units tested, bag numbers and number of units issued.

A total number of 12 categories of information (Variables) that were relevant to the study were selected and entered in MS Excel worksheet.

Sample Size

A total number of 3188, 3845 and 4946, request forms for the years 1997, 2000, 2003, respectively, were included in the study, taking all the forms received every alternate month for each selected year. This covered the annual cycles of morbidity.

Data Analysis

A total of 12 categories of information that were relevant to the study were selected for analysis. The data extracted from the request form included, age, sex, hemoglobin value of the patient, diagnosis, specialty, unit, ward/bed, emergency or routine demands; blood group, type of component required, number of units required, number of units matched and number of units issued.

Patient identification number, age /sex, ward /bed number, was used to identify the patients. Name of departments helped to categorize the patients into different groups. The diagnosis

provided information on the need for transfusion and the type and quantity of the component. It also provided information on whether the case was posted for elective surgery or was an emergency. Hemoglobin of the patient gave an estimate of the number of units required. The other clinical parameters of the patient are not routinely available on the request form hence there was limited information in this regard.

The data was then coded, entered and validated. A data base was created in MS Excel worksheet and SPSS version 13 was used for analysis. Measures of central tendency and dispersion, was calculated for the mean value of hemoglobin at which requests were made, proportion of each component used, proportion of demands for various components by different specialties. Pearson's coefficient of correlation was estimated to see the association between demand and supply.

Analysis of the data helped identify the departments using the blood banking services the most, the common conditions for prescribing transfusions in the hospital and provided tentative insights into the possible forms of non-adherence to WHO guidelines.

(B) Interviews with 97 Prescribers for Levels of Awareness and Perceptions about Blood Prescribing Practices

Literature review and preliminary interactions with the prescribers led to developing a hypothesis about the factors influencing prescribing practices. It was hypothesized that the various factors influencing prescribing practices could be the following:

a) Knowledge of guidelines, i.e., about indications for transfusion
b) The perception of blood safety with respect to transfusion-transmitted infections and risk of transfusion reactions,
c) Problems faced in translating guidelines into practice, influence of the practice environment,
d) Availability of blood and blood products and the general functioning of the blood bank
e) Changes in cases or case management strategies over the years
f) Influence of socioeconomic background of the patients.

A schedule-based interview was conducted with ninety-seven clinicians for eliciting responses about,

1) The levels of knowledge of clinicians about blood /component use and safety

2) Problems faced in adhering to the WHO guidelines

3) Change in practice style in the wake of discovery of the AIDS virus.

4) Effect of socio-economic status of the patient in transfusion decision-making

5) Scope for optimizing blood and product use in the given circumstances.

Sample Size

Based on the analysis of the requisition forms, the departments commonly prescribing transfusions were identified. A list of doctors from the departments that used blood and blood components for treatment-Anesthesia, Medicine, General Surgery, Burn and Plastic Surgery, Paediatrics, Obstetrics and Gynecology and E.N.T. was drawn. Clinicians from those departments that did not use blood or components like, ophthalmology, psychiatry, radiology, dermatology, were excluded from the sample. The most important criteria for selection of the clinicians were that they should have been in practice for at least 5 years. This was done to ensure that they would be informed about the blood safety initiatives taken by the government of India and the resulting changes that took place in the blood transfusion services, subsequent to the discovery of the AIDS virus. The residents were not included because Transfusion medicine is not taught at the undergraduate level and they get their first exposure to transfusion practice only when they start their training in the hospitals. Further, they are less experienced and their practice is influenced to a large extent by the practice of their seniors.

This list consisted of a total of 156 senior doctors. From this list a random sample of 104 clinicians was drawn. Ten percent of the respondents approached did not consent to be a part of the study and so they were replaced by others from the same department in the list. A total of 97 out of the selected 104 clinicians participated in the study. Of these, 30 percent were surgeons, 24 percent were physicians, 19 percent were pediatricians, 16 percent were gynecologists and 11

percent were anesthetists. The remaining seven clinicians were not available for interview in spite of persistent reminders and they were not replaced. They were three physicians, two surgeons, and two anesthetists.

Administration of Questionnaire (or schedule)

A set of ten questions was asked to the clinicians. The questions of the schedule-based interview were framed on the basis of the understanding of the situation, literature review, and preliminary discussions with the users. For further refinement, the questionnaire was pilot tested on ten clinicians and changes were incorporated accordingly. A mutually convenient time was fixed with the clinicians and most of the interviews were held in their respective chambers. A few respondents offered to come to the researcher's chamber. A brief introduction of the study was given as a background to orient the clinicians about the research. The interview took approximately 10-15 minutes, on an average. The answers were noted down manually. Most of the questions were well understood, but one on the influence of social factors of decision-making needed clarifications. Some of the social factors that could affect transfusion practice had to be spelt out to most of the respondents as examples. Sometimes discussions ensued, which took up to half an hour. Time was a big constraint as the clinicians have a busy schedule and sometimes, the interview had to be rescheduled, because of this reason.

(C)Analysis of Case Series of 80 cases of 'Inappropriate' Blood Use

A total of 80 cases were identified as inappropriate for blood use based on WHO criteria. They provided the basis for discussion with the prescribing physicians on the following:

(1) Their rationale for prescribing the transfusions

(2) Problems faced by them in translating guidelines into actual practice from their perspective.

Methods

In order to understand the perspective of the treating clinicians, on the factors that influenced decision making regarding prescribing transfusion, a retrospective study of 80 cases, 20 each, from 4 categories of elective gynecological surgery, elective general surgery, anaemia and Acute

blood loss, that had received inappropriate transfusions in the years 2004-2006, was undertaken. The current cases were studied for better recall of events. The cases were categorized into the above four groups, depending on the basis of the patho-physiologic / hemodynamic differences for which blood or blood products are required. Assessment of appropriateness of the transfusions was made according to the WHO guidelines and inappropriate transfusions were identified from the records of the request forms received at the blood bank. Patients selected were all adults, extremes of age were avoided. Patients undergoing open heart surgeries, malignancy or suffering from complications or co morbidities were excluded from the study.

The inappropriately transfused cases were identified from the request forms and then case sheets were sought from the medical records department. The criteria used to identify these cases in line with WHO guidelines were as follows:

(a) Requests for Whole blood or packed cells Red Cells with hemoglobin between seven gm percent to ten gm percent.

(b) Request for FFP/platelets when dose was inappropriate or requested for conditions where transfusion was not indicated.

(c) Request for transfusion of Single units of whole blood or packed red cells for surgical cases.

The following details were recorded from the case notes:

1) Registration number,

2) Speciality

3) Unit in charge

4) Diagnosis

5) Presenting complaints

6) Duration of hospital stay

7) Date of surgery

8) Date of transfusions with relation to date of surgery or admission or availability of lab reports

9) Investigations especially preoperative /post-operative Hb values, Hb at the time of admission/discharge, special investigations like the platelet count and coagulation profile etc.

10) Type of surgery performed.

11) Any other documentation related to transfusion, like fall in Blood pressure, excessive blood loss, or any other complication leading to transfusion was noted.

With the help of the available data, the reason for inappropriateness or deviation from the guideline was established. Then questions based on these observations were posed to the treating physicians to understand their rationale for the transfusions.

The studies were classified into four categories.

1) Appeared to be rational on detailed scrutiny

2) Clearly irrational and found to have low awareness of guidelines

3) Differed from guidelines but had a reasonable justification

4) Differed from guidelines and difficult to judge as rational or irrational, as had elements of both (2) and (3)

Transfusions for Elective Surgical Cases

The preoperative hemoglobin level is an indication of the patients' general condition.

The patient is considered to be fit for anesthesia at hemoglobin level of ten gm percent. In such patients if the blood loss was less than 1000ml, no transfusion would be required because in normal patients the body has enough capacity to compensate for the loss. Going by guidelines such cases should be managed by transfusion of colloids or crystalloids alone. However red cell transfusion is required only if the loss was more than 1000ml.As proper assessment and documentation of intraoperative loss was not done; the post-operative hemoglobin level gave a rough estimate of the amount of blood lost during surgery. This was an important parameter for assessment of blood loss because the amount of blood lost during surgery was rarely documented on the case sheets. The hospital stay was also an indication of the condition of the patient in the post-operative period. Diagnosis was an important indicator of the amount of blood that could be

required for a particular type of surgery. Maximum Surgical Blood Order Schedule (MSBOS) was used to predict the anticipated blood loss and preparedness for transfusions for particular type of surgery. According to guidelines Preoperative transfusions to raise the hemoglobin should be avoided until there is excessive bleeding for which surgery was indicated immediately. Oral and parenteral hematinic should be used to raise the hemoglobin before and after surgery.

Transfusions for Medical Indications

The hemoglobin level is an important indicator for transfusion decision making though decision to transfuse should not be based on this cut off alone. A combination of clinical indicators and laboratory indicators are used to make a judgement. The platelet count and the coagulation profile are used similarly to decide for platelet and fresh frozen plasma transfusion. In cases when there was no active bleeding and the patient was not in congestive heart failure; transfusion should be avoided and anemia should be treated by oral and injectable hematinic.

Transfusions in Acute Blood Loss

Proper clinical monitoring is essential in cases of acute blood loss for an estimation of the

amount of blood loss. Clinical parameters like the pulse, blood pressure, give a fair

assessment of blood loss and the requirement of transfusion.

Questions based on observations were posed to the treating physicians to understand their rationale for the transfusions. The questions mostly related to the decision to transfuse when the hemoglobin was borderline, the component chosen, the number of units transfused in relation to the type of surgery or the hemoglobin level, the timing of transfusion in relation to admission and surgery- whether given in the preoperative, intra operative or post-operative period and also hemoglobin at the time of discharge was taken into account.

The results were analyzed, (a) to understand the prescriber’s rationale and (2) to identify the areas this required change or intervention to encourage good transfusion practice.

(D)Focus Group Discussion with Prescribing Clinicians

Focus Group discussions were conducted with the prescribers with the following objectives:

(1) To get feedback from the study group on the results of the previous two components of the study, especially on the problems identified.

(2) To reach a consensus among prescribers on what could be the best possible transfusion prescribing practice in the given circumstances.

(3) To identify changes required in the blood bank procedures.

(4) To identify areas that could be improved for good transfusion practice.

Sample Selection

The participants for the focus group discussion were taken from the departments of Surgery, Medicine, Obstetrics and Gynecology and Anesthesia consisting of eight-ten doctors in each group because they were the major users of blood and components. Some of the participants had earlier taken part in the schedule-based interview and were also the prescribers for these 80 cases.

The group consisted of consultants, residents and post graduate students. The decision to include the junior doctors in the group discussion was made because although they did not have much role in the decision making, it was they who carried out orders and were closely involved with patient management. Thus, it was the residents who actually faced problems at the ground level, both from the patients/ relative's side and the blood banking procedures.

The Process of Interview

A mutually suitable date was fixed in advance with the heads of the departments of the selected specialties. The group discussion was held in the office/chamber of the respective departmental heads. Important findings from the study conducted so far were presented as a power point presentation and comments were elicited from the respondents. The presentation took approximately thirty minutes. Discussion took approximately forty-five minutes to one hour and recorded on a voice recorder. Important points were also noted manually. Attempt was to make it

a participatory process where we were together looking at the appropriateness of the WHO Guidelines.

(F) Estimating Cost of Blood and Blood Components

Objective

The objective of the study was to estimate the cost of one unit of whole blood and each of the three components-red cells, platelets and fresh frozen plasma. Cost of providing a unit of whole blood and component was evaluated for the year 2008. The total collection for the year 2008 was 9586 units, with 49.5 percent of the collection being separated into components.

Methodology

The methodology used was based on the costing guidelines provided by W.H.O. and some adaptations were made to suit the situation and the study objectives. Separate estimates were made taking different health service conditions into consideration.

W.H.O. costing guidelines is based on the estimation of both direct cost and the indirect or hidden cost associated with the blood transfusion services. This is the total economic cost, which includes all resources including the 'societal cost' for example, including the cost of time the volunteers give for social work and receive no payment. In addition to these there are many other indirect or hidden costs like a large number of resources provided free of charge such as building, space, electricity and administrative support staff, by the hospital in which the blood bank is situated. These facilities may not be provided free for indefinite period. The activities of the blood bank were classified into four groups: 1. blood donor recruitment, 2.blood collection, 3.blood processing and 4.blood storage and distribution. The cost output measurable indicators were defined for each one. Then the capital and recurrent costs for each area was worked out (WHO Costing Guidelines 1998).

For this study, as the supply depended on replacement donors and blood was utilized within the hospital, only the cost of collection, processing and storage were included in the calculation.

The capital and recurring costs were enumerated separately. The cost of building and maintenance were not included in the capital cost as the blood bank was part of a tertiary care public hospital. The recurring expenditure included staff salaries, consumables and miscellaneous items. A list of consumables and their consumption, all the staff and their salaries, equipments in the blood bank, for the year 2008 were drawn up. The total collection was 9586 units, with approximately 50 percent of the collection separated into components. The total number of whole blood and component units that were issued was 16,790.

Calculation was based on the costing tools provided by the Blood Safety Unit of WHO (World Health Organization, 1998). The unit of output was the cost of a single unit of blood or blood component and it was assumed that all components had equivalent costs. Similarly, a large number of other resources that were provided by the hospital like, electricity and administrative support staff were not included in the costing exercise. Only the cost of equipment and their maintenance was included in the capital cost. Maintenance was calculated as 3 percent of the total equipment cost, annually.

Economic costs of equipment on an 'annualized' (cost per year) basis, was used to estimate the annual cost of equipment. It took into account the current value, useful life of the equipment, and a discount rate of 10 percent fixed by the World Bank, to calculate the annualization factor. Annualization factor of 3.791 was used for calculation (discount rate of 10 percent and average life of the equipment was taken as 5 years) from the chart provided in the WHO costing guidelines. The cost of the equipment divided by the annualization factor gave the Annual economic cost of the equipment.

The annual expenditure on salaries and consumables (recurrent cost) were then added to the annual economic capital cost and annual maintenance cost. The total annual expenditure was then divided by the total number of blood and components issued in the year 2008. This represented the 'investment' per unit of blood and components produced in the year. Calculations involving the cost of blood components assumed an equivalent cost for all components.

Analysis: Linking the Multiple Data Sets

Epidemiology and service demands cost effectiveness. Contextual issues are closely linked to this and must be considered for any policy prescriptions. We have tried to capture these aspects in a holistic manner with the methods adopted. The linkages across the findings of the five methods used were brought together in a systems framework to bring out the implications for:

(a) Use of guidelines and their appropriateness in different context

(b) Issues for consideration for rational blood use policy

(c) Issues in strengthening of processes of blood banking.

Limitations of the Study

Since prescribing practices were initially obtained from the blood/ blood product requisition forms sent by the prescribing clinicians, it was dependent on the quality of forms, 18 percent of the request forms were incompletely filled up. There was also sometimes improper or incomplete documentation in the case sheets.

Since this study has been conducted in a tertiary hospital in the public sector, the results could only be generalized to other public tertiary hospitals. However, it does provide information that can be useful in general policy formulation and operationalization.

Ethical Considerations

1. Patients were not involved in the study. Data on patients was abstracted from existing records. The possibility of inadvertent disclosure of personal information was minimized by maintaining confidentiality and no names or other personally identifying information was retrieved.

2. Due permission for the study of these documents was taken from the hospital authorities.

3. No biomedical intervention was used in the methodology.

4. Only those prescribing clinicians who were willing to participate were included in the study.

5. Focus group discussions held with the prescribers helped by getting their feedback and in adding to their awareness of blood safety issues.

CHAPTER-3

Blood Banking in Delhi: Contextualized within the Health Service System

India is divided into 28 states and 7 union territories with a total number of 640 districts (2011 census). As per the 2001 census, the total population of India was 1.027 billion persons, with a decennial growth rate of 21.34 percent. Of the total, 34.2 percent of the population was between 0-14 years of age, those above 60 years age group comprised 7.5 percent of the population and adults 15-59 years comprised 58 percent (Central Bureau of Health Intelligence 2010). The urban population was 27.8 percent of the total population with the vast majority in rural areas.

Health Service System of India

There is a mix of public and private health care in India. High-technology hospitals and diagnostic centres (both private and public) found largely in metropolitan cities on the one hand and village health guides, folk healers, faith healers and quacks (those who practice allopathic medicine without a formal degree) abound in urban and rural areas on the other. Between these two extremes there are district general hospitals (civil hospitals), private hospitals and nursing homes, 'trust' hospitals, general private practitioner clinics, government dispensaries and clinics (allopathic, ayurvedic and homeopathic), rural hospitals, primary health centres and sub-centres.

There were 1,45,894 sub centres, 23,391 PHCs and 4510 CHCs in India as on March 2009.

In the public sector, the number of rural hospitals are 6,795 with the number of beds being 1.5 lakh, urban hospitals are 3,748 with almost 4 lakh beds, thus the total hospitals are 12,760 and the total number of beds are 5, 76,793. Population per government hospital is 90,972 and population per government hospital bed is 2012 (Central Bureau of Health Intelligence 2010).

The Commercial Health Sector in India

The private health sector in India consists of the for-profit organizations with a dominant presence in all areas of health care. The diversity of the composition of the for-profit sector

ranges from registered, research and ‘charitable ‘institutions, corporate, standalone specialist services, diagnostic laboratories, pharmacy shops, unqualified providers. Individual practitioners from the various systems of medicine provide the bulk of medical care in this sector chiefly comprising sole practitioners or small nursing homes serving the urban and the semi urban areas, focused on curative services. In the rural areas a large group of providers are the informal providers-quacks (who practice allopathic medicine without a formal degree), bonesetters, traditional healers, traditional birth attendants etc. There is no uniform estimate or complete information on the extent of private sector in health care delivery. According to World Bank estimates, at independence private sector comprised only 8 percent of health care facilities which rose sharply to 93 percent of all hospitals, 64 percent of beds, 80-85 percent of doctors, 80 percent of outpatients and 57 percent of inpatients (World Bank report 2001).

The private sector is influenced by an interplay of complex factors like the nature of financing and payment systems, type of technology, regulatory framework etc. There is an absence of regulations governing location, standards, pricing etc. (Report of the national commission on macroeconomics and health 2005). The private health market was over Rs 71,000 crores and another Rs 31,000 crores if pharma industry was included. It was expected to double to Rs 1,56,000 crore by 2012, besides an additional Rs 39,000 crores if health insurance industry picked up CII- Mckinsey report in 2004. The hospital industry in India stood at Rs 4 lakh crore (US$ 61.79 billion) in FY17 and is expected to reach Rs 8, 60,000 crore (US$ 132.84 billion) by FY22 (Indian Healthcare Industry Analysis | IBEF, 2017).

Non-Governmental Not-for-Profit Sector

The not-for-profit, non-government sector is heterogeneous, with varying objectives, sizes and the areas they cater to. This sector consists of the NGOs, trust operated health service providers, faith-based health service providers etc. which are largely not-for-profit (India et al., 2005).

At all-India level, of all NGO’s working in primary health, 3.3 percent have hospitals as main health activity and 8 percent have OPD clinics (Das & Kumar, 2016).

Pattern of Health Care Utilization

According to NFHS-3 data, the private medical sector is the main source of health care for 70 percent of urban households and 63 percent of rural households. Wealthier households are less likely to use the public medical sector than household in the lower quintiles of the wealth index. The reasons cited for not utilizing public facilities, was poor quality of care (58 percent), lack of nearby facility (47percent) and long waiting time (25 percent) (Source of health care: NFHS-3). India ranks among the top 20 countries of the world in its private spending at 4.2 percent of the GDP. Employers pay for 9 percent of the spending on private care, health insurance 5-10 percent, and 82percent is from personal funds. As a result more than 40 percent of the patients have to borrow money or sell assets (Sengupta & Nundy, 2005). An increasing number report "non-treatment' due to financial constraints (NSSO 2010)

Blood Banks in India

Blood and blood component transfusion is an integral part of medical services and is a very specialized area with complex ethical and logistical issues related to its source of 'supply', banking and demand. Along with the growth of the private medical services the private blood banks have also flourished.

As per NACO Annual report 2009-10, there were 1,103 NACO supported Blood banks, 197 in the charitable sector,714 private hospital based and 648 commercial blood banks, including 130 Blood Component Separation Units (BCSU) and 10 Model Blood Banks. There were 31 districts that did not have blood banks. The total number of licensed Blood Banks in India was 2662 (Annual Report 2009-10). There were 440 blood storage centers that were operational and requirement of 3222 BSC's were identified in FRU during NACP –III.

The blood banks have been categorized by their ownership i.e., whether they are owned by the government, private organizations, trusts or voluntary nongovernmental organizations. The Blood storage centers (BSCs) at the First Referral Units (FRUs) were planned to ensure availability of blood chiefly for the obstetric cases with complications leading to hemorrhage in the far-flung areas. A total of 391 Blood storage centers (BSCs) have been established so far (2008). Equipment and manpower were provided by National Rural Health Mission (NRHM)

and the role of NACP (National Aids Control Program) was to provide training, operation and ensure transportation to BSCs (Blood Storage Centers).

History of Blood Banking in India

The blood banking system in India is highly fragmented, uncoordinated and under regulated, reflecting the condition of the general health services, of which it forms a small but important part. A few civilian blood banks were present before the Second World War, that were located in pathology departments of government hospitals. An organized effort to establish blood banks was made only in response to the needs of the Second World War. The first government blood bank was established at the All-India Institute of Public Health and Hygiene, Calcutta in February 1942. By August 1942 there were 15 centers in the following provinces-Bengal, Bombay, North West Frontier Province, Bihar, Delhi, Madras and Punjab. These comprised of Haffkine institute (Bombay), Lady Reading Hospital (Delhi), Peshawar-North west frontier province, Prince of Wales Medical College (Patna), Blood Bank Dhanbad (Bihar), Irwin Hospital (New Delhi), King Institute Guindy (Madras), Erskine hospital, (Madurai), Pasteur Institute (Conoor), King George's hospital (Vizagapatam), Lady Willingdon Hospital (Lahore) (Raina, 1955) (Combined Inter Services Historical Section-India and Pakistan).

Later several commercial blood banks opened to cater to the needs of the private nursing homes that were flourishing and coexisted along with the government blood banks. Between 1950 and 1970, almost 300 blood banks and five dry plasma plants were established (Bharucha, 1996). By the late 1980s, there were 1018 blood banks known to be operating of which 616 (60.51 percent) were unlicensed (including 528 -51.86 percent in the government sector), collecting about 1,950,000 units per year. Professional donors comprised 29 percent of all donors, 42 percent were replacement donors and 29 percent were volunteers. These findings were reported by Ferguson and company (1990) which conducted a study which was commissioned by Government of India to study the blood banking services in the wake of the discovery of AIDS (Makroo, 1993)

Until the effects of the AIDS virus on the blood transfusion services became known worldwide, i.e., till the mid-1980s, not much attention was given to the blood transfusion services in India. This sector saw major changes from the early 1990s partly by the grants received by the

government for the AIDS control programme and partly as a result of directions of the Supreme Court of India.

Evolution of the Blood Safety Programme

ICMR Task Force on AIDS

An ICMR task force on AIDS met in October 1985, with the objective to find out whether HIV infection had reached India and screening (sero surveillance) of high-risk groups was started. It was started as a collaborative effort of ICMR, DGHS and state health authorities at the National Institute of Virology (NIV) at Pune and the ICMR's Virology research Centre at Christian Medical College Vellore, by testing serum samples from female sex workers in Chennai and Mumbai. In six months ICMR established a network of 5 reference centers and 43 surveillance centers.

The first phase of the program began in October 1985 with the screening of 3027 people from high risk groups; 10 prostitutes were found to be infected with HIV. In April 1986, the first evidence of HIV infection was found among female sex workers in Madras. The 1st AIDS case was detected in May 1986 (Ramachandran, 2012). In May 1986, ICMR reviewed these findings and recommended that a national sero-surveillance program for screening high risk and vulnerable groups for HIV infection should be initiated.

That same year, ICMR moved on to phase II, surveillance which started in late 1986 and went up to October 1987. The objective was prevention and mode of transmission of HIV in India. Sero positivity was found to be higher among paid blood donors, patients attending STD clinics and female prostitutes. A national sero-surveillance and clinical surveillance was designed to gather information on prevalence and major modes of transmission. The 2nd phase, which ended on October 1987, screened a total of 53,907 persons. 135 HIV infected and 14 AIDS cases were reported, indicating a low rate of infection even among high risk groups.

Phase-3 sero surveillance began in November 1987 and ended on October 1988. The objective was to monitor trends in prevalence of HIV infection in high risk groups in different parts of the country. In the 3rd phase 1,09,632 individuals were screened and 387 sero positive and 11 AIDS

cases were detected. Screening of blood donors and antenatal mothers also started on a regular basis in this phase (Ramachandran, 2012) (Table-3.1).

Table 3.1 Sero Surveillance Program by ICMR

SN	Duration	Objective	No. Samples Screened	Sero Prevalence	AIDS Cases
1	Oct 1985	Screening of High Risk Groups-Female prostitutes	3,027	10	1
2	Dec 1986-Oct 1987	Prevalence and mode of transmission of HIV- paid blood donors, patients from STD clinics and Female prostitutes	53,907	135	14
3	Nov1987-Oct1988	Monitoring trends in Prevalence in High Risk Groups-whole country	1,09,632	387	11

Sero-surveillance program for HIV ICMR

(ICMR 1987 Anonymous. Sero-surveillance for HIV infection in India, ICMR Bull 1987; 17:111-9)

The National AIDS Control Program of India was launched in the year 1987. Between April 1989 and March 1990, the total numbers of samples screened by the 28 Zonal blood testing centres were 3, 52,470 and the number found positive by ELISA were 3613, a rate of 10.3 per 1000. This high sero-positivity rate among the donors prompted the government to screen all blood units for infection (Makroo et al., 1996). Between the years 1989 to1992, 138 blood banks, each generating 2000 units of blood per annum were provided financial assistance by the DGHS for modernization of blood banking service. Equipment for screening each blood unit for HIV

with the ELISA technique was provided, along with technical training of doctors and technicians.

At the international level, there was concern that although the spread through blood transfusion was only 6-10 percent of the total spread of HIV, the outcome of a contaminated blood transfusion was considered to be inevitably fatal. In the year 1988, a Global Blood Safety Initiative (GBSI), was constituted by WHO, to focus exclusively on the transfusion issue. GBSI focused on assessing the then prevailing situation in the world, planning, facilitation and implementation of safe and sustainable blood supply systems all over the world.

National Aids Control Organization

In India, a World Bank funded project started from 1992 and NACO was set up in the health ministry under a project director of the rank of Additional Secretary. Blood safety was a major thrust area in Phase -1 of the project and an integral part of the National AIDS Control Program. As a result of decisions taken at the policy and regulatory levels, several initiatives were taken in the blood banking sector, like modernization of blood banks, setting up of ZBTCs (Zonal Blood Testing Centres), CSUs (Component Separation Units) and training of doctors in 'Rational' blood and component use. The NACP received a soft loan of 84 million dollars from the World Bank for Phase -1 of the project (1992-1997), 39.72 percent (45,017 out of 113,329 crores) of the total budget for AIDS control went to blood safety (Project Performance Assessment Report, 2003 World Bank). At the end of this phase, 154 zonal blood testing centres were set up and 815 public sector and voluntary blood banks were strengthened by way of financial support, training and equipment.

The aim of the blood safety component of the Phase –II of the project (1999-2004) was to reduce blood borne transmission of HIV to less than 1 percent. The total project cost was estimated at US $ 229.8 million (Rs.1155 crores), out of which 23.58 percent (272.4 out of 1155.1crores) was earmarked for blood safety. At the end of Phase-II, transmission of HIV through blood transfusion reduced considerably- from 6.07 percent (1999), 2.07 percent (2004) to 1.44 percent (2005) as did HIV sero-reactivity among blood donors-0.41 percent (2004), 0.34 percent (2005). A total of 938 blood banks, (255 major blood banks and 683 district level blood banks) were

supported by NACO under the scheme of modernization in Phase-2. An additional 200 district level blood banks were supported during this phase. A 'National Blood Policy' was formulated in April 2002 and an 'Action Plan' worked out in 2003.

The National AIDS Control Program entered its third phase from the year 2007, with priorities shifting from prevention to treatment of the AIDS patients. The proportion allotted for blood safety for the financial year April 2007 to March 2008, was 8.58 percent (70 out of 815.50 crore rupees). From the start of the program in 1992 to 2015 the sero reactivity among blood donors has declined to 0.2 percent (NACO Annual Report 15-16). The fourth phase started from 2017.The allocation for blood safety was further reduced to approximately 8% (from NACO sources). However, funds for blood safety are also being released to the states from the National Health Mission in line with government policy.

The National Blood Policy and Action Plan

The aim of the National Blood Policy (NBP) of 2002 was to ensure accessible and adequate supply of safe and quality blood and components collected from voluntary, non-remunerative, regular, blood donors, free from TTIs, stored and transported in optimum conditions. To meet these aims, eight objectives were listed out and an action plan formulated in April 2003 to operationalize the NBP 2002 (Annexure-3).

The primary objective was to reorganize the existing BTS into a well-knit and centrally coordinated program for providing screened safe blood, when and where required, at reasonable cost; and to link vertically and horizontally all blood banks and blood testing centers with a mandate for quality assurance.' Action required to be taken to meet each objective of the NBP 2002 was clearly spelt out, with well-defined budgetary sources, licensing of blood banks, identifying officers responsible for carrying out the plans in a time bound manner.

The action plan has proposed a three-tier system; however, some operational aspects like transport of blood and components from the regional centers to the blood storage units, ensuring regular supply of electricity and basic facilities required for running the laboratory have not been clearly spelt out. Management of these centers would be difficult in remote and peripheral areas.

Table 3.2 State Wise Density of BTS by Population					
SN	**State**	**Population 2011(000)**	**Blood Banks November 2012 (CDSCO)**	**Banks per 1000 Population**	**NACO supported Blood Banks February 2012 (NACO)**
1	India		2,545		1,149
2	Andaman Nicobar Islands	3,79,944	3	0.007	2
3	Andhra Pradesh	8,46,65,533	286	0.003	114
4	Arunachal Pradesh	13,82,611	7	0.005	1
5	Assam	3,11,69,272	66	0.002	26
6	Bihar	10,38,04,637	67	0.006	47
7	Chandigarh	10,54,686	4	0.003	4
8	Chhatisgarh	2,55,40,196	45	0.001	15
9	Dadra and Nagar haveli	3,42,853	1	0.002	1
10	Daman and Diu	2,42,911	1	0.004	1
11	Delhi	1,67,53,235	63	0.003	20
12	Goa	14,57,723	4	0.002	3
13	Gujrat	6,03,83,628	152	0.002	75

14	Haryana	2,53,53,081	65	0.002	21
15	Himanchal Pradesh	68,56,509	20	0.002	14
16	Jammu and Kashmir	1,25,48,926	26	0.002	20
17	Jharkhand	3,29,66,238	45	0.001	24
18	Karnataka	6,11,30,704	170	0.002	65
19	Kerala	3,33,87,677	171	0.005	45
20	Lakshadweep	64,429	X	X	X
21	Madhya Pradesh	7,25,97,565	132	0.001	60
22	Maharashtra	11,23,72,972	289	**0.025**	45
23	Manipur	27,21,756	4	0.001	3
24	Meghalaya	29,64,007	6	0.002	5
25	Mizoram	10,91,014	10	0.009	10
26	Nagaland	19,80,602	5	0.002	8
27	Odisha	4,19,47,358	83	0.001	56
28	Puducherry	12,44,464	13	**0.010**	5
29	Punjab	2,77,04,236	99	0.003	46

30	Rajasthan	6,86,21,012	88	0.001	45
31	Sikkim	6,07,688	3	0.004	2
32	Tamil Nadu	7,21,38,958	277	0.003	94
33	Tripura	37,71,032	7	0.001	7
34	Uttar Pradesh	19,95,81,477	201	**0.010**	76
35	Uttarakhand	1,01,16,752	23	0.002	18
36	West Bengal	9,13,47,736	109	0.001	62

(Source: Census, NACO and CDSCO) in 2011-12

Blood Banking in Delhi: Contextualized within Delhi's Health System

Health Services of the Delhi State

Delhi, a metropolis with a large number of secondary and tertiary level hospitals, has a well-developed blood banking system.

Delhi is divided administratively into 9 districts, with a total area of 1483 sq km, out of which 62 percent comes under urban area, and 38 percent comes under rural area.

According to the 2011 census the total population of Delhi was 1.6 crores with a decennial growth rate of 21.1 percent. Out of the total population, 97.50 percent lived in the urban areas and 2.50 percent lived in the rural areas. The proportion of population between the age group of 0-14 years was 29 percent, 15-59 yrs was 65.3 percent and above the age of 60 years was 7.5 percent (SRS 2010).

In addition to its own, Delhi has to accommodate a migrant population and this group is increasing rapidly. In the year 2000, the increase in population over previous year was 4.78percent, out of which increase due to migrant population was, 2.41 percent. Ratio of natural increase vs. immigrants is 1:1.24.The migrants are mostly from UP, Bihar, Haryana, Uttaranchal, Punjab and West Bengal. It is difficult for the existing infrastructure to cope up with the existing and increasing population.

There are 588 large and small hospitals in Delhi of which 130 are government hospitals, with 32,188 beds of which 24,000 are in government sector (central bureau of health intelligence CBHI, 2010). This includes all beds in the hospitals dispensaries, PHCs, maternity homes, poly clinics etc. Bed population ratio per 1000 is 2.22. Population served per government hospital is 1, 34,016; population served per government hospital bed is 778 (Delhi govt website).

Manpower

The number of Allopathic doctors registered with the state medical council is almost 7 lakhs (2007), whereas the number of dental surgeons are 4 thousand (2007). Population per Allopathic doctor in Delhi is thus 3933(2003) and population per dental surgeon is 2,01,028 (CBHI 2010 www.cbhidghs.in).

Comparison of Morbidity Rates and Curative Services at the National level and Delhi

As per the 60th round of NSS , 2004 (on morbidity health care and condition of the aged in Delhi), proportion of persons reportedly ailing but not requiring hospitalization in Delhi was at 1.6 percent for rural and 1.7 percent for urban areas. The national average was 8.8 percent and 9.9 percent for rural and urban areas respectively. This could be due to a younger, healthier population, as the data on morbidity also suggests.

Morbidity Rates

The morbidity rate in Delhi was estimated as 1727 per 1 lakh population. Urban areas accounted for 93.65 percent of the total and rural areas accounted for only 6.35 percent of morbidity. Rate of hospitalisation per lakh population was 1559 cases in rural and 1683 in urban areas, which was much less than the national average of 2599 for rural and 3482 for urban areas, indicating a

relatively better health profile of the people of Delhi. Proportion of ailing persons was higher in the extremes of age i.e., among children and those 60 years and above.

Utilization of Public versus Private Hospitals

Share of government institutions in the treatment of hospitalized cases in Delhi was higher than the national average in both rural and urban areas. It was 46.35 percent in Delhi as against 41.7 percent at the all India level. Similarly in urban areas share of government hospitals of Delhi accounted for 58.75 percent as against only 38.2 percent at the national level.

Of the hospitalized cases in Delhi, heart ailments were 12.4 percent, accidents were 9.7 percent, unknown fevers were 9.5 percent, diarrhea / dysentery 8.3 percent and kidney related ailments were 6.1 percent. Other diagnosed ailments contributed to 15.5 percent of the total hospitalizations. The private hospitals provided free ward facility in only 2.61 percent of the total cases of hospitalization in Delhi.

Expenditure Incurred per Hospital Treatment in Delhi

The average amount spent per hospital treatment in Delhi was highest in the country. The average expenditure incurred for treatment per hospitalized case by people in the urban areas was Rs 8851 and Rs 5695 in the rural areas. There is a huge variation in the prices charged for similar services provided by the private sector with government prices being three times lower than the market prices.

Perception of Quality of Health Services

Among the lay people ‘Quality’ of health services is equated with sophisticated technology and good value for money and is perceived to be expensive. Quality is an issue for the public and private sectors, the public being poorly funded and the private cut costs to maximize profits.

Health care utilization patterns from the urban areas in the mid-1990s show that the private sector is preferred for minor ailments while the government sector is preferred for hospitalization, maternal services and surgery, especially for the lower-income groups (Nanda, 1993). Similarly, in the rural areas PHCs and hospitals are mostly preferred for prolonged ailments or severe ailments not cured by other sources by those from the low income group. Those with higher incomes preferred the private practitioners for 'quick relief' of ailments (Sood & Nagla, 1994).

History of the Blood Banking System of Delhi

The first blood bank of Delhi was established at Irwin Hospital in the year 1942.The first commercial blood bank of Delhi was started in the year 1949 by Dr. V. B. Lal, and was inaugurated by the then President of India Dr. Rajendra Prasad. The Red Cross Blood Bank was the only one in the voluntary sector established in 1962 with a grant of 2 lakhs from the health ministry. It collected blood from camps held in and around Delhi and supplied blood free of cost mainly to the government hospitals and nursing homes. Most of the other Delhi blood banks were established during the Chinese aggression in the year 1962.

According to an estimate, in the year 1987, 60 percent of Delhi's total blood requirement of 1,20,000 units was met by non-commercial blood banks belonging to both the public and voluntary sectors. The rest was supplied by commercial blood banks (Nanu, 1999). As a result of a better understanding of the epidemiology of the TTIs and as part of AIDS control efforts, there was a gradual increase in the replacement and voluntary donors and a decrease in paid donors. It can be seen from the data in that paid donors constituted about 40 percent of Delhi's blood supply in 1989 and were still 32 percent in the year 1993 (Table-3.3).

Table 3.3 Distribution of Blood Donor Categories in Delhi 1989-1993

Category	**1989** **Units (%)**	**1990** **Units (%)**	**1991** **Units (%)**	**1992** **Units (%)**	**1993** **Units (%)**

Voluntary	22276 (18.2)	33392 (20.4%)	34047 (19.2%)	40905 (21.53%)	47506 (23.75%)
Replacement	51824 (42.5%)	77079 (47%)	83659 (47%)	87409 (46.07%)	88750 (44.37%)
Professional	47924 (39.3%)	53400 (32.6%)	59977 (33.8%)	61508 (32.38%)	63747 (31.87%)
Total	1,22,024	1,63,871	1,77,683	1,89,903	2,00,003

(Source: Makroo et al Indian J.pathol.Microbiol. April 1996)

After the Supreme Court judgment of 1997, paid donation was banned and commercial blood banks were to be phased out. Few commercial blood banks that satisfied the regulatory norms (mainly depending on the available physical facilities) were given the license to continue. To fulfill the eligibility criteria and to comply with new regulations for license, two commercial blood banks changed their ownership into trust operated blood banks-e.g., Pusa Road Blood Bank (a commercial blood bank) changed to Blood Bank Organization (trust operated). Only one blood bank that could not fulfil the new requirements had to shut down after the judgment.

Screening of HIV Infection was made mandatory for every unit of blood collected for transfusion in Delhi, India since 1989. This was carried out at 10 Zonal Blood Testing Centers which tested donor units for HIV, for all the twenty-nine blood banks of Delhi. Data showed that the highest proportion were replacement donors at 45 percent, professional donor were 35 percent and voluntary only 20 percent. Analysis of trends for HIV showed that among voluntary donors the rates were 0.63, 0.45, 1.9, 3.03 and 3.87 per 1000 in 1989, 1990, 1991, 1992 and 1993, respectively. Among replacement donors, it was 0.46, 0.50, 1.9, 5.24 and 7.48, per 1000 respectively for the study years. Among professional donors, these rates were 1.50, 0.90, 1.3, 3.28 and 3.76, respectively. There was a significant increase in HIV infection among replacement donors. The authors were of the opinion that many professional donors donated discretely as replacement donors and were paid directly by the family of the patients. Based on these observations, they recommended that screening of blood units must be made mandatory (Makroo et al., 1996)(Table-3.4).

Table 3.4 HIV Sero-reactivity in Different Blood Donor Groups (1989-1993)										
Category	**1989**		**1990**		**1991**		**1992**		**1993**	
	No. Pos	**Rate %**	**No. Pos**	**Rate %**	**No Pos**	**Rate %**	**No. Pos**	**Rate %**	**No. Pos**	**Rate %**
Voluntary	14	0.06	15	0.04	65	0.19	124	0.30	184	0.38
Replacement	24	0.04	39	0.05	157	0.18	546	0.62	664	0.74
Professional	71	0.14	51	0.09	79	0.13	202	0.32	240	0.37
Total	109	0.08	105	0.06	301	0.16	872	0.45	1088	0.54

(Source: Makroo et al Indian J.pathol.Microbiol. April 1996)

Organizational Changes in Delhi after the Supreme Court Judgment

As on April 2008, Delhi had a total of 54 blood banks out of which, 20 (37.03 percent) were in the government sector, 4 (7.4 percent) were voluntary blood banks, 23 (42.59 percent) were private hospital based and 7 (12.96 percent) are stand-alone blood banks. Different categories of blood banks coexist with different types of funding, leading to disparity in pricing. The blood banks of Delhi are faced with the challenge of providing safe blood at an affordable cost

Like the condition of the blood banks in the rest of India, the services are fragmented, uncoordinated and by and large function in isolation. In an effort to organize the blood banks and facilitate access to safe blood near the point of utilization, in the year 2002, eight regional centres were established. They are located in the government hospitals or other non-commercial blood banks—All India Institute of Medical Sciences blood bank, Lok Nayak hospital blood bank, Guru Teg Bahadur hospital blood bank, Deen Dayal Upadhyay hospital blood bank, Hindu Rao hospital blood bank, Armed Forces Transfusion Centre, Indian Red Cross Society blood bank and Rotary blood bank. These blood banks are responsible for holding blood donation camps in

their respective regions and supply blood to the nursing homes situated in their areas. This arrangement facilitates formal networking between blood banks and blood storage centers of the region required to facilitate a two-way exchange of blood and components, quality assurance, problem solving and training. Besides these eight regional blood banks, other banks permitted to hold camps independently are Blood Bank Organization and Emergency Blood Bank, which are run by registered private trusts. User fees are charged for blood provided to the private nursing homes. However no payment is required for blood sharing between the government blood banks, but no organized system of blood sharing exists.

The Regional Blood Centre has the responsibility of collection and processing of blood units and screening them for transfusion transmitted infections, regular supply and a more equitable distribution of blood.

At the state level, the regulatory bodies responsible for policy formulation and providing licenses to the blood banks are the Drugs Control Department, State Blood Transfusion Council and the Delhi State AIDS Control Society. Multiplicity of regulatory authorities, with ill-defined scope and little coordination, has also led to the duplication of their roles. The role of the Drugs Controller is limited to issuing or suspending licenses of the blood banks, criteria based mainly on the physical parameters like infrastructure, manpower and proper maintenance of records. It has no mechanism to control quality issues and has no control on the amount charged by the private hospitals for blood and components. A minimum amount of Rs.650 had been proposed by NACO and fixed by State AIDS Control Society (SACS, 2003) as processing fees. But only the Regional blood transfusion centres under the Delhi government and the IRCS that receive government subsidy comply. The private hospitals charge exorbitantly, their rates depending upon the various types of tests performed in the name of quality, whether mandated by NACO or not. In the year 2007, the charges in Delhi's private blood banks ranged from Rs. 3000 to Rs. 5000 per unit. As per government guidelines only ELISA is mandatory for the three viral infections. Some hospitals also perform Nucleic Acid Testing (NAT) for viral infections increasing the cost of testing by approximately Rs. 1000 per unit. Similarly, if blood bags with integral filters are provided then an additional Rs.1500 is charged. This variability in cost has led to the services becoming more restricted in their coverage and isolated, with blood sharing between public and private sector nonexistent.

Donors the Backbone of the System: Source or the "Raw Material"

Blood is sourced from humans (donors) who are categorized into three- Voluntary, Replacement and Paid. In the developed countries, when the blood banks were established by the army, blood donations were made by service men and were voluntary in nature. It is only when the plasma fractionation industries were set up, that commercialization took place and a system of payment for donated plasma was introduced.

In Delhi, since inception i.e., year 1962, commercial and government blood banks depended chiefly on 'paid donors'. 'Replacement donors' i.e., family and friends of the patients who donated in times of need were few. By mid 80s, proportion of replacement donors increased.

The paid donors were engaged through the *'dalals'* or middlemen. There are several studies from the developing as well as developed countries that establish the fact that blood collected from voluntary donors has low rates of infectivity for transmissible infections as compared to the paid donors because the paid donors do not give correct history for fear of deferral (Bharucha et al., 1994; Garg et al., 2001; Patil et al., 1996; Satoskar & Ray, 1992; Singhvi et al., 1990).

The name 'paid donor' and 'professional donor' is used synonymously in India. The paid donors were earlier remunerated by the blood banks for their blood donation. Later when paid donation became illegal, these donors sold their blood discretely, brought by the patients' relatives as replacement donors. Studies on the demographic profile of the paid donors from developed countries show that they belong to the lower socio economic strata, with low levels of nutrition, where alcohol and drug abuse may be common (Beal & Van Aken, 1992). A study based in India also found that the paid donors were mostly heterosexual, promiscuous, males, unmarried and had donated blood frequently (Chattopadhya et al., 1991). However this interpretation has been critiqued as a biased approach due to social prejudices that ignore the other likely source of high infection rates, the 'occupational hazard' to 'professional blood donors'(Priya, 1994).

Payment for plasma donation was the norm in the West. In fact, the concept of paid donation came from this system which was common in the U.S. and also in Nicaragua and Haiti in the 1960s and 70s. "Trade in red gold" as it was called, earned a lot of criticism because of exploitation of the donors (Leikola, 1998). There were reports that the commercial plasma donors were infected by the unsterile equipment used for donation by the plasma fractionation

industry itself, in the early days of the epidemic (Navarro et al., 1988) (C et al., 1989). Similar incidents were reported from Pune in India as well as other countries, of the plasma donors getting infected by the Plasmapheresis machines (Navarro et al., 1988) (C et al., 1989). Irrespective of the source, high rates of infection among paid donors, led to a strong movement for promotion of voluntary donation in the developed countries.

In the U.S., at the Plasma fractionation centres, the collected Plasma is tested and treated using modern technology and quarantined for a period of 60 days to allow manufacturers to retrieve units from donors who subsequently test positive or are disqualified for other reasons. Regulations are stringent and strict compliance is ensured (Steinhardt, 1998).

Delhi's blood supply chiefly comes from Replacement donors i.e. blood donation by friends or family of the patient who requires a transfusion. Few professional donors posing as family members still donate in exchange for money.

Delhi is one of the low performing states in terms of voluntary donation, has increased marginally since the 1990s. A lot of government efforts are directed towards increasing voluntary, non-remunerated donors. Only the government and NGO blood banks are allowed to hold voluntary blood donation camps. Since the private blood banks are not allowed to participate in camps independently, this results in a high proportion of replacement donations.
There has been a gradual increase in the proportion of voluntary donors during the period between 2000 and 2018, from approximately 17 percent to 50 percent (Table-3.5).

Table 3.5 Annual Blood Collection Delhi (2000-2018)

Year	Voluntary	%	Replacement	%	Total
2000	37183	16.9	182389	83.1	219572
2001	42379	16.4	216042	83.6	258420

2002	63586	20.4	248322	79.6	311908
2003	59751	24.4	184856	75.6	244607
2004	58421	22.9	196421	77.1	254842
2005	71110	26	202132	74	273242
2006	84045	27.5	221395	72.5	305440
2007	206365	45.1	251549	54.9	457914
2008	157884	35.5	286396	64.5	444280
2009	228470	48.8	239481	51.2	467951
2010	270759	51	260316	49	531075
2011	263175	52.6	237260	47.4	500435
2012	285341	53.5	248097	46.5	533438
2013	251772	48.4	268347	51.6	520119
2014	244946	46.8	278426	53.2	523372
2015	260500	46.8	296337	53.2	556084
2016	247219	45.2	299771	54.8	546990
2017	252714	45.9	298162	54.1	550876

2018	287709	48.7	303339	51.3	591048

Delhi Annual Blood Collection (Source: DSACS-Unpublished Data)

Reasons for Low Voluntary Donation in Delhi

There are several interrelated factors that hinder people from coming forward to donate voluntarily. In addition to the myths and misconceptions towards blood donation, reasons like, policy, programmatic issues and regulations, honoring of voluntary donor cards, problems with the voluntary camps, counseling services and I.E.C for awareness are contributing factors.

Problems with Regulations

Low rates of voluntary donation is directly linked to the way the health service system functions in Delhi and several factors contribute to this phenomenon. In an effort to reduce the shortages, government has licensed new blood banks in the last few years. Some experts are of the opinion that strengthening the already existing blood banks backed with efforts to recruit voluntary donation, would have been a more appropriate step. The already existing regular voluntary donors shift from one blood bank to another, with more choice of centres, but without an actual increase in the voluntary donor base. In addition, processing charges have been levied by these newer blood banks as a mechanism for cost recovery. There is no uniformity in the charges and the rates are variable suggesting that the voluntary donation is being used by some for commercial gain.

The private hospital based blood banks, bill their patients depending upon the type of tests they conduct for screening and this aspect is largely unregulated. Some of the tests like chemiluminescence assay or NAT are very expensive but are not mandatory tests prescribed by NACO. The extra cost incurred by these tests is passed on to the patients.

Rotary blood bank, an NGO blood bank established in the year 2002, was permitted to charge for blood and components as a mechanism for cost recovery. Indian Red Cross Society which was not charging earlier also followed on these lines. Same was the case with the regional centres supplying to private nursing homes. Levying of 'processing charge' has led to confusion among the voluntary donors who feel cheated when they have to pay for blood in times of need and get discouraged for future voluntary donations.

There is a great deal of confusion over how donations can be increased. By increasing the number of blood banks, problems of financial sustainability has arisen, resulting in levying of processing charges, ensuing ethical questions, coupled with non-availability in times of need, thus eroding faith of the common man in the system of voluntary donation. Under these circumstances replacing blood for needy relatives i.e., Replacement donation, at least ensures availability.

Programmatic and Policy issues

The main emphasis of the blood safety program was on testing of donated blood. Very little was done in the first two phases of the AIDS control program, for raising awareness among the masses about the importance of voluntary donation. Experience from developed countries has shown that, to achieve the best results, a multi-pronged approach incorporating all the three aspects, namely collection of blood from regular, non-remunerative, voluntary donors, proper testing and rational blood use should complement each other and be done simultaneously. Though the understanding of the problem was holistic, action was compartmentalized. The policy of privation of health services has resulted in establishment of private blood banks, which charge for each unit of blood to meet testing and processing costs.

Voluntary Donor Cards

Voluntary blood donor cards are not honored by all the blood banks and come with a rider. Valid for one year, blood can be issued to only family members, in spite of the fact that it is very difficult to verify relationship of the donor and the patient. This system was started to curb 'selling' of voluntary donor cards by some donors, believed to be formerly 'paid donors' who have now shifted base and donate in camps or in the guise of relatives, for replacement. The

hospital-based blood banks that mostly depend on replacement donation for their supply find it very difficult to honour demands from other hospitals, on donor cards due to low stocks. Preference is given to patients admitted in their own hospitals. When voluntary cards are not honored due to shortages, their pursuit often ends in vain, leaving the donors disheartened and discouraged. *'Tab is card ka kya fayada. Jab diya tha tab ye nahi bataya gaya tha."*(What is the use of this card if we cannot get blood .This was not told at the time of donation). Hence people prefer to donate as replacement donors to help relatives in times of need. Non-availability acts as a deterrent for future voluntary donations. Thus a vicious cycle of non-availability, voluntary donors opting out, leading to more shortages, is created. Further, there is no coordination between blood banks with respect to blood sharing. A proper system of sharing of surplus blood and components could ease out the problem of voluntary donor cards to some extent.

Problems with Voluntary Donation Camps

Camps are a major source of getting blood from voluntary donors. However, lack of resources, lack of professional management, myths and misconceptions arising from cultural and social differences also form a barrier to voluntary and replacement blood donation.

Professionalism in conducting these camps has evolved over the years, but proper counseling facilities are lacking. The emphasis is more on the quantity of the collection rather than the quality of the donors (Bray et al., 2002).

Several different organizations with varied motives are involved in organizing these camps. Religious and political organizations play a big role in organizing camps. It has been observed that in some camps organized by religious organizations, it is difficult to dissuade the unfit donors from donating because the followers are emotionally charged and consider deferral as going against the wishes of their spiritual leader. Some religious leaders prescribe blood donation to their followers as the best way to atone for their sins (Copeman, 2009). Then the 'voluntary' nature of donations becomes questionable. Same concerns have been raised with camps that are organized by the political parties to please their political leaders and get publicity. A major disadvantage of holding camps as 'mega events' to commemorate special days is that a large number of units are collected on a single day, with its accompanying logistic problems. Sometimes up to 2000 units are collected on a single day and there is competition among the

various organizations to ‘beat’ each other’s’ records (Copeman, 2004)**.** In order to ensure a regular uninterrupted supply, such camps should be held at regular intervals and not sporadically.

Health care in India is delivered through a mix of public and private organizations with the private sector having a larger share. The health system of Delhi also reflects it and being a metro many tertiary care hospitals are concentrated here. The tertiary canters perform blood intensive procedures and have to be supported by blood banks and hence blood banks are established in the government, private and the charitable hospitals, the largest proportion being in the private sector. The blood banking system of Delhi is fragmented, uncoordinated with multiplicity of regulatory authorities leading to variability in its functioning. Nonetheless it has evolved over time after discovery of AIDS and the Supreme Court directives of January 1997.Voluntary donation is low and sourcing is mainly dependent on replacement donors, a major challenge specially for outstation patients. Blood sharing between blood banks of public and private sector does not exist due to financial implications thus increasing dependence on replacement donors. Component separation is ongoing in many blood banks which could be better utilized with a well-coordinated systematic effort of sharing between the blood banks. The blood banks are licensed and regulated by the DCGI, which are autonomous but work within the larger policy framework provided by NACO.

With this background we move to the next chapter that describes in depth, the functioning of the blood bank located in a tertiary public sector hospital in which the study was carried out.

CHAPTER-4

Profile of the Blood Bank in a Tertiary Hospital in Delhi

Delhi has three public hospitals under the central government's administration, Safdarjung Hospital, Lady Harding Medical College and Hospital and Dr. Ram Manohar Lohia Hospital. This study was undertaken at one of the three, the Dr. Ram Manohar Lohia Hospital. It is a not-for-profit super specialty hospital which provides both preventive and curative services to the people from and around Delhi, through its various specialty and super specialty departments.

The Study Setting

The Dr. R.M.L. Hospital, formerly known as Willingdon Hospital was established in 1932 by the British government. A 'nursing home' was established during the year 1933-35 out of donations from his Excellency Marchioner of Willingdon and hence the name. After independence it was transferred to the New Delhi Municipal Corporation (NDMC) and subsequently taken over by the central government in 1954. It has come a long way from a modest beginning of 50 beds in 1954 to a multi-specialty hospital with 1000 beds. It spreads over an area of 30 acres and is strategically located in the heart of the city in close proximity to president's estate, central secretariat and Connaught Place. In addition to the general wards it has a 50 bedded nursing home and a 25-bedded maternity nursing home. The nursing home has independent rooms meant chiefly for the Members of Parliament and senior government servants. However, depending upon availability, rooms are let out to non-entitled patients also at nominal charges. The hospital is funded by the central government and since 2008 become an institute for post graduate teaching offering courses in medical education and research. The degrees offered are MD, MS, DNB and MCH(Table-4.1).

Table 4.1 Hospital Data for the Three Study Years (1997, 2000 and 2003)				
SN		**1997**	**2000**	**2003**
1	Total Hospital beds	937	981	998
2	Actual sanctioned beds	800	800	800
3	Average length of stay	5.5	5.3	6.1
4	Total Bed occupancy rate (BOR)	71.5 %	65.1 %	67.3 %
5	BOR-Medicine &specialties	60.4 %	58.4 %	73.5 %
6	BOR-Surgery & specialties	77.8 %	62.1 %	87.0 %
7	BOR-Pediatrics & specialties	103.2 %	93.5 %	97.9 %
8	BOR-Gynecology &specialties	98.6 %	71.0 %	63.9 %
9	Total admission	40645	44932	47500
10	General wards admission	11,266	14,725	28,915
11	Emergency admission	25,831	26,352	47,500
12	Nursing home admission	1,747	1,933	1,589
13	Maternity Nursing Home admission	1,119	1,169	953
14	Total Hospital attendance	11,84,596	12,85,529	14,09,409
15	General OPD attendance	8,86,856	9,42,520	9,96,932
16	Special clinic attendance	1,39,519	1,93,599	2,22,630
17	Emergency attendance	1,58,221	1,49,410	1,69,016
18	Major operations	6,473	8,457	9,705
19	Minor operations	45,461	39,938	30,788
20	Total tests done in blood bank	1,42,931	1,74,860	2,95,067

Treatment Facilities Available

The hospital provides services in almost all major specialties and super specialties like Neurology, Neurosurgery, Cardio Thoracic Vascular Surgery (CTVS), Burns and Plastic

Surgery, Nephrology and Gastroenterology etc. It is a WHO recognized centre for DOTS therapy and Anti –retroviral therapy for AIDS. A trauma centre to cater to the trauma cases coming from the central Delhi area and a hospital waste management department have been established.

The hospital caters to an average daily OPD attendance of 5236 and annual patient admission of 60,568 supported by 1065 beds and managed by 2270 employees (2011).

All indoor patients are treated free of cost. For the outdoor patients consultation is free of cost. Whereas most of the basic investigations are free, 'user fee' has to be paid for some special investigations.

The hospital has a well-equipped blood bank with facilities for component separation comparable to the best standards available in Delhi. Blood and components are supplied free of cost against replacement donation.

Hospital Staff

The hospital staff comprises of the doctors, nurses, paramedical staff and other support staff.

Doctors

There are three cadres of doctors in the hospital, specialists, general duty medical officers and teaching faculty. In addition to these, there are the junior residents and the senior residents, who come as trainees for a period of 1 year and 3 years respectively and work under the guidance of the senior doctors. The junior doctors chiefly man the emergency services and wards. There are 201 regular doctors, 270 senior residents, 231 junior resident doctors and 298 postgraduate students in the hospital (2011).

The doctors working in the hospital are from Delhi and also other states in India. The selection of the doctors is done through the Union Public Service Commission. Delhi is preferred by doctors to other cities in India because it offers better opportunities and better salaries. The doctors are well qualified, experienced and most hold post graduate degrees. Training programs and regular Continuous Medical Education C.M.E.'s is organized to keep them updated with recent advancements in the field of medicine.

Each doctor attends to approximately 70-90 patients in the OPD, in a span of 4 hours.

Other Staff

The other personnel employed in the hospital are nurses, technicians, clerical staff and group D employees. There are 1065 nurses, 376 technicians and 687support staff (Group D employees). (2011 hospital data)

From the year 2003, some of the group D services like, cleaning, attending, porter service have been outsourced, with an additional 219 workers and 14 supervisors. The hospital security has also been outsourced to private security agency.

Social Characteristics of the Patients

Situated in the capital of the country, this is one of the largest public hospitals providing services free of cost to senior politicians and bureaucrats, central government employees and the general public. Majority of the patients coming for treatment are from Delhi and its neighboring rural areas, or other nearby states of Rajasthan, Haryana, Uttar Pradesh and as far off as Bihar and West Bengal etc. Most come to Delhi after having spent large sums of money in private clinics or have been referred to tertiary canters due to lack of facilities in their respective states.

The patients are aware of the free health care services provided by the government hospitals in Delhi therefore prefer Delhi for treatment. Some patients especially from UP and Bihar are helped by their local political leaders who facilitate their treatment and in turn depend on them for votes. This results in undue load on the already overburdened services compromising on quality of patient care.

The private sector hospitals of Delhi cater to the rich and upper middle class and also those who are covered by insurance schemes. Many government servants also prefer to get treatment from private hospitals because of the general perception that quality of services are better in the private hospitals than the government hospitals. Further, the CGHS permits its beneficiaries to be referred to the empaneled private hospitals.

Dr. R.M.L. hospital occupies a special position in the curative services of Delhi since it is one of the three hospitals funded by the central government, the other two being Safdarjung hospital and Sucheta Kriplani hospital (formerly known as Lady Hardinge medical college). Safdarjung has been a teaching hospital with post graduate teaching since last 30-40 years and undergraduate teaching since 10 years. Safdarjung hospital in addition to having a renowned

center for Orthopedic treatment also has specialized oncology department. Patients diagnosed with malignancy in Dr RMLH are referred to Safdarjung hospital for further management. Dr. RMLH has become a post graduate teaching hospital since 2008. Between the two hospitals, some purchases are made jointly and some independently. Rate contracts finalized for the purchase of equipments, drugs and consumables are applicable to both the hospitals.

Lady Harding Medical College now known as Sucheta Kriplani hospital, is located in close vicinity (2 kms) and caters to all specialties but mostly general Obstetrics and Gynecology patients. Dr. RMLH treats only those Obstetrics and Gynecology cases that are entitled for nursing home admission. Undergraduate students from Lady Harding Medical College come for clinical training to Dr RMLH.

In addition to the three central government hospitals in Delhi there is the All India Institute of Medical Sciences, the premier research and referral hospital in the country. All these hospitals have their own blood banks.

Profile of Blood Bank

The blood bank in the erstwhile 'Willingdon Hospital' was started on 21st October 1962 during the Indo China war to fulfill the urgent need for blood. Interviews with Shri Ganga Ram Bhatyal, the first blood bank technician employed since the founding of the blood bank, was conducted to obtain information on the early years of establishment of the department which was further supplemented by old blood bank records.

History

The major events of the blood bank at the study hospital can be divided into the following phases: 1962-75, 1976-86, 1987-1992, 1993-1997 and 1997 onwards

1962-1975: Since its inception in the year 1962, the blood bank was part of the department of pathology and was situated in the barracks adjacent to the main hospital building. Manpower was limited with four staff members-i.e., one doctor, 2 technicians and one safai karamchari, were initially posted in the department. A doctor of the general duty medical officer cadre always headed the blood bank, as pathologists considered it a low priority area. Later one pharmacist was appointed for making anticoagulant solutions and maintaining records. Only cross matching with patient's blood was done to check for compatibility. There was no screening for

transmissible diseases. Stock was low and the surplus blood was stored in domestic refrigerators. Dr. Karan Singh, the then health minister inaugurated the new building in January 1976.

1976-1986: Blood bank was shifted to the ground floor of the new X Ray block, which had facility for cold storage in the form of a specially constructed walk-in cold room. Anticoagulant solutions were still prepared in-house and glass bottles were used to collect and transfuse blood. In the year 1986, testing for hepatitis B virus was started, for which technicians received training from the Indian Red Cross Society. License was issued in 1982 by the Drug Controller. In this period paid donation was gradually phased out and replacement donation became the main source of supply. In the year 1986 there was just one paid donor mentioned in the hospital records. It is noteworthy that this step was taken much earlier than the Supreme Court directive of 1997.

1987-1992: This period witnessed important changes in terms of testing for transmissible diseases. Testing for malaria parasite and syphilis was introduced from March 1987.

Donor blood screening for hepatitis B, syphilis and malaria was made more stringent and screening for HIV was initiated. Donor blood samples were initially sent to NICD (National Institute of Communicable Diseases) and later to IRCS blood bank for serological testing for HIV. During this period doctors and technicians were trained in serological testing by ELISA by NICD (National Institute of Communicable Diseases).

1993-1997: The hospital received support in the form of manpower, equipments and funds from NACO for testing for transfusion transmissible infections. The hospital blood bank was given the status of Zonal Blood Testing Centre (ZBTC) and serological testing for HIV by ELISA was started. Two other private blood banks were attached to the hospital for the purpose of testing of donated units for HIV.

1997-onwards: In the year 2000, component separation unit was installed in the hospital blood bank. Funds, manpower and equipments were provided specially for this activity by NACO. In the same year hepatitis C screening was started in addition to HIV and Hepatitis B.

Sourcing of Blood: Donor Selection, Bleeding and Post Donation Care

Since 1987, blood was predominantly sourced from replacement donors. More than 90percent were Replacement donors, only 2-6 percent were voluntary donors. Some paid donors also managed to sneak in as relatives, estimated by on the staff's experience and judgment to be approximately 2 percent to 8 percent of the total collection.

Initially all the blood supply came from 'paid donors', brought in by middlemen or *"dalals"* who worked for a commission. The amount paid to these professional donors was Rs. 15 for each unit with positive blood groups and Rs. 50 for units of blood belonging to the negative groups. Payments were taken from the relatives and passed on to the donors in the blood bank itself. Later a centralized system of payment by the hospital accounts department was started. These donors belonged to the extremely poor sections of the society, were rickshaw pullers , daily wagers or beggars. After the blood bank shifted to the present facility, the system of paid donation was gradually phased out and shortages were made up with blood sourced from voluntary donation camps organized by the Indian Red Cross Society. Although records continued to have a column for paid donors, blood bank records show that by the year 1987, the system of sourcing blood from the paid donors had been stopped and shifted to voluntary and replacement donation. It was only after the Supreme Court judgment of 1997 that this heading was deleted from the records (Table 4.2).

Table 4.2 Breakup of Donors (1984-1987)

Year	**Paid Donor**	**Replacement Donor**	**Voluntary Donor**
1984	95	2050	46
1985	18	2745	60
1986	1	3335	44

1987	NIL	3533	45

Source: Data retrieved from old records

In Delhi and other cities across India, the Indian Red Cross Society (IRCS) has done pioneering work in the field of voluntary donation. The IRCS provides blood to all major hospitals and nursing homes. Dr. R.M.L. hospital also depends on the IRCS in times of shortage. Earlier a team consisting of doctors, technicians and paramedical staff from the hospital assisted in camps organized by the Indian Red Cross Society (IRCS), but now hold camps independently.

The replacement donors are sent to the blood bank by the treating clinicians. Usually a request for bleeding the donors with the number of units of blood required for a particular case is sent along with the prospective donors.

Once blood is donated the donor is given a card carrying the name of the patient and the name of the unit head. This card is then deposited at the time of issue of blood units for the patient. One card is meant for issue of one unit of any of the four components and is valid for a period of one year for the same patient only. Many patients who come for treatment to the hospital are referred from nearby areas and are accompanied by only one or two attendants. In such cases, when several units are required, or when the patient's attendants are found to be unfit for donation, the blood bank provides blood without replacement. Whenever maintaining a balance between supply and demand becomes difficult, the deficit is made up by holding camps or borrowing surplus blood units from other government blood banks.

The blood bank also supports patients admitted with chronic diseases and cannot arrange multiple donors. Most VIP's also manage to get away without having to make replacement donation especially when they are admitted in the nursing home.

Since treatment is provided free of cost in the study hospital, most of the patients who come for treatment, belong to the low socioeconomic strata. Some patients also belong to the middle income group and it has been observed that their relatives and friends are more forthcoming as replacement donors. Among the migrant laborers it is seen that the friends and relatives from their village come forward to donate. In case of the well-to-do sections, it is seen that their

personal staff are brought as replacement donors for their family members. It has also been observed that employers rarely come forward to donate for their workers or staff; instead they are ready to give monetary support for treatment. Most of the donors are males only 2-5 percent are females. In the year 2004, out of the total donors at the study hospital, 95.15percent were males and 4.8 percent were female donors. The age group of the donors is generally between 25-40 years.

Screening of Donors: Reasons for Donor Deferral

A donor questionnaire for donor selection and deferral has been framed by the DSACS and is more or less uniformly followed all over Delhi. The prospective donors fill up the form, are counseled and then sent to the doctor for clinical assessment. Those found medically fit for donation, are bled. Approximately 15-20 percent of the donors are deferred and out of these the most common reason for deferral is anaemia. The other important reasons for deferral are, allergy/rashes at the phlebotomy site, fever, ongoing medication, any infection/septic foci in the body, major illnesses like asthma and diabetes or a past history of being on anticonvulsant therapy. For some conditions the donor is deferred for a small period of time after which he can donate, while for others lifelong deferral is indicated. It is commonly seen that donors who do not want to donate blood feign illness. On the other extreme, some donors conceal facts, especially when the life of a near and dear one is at stake. Most of the surgical departments do not admit patients for elective surgery until the required numbers of cards are not shown to them in advance. Only the urgent cases are taken up without donation after telephonic requests to the blood bank. Some of such units issued are replaced later on. The medicine department on the other hand is not as rigid and proactive about replacements in critical patients requiring transfusion as a lifesaving intervention and want immediate release.

Until 2007, there was no counselor posted in the blood bank, so the doctor doubled up as counselor for which they received no special training. Counseling skills were self-taught and the focus was on eliminating those donors who could have a high risk of carrying transmissible infections and also those impersonating as relatives.

Efforts for Weeding Out of Paid Donors

Careful selection of donors is important for the benefit of both the donor and the recipient. An important job of the doctor is to verify the relationship of the donor with the patient. This is done to keep a check on the paid/professional donors who come in the guise of relatives. It is difficult to identify them even after rigorous questioning. This is a very cumbersome process and the most difficult part of donor screening.

After the Supreme Court ban on professional donors it became important to ensure that no exchange of money has taken place, between the patient and the donors. Amount charged by the paid donors ranges between Rs. 500 to Rs 3000 or more. Often these donors are able to trick the doctor in spite of detailed verification but sometimes they get identified. The behavior of such donors is suspicious. They may be either very aggressive, pose to be very confident or very scared when questioned. Multiple prick marks on the *cubital fossa* (area of the forearm where the needle is inserted) help in identifying those who donate repeatedly. These donors generally move in groups from one hospital to another. The system runs with the help of touts. These touts or middle men befriend the hospital staff or the shop keepers outside the hospital and operate from there. When it is established beyond doubt that the donor has taken money, a written complaint is made and he is handed over to the hospital police for taking appropriate action. Once a paid donor is 'caught' word spreads among the members and the gang shifts to another hospital, but they still manage to operate discretely.

Role of Clinicians in Motivating Replacement Donors

Motivating the relatives of the patients to donate blood, is the responsibility of the treating clinicians as the blood bank staff does not come in direct contact with the patient's relatives at this stage. Blood for elective surgeries have to be arranged in advance. Unwilling relatives are sometimes coerced to donate blood for their patients. Many times the surgery is postponed if the donations have not been made and the cards have not been collected from the blood bank, a problem mostly faced by outstation patients. In emergency situations when no suitable donors are found blood is released after a written or verbal request is made by the clinicians. Few replacements are made after surgery, which also depends upon the persistence of the treating

doctors. Another major factor which comes in the way of donor recruitment is that the clinicians lack counselling skills, are busy and do not have enough time to spend on coaxing and convincing the relatives. Every month each department is informed about the number of units issued and the number replaced. This information encourages them to motivate donors and maintain a balance between demand and supply. However, efforts to counsel the donors to convert them into a regular, repeat, voluntary donor are difficult because of time constraints (Table-4.3).

Table 4.3 Blood Donation Trends at Dr. RMLH Blood Bank: 1995-2006

SN	Year	Replacement Donor%	Voluntary Donor%	Three Year Moving Average%	Units collected	Units Issued
1	1995	99	0.99	1.84	5067	7306
2	1996	97.1	2.89	2.15	5697	8919
3	1997	98.56	1.64	4.33	4736	6612
4	1998	98.07	1.93	5.60	4647	6037
5	1999*	90.57	9.42	6.01	5611	6678
6	2000	94.54	5.45	3.70	5833	7192
7	2001	96.83	3.16	2.38	6706	10009
8	2002	97.48	2.51	2.07	7356	11602
9	2003	98.52	1.47	7.17	7923	11366
10	2004	94.14	2.23	8.04	7468	13599

11	2005**	82.16	17.83	10.94	6769	11399
12	2006	95.93	4.06	-	6929	12575

*Note-High proportion of voluntary donation *Kargil war (1999) and **Delhi serial bomb blasts (2005)*

Motivations to Donate Voluntarily

The attitudes and beliefs of the donors towards blood donation appear to be moulded by diverse factors, ranging from the socio-cultural environment, religious beliefs, their experiences with blood banks and the health service system. Within India too there is wide variation in the proportion of voluntary donors between states, the reasons for which are not clearly known. On the one extreme people hesitate to donate even for an ailing relative and on the other, highly motivated 'regular voluntary donors' get offended when temporarily deferred due to health reasons. Most voluntary donors donate at camps and some have fixed centres of their choice. They are usually males, educated and from middle class backgrounds.

Interaction with the blood donors and their relatives has helped understand the perceptions about blood donation among the community. The most common reason for voluntary blood donation is altruism and a sense of pride from helping someone in times of need.

The reasons for motivation among volunteers are varied:

-Many Donors feel that by donating for the needy they are fulfilling their duty towards the society.

-Sometimes a sick family member, who was saved by blood transfusion, is a source of inspiration.

-some have been motivated by a family or friend who is a regular voluntary donor.

-Few come to donate while visiting an ailing friend or relative in the hospital, or sometimes while passing by the blood bank.

-Many donate on a day special to them, like their own birthday or that of a loved one, or their wedding anniversary.

-A unique behavior among the masses is seen in times of national calamities, or in war or terror attacks, when many donors come forward in large numbers. This behavior is a global phenomenon, was seen recently in the 9/11 attacks on the world trade centre in the U.S. and has also been experienced during the Kargil war in 1999 and bomb attacks in Delhi in the year 2005.

The case of a well-educated male aged 24 years, from a middle class family, illustrates the common pattern. It also illustrates that trust in safe procedures can bring them back as repeat regular donors. A third time donor, he started donating at the age of 19, got motivation from media messages. He wanted to contribute to the society in this manner. He said that he chose this centre for the clean environment and faith that the needles used are sterile and not recycled. Also proximity to his residence was another factor that he chose this centre.

Some others donate because they believe that blood donation would keep them healthy and donating regularly replaces old blood with new. Overweight people donate, as they think that body weight is shed by donating blood.

There were instances of young adults generally in the age group of 18-30 years who came as voluntary donors to get their blood tested for HIV status. On enquiring, it was found that testing at blood bank was devoid of stigma that was attached to the HIV testing centre.

Reasons for not Donating: Basis of these Beliefs

Several myths and misconceptions about blood donation are prevalent in India. The chief one is that blood donation causes weakness, decreases libido and is harmful for one's health.

-A labourer-rickshaw puller believes that he does not have enough blood in his body, as he is undernourished and underweight. The blood in the body gets burnt off as sweat when he pulls the rickshaw that involves heavy physical activity. He could fall sick or even die if he donated.

Another common reason is related to gender equations in the Indian society. It is often seen that husbands hesitate to donate for their wives, but when the husband is in danger the wife come forward immediately.

An interesting case came to our notice where the mother in law objected to the son donating for his wife, because his blood when transfused to the daughter in law would make them siblings! Hence, her brother should donate instead.

-*Wife does not want her husband to donate because she believes he requires more blood in his body for hard work, whereas because she does light, house hold work, blood donation would not harm her.*

An important issue related to class disparities is commonly observed when the poor are

unable to 'manage', in times of need. This class also get deferred more often than the

upper class for reasons of being underweight or anaemic.

As correctly analyzed by a prescribing doctor, the poor who have no money or clout to get blood without donation are the ones who are forced to donate and those who can arrange for donors and have 'connections' often get away without replacing for their patient.

Biomedical Criteria for Donor Selection

Hemoglobin

The most common cause of deferral of donors is anemia. The minimum cut off hemoglobin for donors is 12.5 percent, important to safeguard the donors' health, especially for those who are regular voluntary donors, but a scientific rationale for fixing the cut off for hemoglobin at 12.5gm percent in the Indian context is lacking. It neither specifies a sampling method or test method nor provides for differences depending on gender or altitude. In view of widespread prevalence of anemia even in the apparently healthy population in India (National Family Health Survey 2003, National Nutrition Monitoring Bureau, 2010) studies are required to determine the acceptable lower limit of hemoglobin for the donors. The cut off value is based on western standards, where the normal values for hemoglobin is much higher than that of average Indians. Some experts have suggested a lower hemoglobin standard for women because the normal range

for women is below 12.5 gm percent. Anemia was found to be present in 55 percent women and 24 percent of men. The mean hemoglobin level among adult men and non-pregnant non lactating women (>20 years) were below the cut-off points suggested by WHO to diagnose anemia. About 55 percent of adult men and 75 percent of women were found anemic, National Nutrition Monitoring Bureau (NNMB 2010).

A study based in India among donors found that the average drop in hemoglobin on the 8th post donation day is only 0.55gm percent and average fall in hematocrit was 2.025 percent and concluded that 450 ml loss of blood from a healthy adult had a negligible effect on donors' hemoglobin, but is definitely a cause of concern in repeat blood donors (Cable et al., 2011). If the minimum criteria for donor hemoglobin level is not adhered to transfusion would fail to bring about the desired result in the recipient. One unit of red cell transfusion increases the hemoglobin levels in the recipient by 1gm percent, but if the content of hemoglobin in the transfused blood is low this rise cannot be affected by transfusion of one unit. Hemoglobin levels have been found to fall in stored blood too. A study by Saini in 2015, based in northern India found that a decrease in hemoglobin and hematocrit was observed in stored blood even under standard storage conditions (Saini et al., 2015).

To adjust for sex differences the accepted levels of hemoglobin for donors have been changed to 12.5 percent for males and 12.0 percent for females, in the USA (Walker, 1990). In the U.K., cut off for males are 13.5 gm percent and for females is 12.5 gm percent (Klein & Anstee, 2014). In India, the cut off hemoglobin value of 12.5 gm percent has been fixed for males as well as female donors, a level that very few females can achieve. NFHS -3 India 2005-2006 data, shows that 55 percent of women in the age group of 15-49 years are anemic and 24 percent of men in the age group of 15- 49 years are anemic and low hemoglobin levels are an important cause of donor deferrals in India. A study among donors of Bombay found that low hemoglobin was the cause of deferral among 61 percent of the females deferred for blood donation (Malhotra et al., 2004). In RMLH blood bank 40 percent of all donors were found to be anemic.

Body Weight

The next most important criteria for donor selection are weight. For separation of blood into components, 450 ml of blood is collected from the donors, for which a minimum weight of 60 kgs is required. From those donors, who are between 45kgs and 60 kgs, 350 ml of blood is drawn from which two components can be made using a double bag, packed cells and protein rich plasma. In our study we found that 15 percent of donors were rejected for being underweight.

Data collected by National Family Health Survey round 3 (2005-2006) on nutritional status of adults, shows that more than one third of all adults are too thin and more than 10 percent are overweight and obese. Thirty six percent of adult women were found to be thin. Thirty six percent of women and 34 percent of men had BMI below normal.

As per National Nutrition Monitoring Bureau (2006) rural survey, at the aggregate level about 33 percent of the males and 36 percent of females had chronic energy deficiency with a BMI of less than 18.5.

As anemia and malnutrition is highly prevalent and a large proportion of the donors are from the lower socio-economic sections, few donors fulfil the laid down criteria. Under these circumstances the desired target of 80 percent of the total collection to be separated into components, is difficult to achieve.

Phlebotomy: Bleeding of Donors

Blood donation is taken from 9 am in the morning to 8 pm in the evening. In the night shift bleeding of donors is avoided routinely because there is no doctor posted for night duty. In an urgent scenario, when it is essential to bleed a donor, the ward doctor on duty examines the donor for fitness and the night duty technician bleeds the donor.

Bleeding the donor is done by the doctors or nurses posted in the bleeding room. The amount of blood to be drawn, 350 or 450 ml is decided according to the donor's weight. If the weight exceeds 60 kilograms then 450 ml is drawn either into a triple bag or a quadruple bag, which is then separated into components. The decision on the number of bags that has to be collected for making component**s** depends upon the time of donation and the requirement from the user departments. On an average 15-20 bags are taken daily for separation into components.

The donation procedure normally takes about 10 minutes. After donation, the donor is given refreshments and is kept under observation for a period of at least half an hour. He is given advice on care to be taken in the next 24 hours. In case any adverse donor reaction occurs, the procedure is stopped immediately and the donor is given supportive treatment. Donor cards are issued to the donors after donation is made which has to be deposited at the time of issue.

Upgraded Manpower and Training

Since 1989, the blood bank at the study hospital was manned by two medical officers, two senior residents,16 technicians, three nurses, a pharmacist cum store keeper, a clerk, 5 lab attendants, a safai karamchari and a driver. Out of the 16 technicians, three were on the pay rolls of DSACS and were employed on contract basis. The permanent staff of the blood bank was employed by the hospital. Such support from NACO still continues.

Earlier the blood bank technicians were not formally trained in blood banking but were trained on the job by the senior technicians. To start with, the procedures were simple and done manually with minimal automation. However, over the years there has been an increase in complexity of testing methods and newer technologies were introduced. Training on the new machines is imparted by suppliers of those machines. When HIV testing was initiated in 1992, one doctor and a senior technician were trained by NICD (National Institute of Communicable Diseases) for serological testing of HIV by the ELISA technique. Since 2007, on the initiative of the State AIDS Control Society, efforts are being made to formally train all blood bank doctors, technicians and staff nurses periodically. For this purpose, NACO has identified some centers all over India. Dr. RML hospital has been identified as a center for the training of blood bank staff of the states of Delhi and Uttaranchal. Since 2007 these training programs have been conducted on a yearly basis for a three-week period-one week each for the doctors, technicians and the staff nurses. The facilitators are drawn from the various blood banks of Delhi. The curriculum involves all aspects of blood banking. The lectures include topics such as, donor selection and care, management of adverse donor reactions, blood grouping and compatibility testing, trouble shooting, TTI testing, component preparation and Apheresis, rational blood use, equipment maintenance and calibration. Lectures are taken in the pre- lunch session and hands on training and demonstration in the post- lunch session. Documentation including making of SOPs, is being given a lot of emphasis as part of quality requirements.

Few CMEs on rational blood use were funded and organized by the DSACS for the clinicians of Delhi.

Processing and Storage of Blood

Initially only three tests were performed in the blood bank- Blood Grouping, Cross matching, and Coomb's testing for detection of antibodies in the patient. Centralized testing for HIV was started in the year 1989 at two government identified centers-the NICD and IRCS. In 1992, as part of the modernization program, the RML blood bank was given the status of ZBTC (Zonal Blood Testing Centre). Thereafter, screening equipments were provided by NACO and doctors and technicians were trained in ELISA testing for HIV. Three private blood banks were attached to this center for testing of the samples. The reports of HIV screening were collected by the respective blood banks on the following day. Gradually this system was phased out as all the blood banks of Delhi were equipped for HIV testing in their own blood banks. In addition to testing of donors, the blood bank also tested for the patients suspected with HIV. Later on testing for hospital patients was taken over by the department of Microbiology.

Since 2002, the donated unit primarily undergoes three main types of processes, before being issued to the patient. They are as follows: (i) testing for TTIs, (ii) separation of one unit into three/four components and their proper storage, (iii) and testing for blood group and for compatibility with the recipient's blood. Standard Operating Procedures for each of these activities are in place and followed by each blood bank. Documentation is a very important part of licensing.

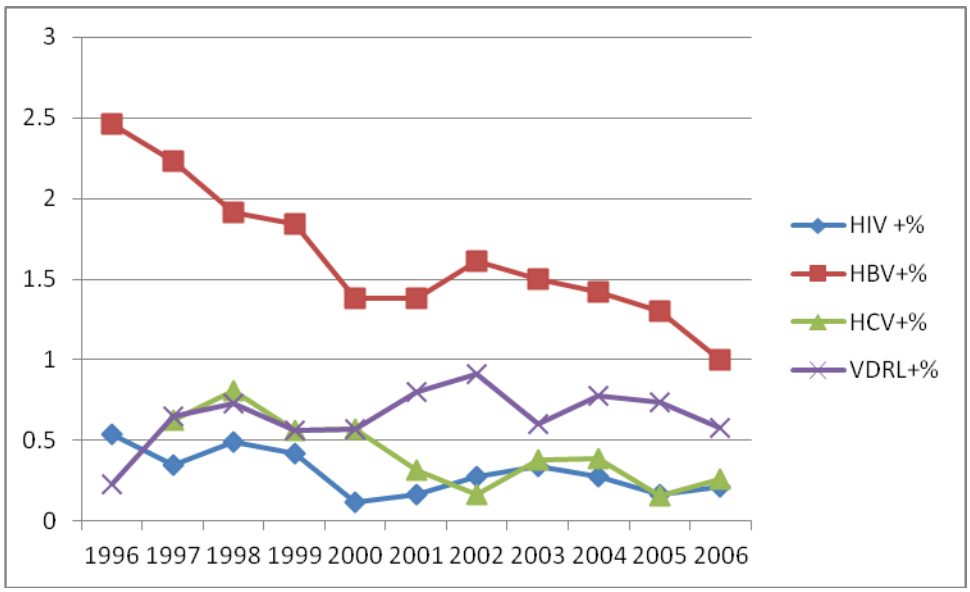
TTI Testing: Sero Positivity Rates

Five screening tests are mandatory as per NACO guidelines. These are serological tests for HIV1&2, hepatitis B, hepatitis C, syphilis and malaria. Guidelines stipulate that if a unit tests positive for infection by any available test it must be discarded. Commercial testing kits approved by the government are used. ELISA is used for the serological testing of the three viral infections. For syphilis testing, 'rapid plasma reagin' method is used. Until recently, malaria used to be tested by screening peripheral blood smears by microscopy, a very time consuming and less sensitive procedure. Later, antigen detection rapid tests for malaria were available.

In addition to these routinely done tests, 'rapid' testing is done when untested blood has to be released in an emergency. The rapid tests are also used on Apheresis platelet donors because the donor has to be screened for transfusion transmissible infections before the donor is put up on the Apheresis machine. However, rapid tests are not as sensitive as ELISA therefore not used routinely.

The TTI laboratory is managed by two lab technicians provided by NACO who have been given special training. Tests are put up every morning on the previous day's sample. All components units that test positive for TTIs are removed physically from the inventory and noted in the master register. The donor sero positivity rates for the five infections tested between 1996-2006 is given below (Figure-4.1)

Figure 4.1 Sero Positivity Rates for Five Infections among Donors (1996-2006)



Sero Positivity Rates for Five Infections among Donors (1996-2006)

HIV positivity rates among the donors showed a decline from the year 2000 onwards with a slight rise in the year 2003.This decline could be attributed to a decline in the number of professional donors or careful donor screening and/or a decline in the positivity rates in the general population.

Hepatitis B and C: If 2002 and 2003 figures can be considered as exceptions data shows a

a gradual decline in Hepatitis B among the donors from 2000 onwards. Similarly, Hepatitis C also shows a decline from 2001 onwards. The most logical explanation is the weeding out of cases of jaundice after proper history taking and proper donor selection, resulting in the decline.

VDRL positivity rates do not show a decline over this period as seen with the other two i.e., HIV and Hepatitis. In fact rates are high in the years 2001 and 2002.

VDRL testing is done by the rapid plasma regain (RPR) method which is a screening test with a high rate of false positive results. The test detects even those cases which were infected in the past and do not have active disease at present. Moreover it is difficult to exclude such cases by history taking alone. Syphilis testing has gained importance as a surrogate marker for HIV. Therefore it is considered to be an important test for screening for blood safety. The rise in venereal disease research laboratory (VDRL) positivity for syphilis has therefore to be watched and analyzed with care (Table 4.4).

Table 4.4 Sero Positivity Rates for Five Infections among Donors (1996-2006)

Year	**Donors**	**HIV +**	**%**	**HBV+**	**%**	**HCV+**	**%**	**VDRL+**	**%**
1996	5647	31	0.54	139	2.46	--	--	13	0.23
1997	4741	17	0.35	106	2.23	30	0.63	31	0.65
1998	4647	23	0.49	89	1.91	38	0.81	34	0.73
1999	5629	24	0.42	104	1.84	32	0.56	32	0.56
2000	6566	8	0.12	91	1.38	38	0.57	38	0.57
2001	6671	12	0.17	94	1.38	22	0.32	54	0.80
2002	7427	21	0.28	120	1.61	13	0.17	68	0.91

2003	7565	26	0.34	114	1.5	29	0.38	46	0.60
2004	7134	20	0.28	102	1.42	28	0.39	56	0.78
2005	6730	12	0.17	88	1.3	11	0.16	50	0.74
2006	7046	15	0.21	71	1	19	0.26	41	0.58

Component Separation

From the early nineties, modernization of blood banks in India was undertaken with financial support from NACO which in turn was funded by the World Bank. Equipment related to screening for infectious diseases and component separation was provided.

It is desirable that 80 percent of the collection should be made into components. With each unit of blood being processed into up to three of its constituents, component use ensures a more judicious and appropriate use of a scarce resource. In 2000, when CTVS department was started in the study hospital, component preparation became an immediate necessity.

In 2001, NACO supplied component separation equipment like refrigerated centrifuge, platelet agitator, deep freezers (for storage of fresh frozen plasma) and blood bank refrigerators. A separate license was issued for the component separation facility by the drug controller's office, a necessary prerequisite and a trained technician was provided by the DSACS, exclusively for the component separation laboratory.

Types of Components and Storage: Complexities and Options

There are three main types of components, namely packed red cells, fresh frozen plasma and platelets. Cryoprecipitate that contains mostly factor V, factor XIII and fibrinogen, is made only on demand as it is used only for rare indications like hemophilia, von Willibrands disease, or

fibrinogen deficiency. Each component has to be stored at the requisite temperature for specified periods depending upon its shelf life. Packed red cells are stored in refrigerators at 2-6 ˚C for a period of 35 or 42 days depending on the anticoagulant used. Platelets are stored in platelet agitators at room temperature at20-24 ˚C for 3 days or 5 days, again depending on the type of the bag used. Fresh frozen plasma is stored in deep freezers at or below minus 40 ˚C for up to one year.

Component separation requires highly specialized technology and trained staff. Earlier packed cells when required, mostly for the pediatric patients were prepared by simply hanging the bag. The red cells being heavier settled down by gravity and the supernatant plasma was transferred into another bag. Since storage facilities for deep freezing the plasma was not available in the blood bank, plasma was procured from IRCS and was mostly used for burn patients. Approximately 70 percent of the collection in the blood bank is processed into components. In addition to a regular requirement from the department of CTVS, platelets and fresh frozen plasma are also used by physicians to treat cases of anemia, liver disorders and dengue.

A limiting factor that prevents all donations from being processed into components is that the donor's weight has to be more than 60 kgs to allow 450 ml to be collected. From those whose weight is below 60 kgs, only 350 ml of blood can be collected. 450 ml blood collected in triple or quadruple bags can be processed into three components i.e., packed red cells, platelet concentrate and fresh frozen plasma. 350 ml blood is collected in single or double bags, from which only two components can be prepared i.e., packed red cells and platelet rich plasma (PRP). The advantage of platelet concentrate is that it has much less plasma than one unit of PRP; hence problems of volume overload are minimized. The disadvantage is that quadruple bags are almost two or three times costlier than the double or single bags.

Component separation is routinely done in only one shift by one contractual technician provided by DSACS. When demand rises, as in the dengue seasons, component separation is done in two or even three shifts to meet the increased requirement of platelets. Utilization of platelets is variable as it is demand based. As the shelf life of platelets is only three or five days, if not utilized within this time it has to be discarded. Approximately 5 percent to 30 percent of the platelets are discarded on an average depending upon the consumption. Discard rates of platelets fall when the consumption increases as seen during dengue epidemics.

Compatibility Testing and Issue of Blood/Components

The patient's sample and the request form is received at the blood bank, blood group of the patient is ascertained and sent to the compatibility testing laboratory. Cross matching[6] of red cells is done with sample from donor blood and the readied unit is preserved in a separate refrigerator until issue. For patients posted for elective surgery (planned surgery) this exercise is done one day prior to the date of surgery to ensure preparedness. Fresh frozen plasma has to be thawed before issue therefore fresh frozen plasma and platelets are matched at the time of issue. All records are documented and maintained for future reference.

Inventory Management and Discard

Average daily collection of blood is approximately 20-30 units and the average issue of all the components taken together is 40-50 units. If a particular unit is in short supply, surplus from other government blood banks is obtained, in crisis situations especially in case of shortage of negative blood groups. In the year 2005, the number of request forms received at the blood bank was 9,588 and the number of units issued was 11,392.

A detailed inventory of the available units of whole blood, red cells and components is maintained showing the date of collection also. The inventory also has the number of negative blood group units available at the blood bank. Ideally units collected first should be issued first. Exceptions are infants and patients who require fresh blood. The stock is updated daily by the night duty technician and physical verification of the units is done weekly. At a given time there are roughly 400 units of red cells and 500 units of FFP, 12-15 units of platelets present in the blood bank (2005).

[6] Tile method-for compatibility testing is now obsolete. Tube method is the standard procedure followed.Coombs test which helps in detecting irregular antibodies (antibody screening) should be done for each cross match. In addition to this Coomb's test is routinely performed for Rh negative pregnant women and diagnosis of hemolytic anemia.

Blood and components units are discarded at the blood bank for several reasons like those that have tested positive for infections, insufficient blood collection, return of unutilized units from the wards or OT's because of postponement of surgery, death of a patient, postponement of transfusion due to fever or other complications, hemolyzed units or leaking bags. Blood leakages are particularly seen with fresh frozen plasma units which are more vulnerable to cracks during storage at minus 40 ˚C or minus 80 ˚C if not stored in a proper upright position. Cases of accidental puncture of the blood bag by residents while connecting the transfusion set sometimes also occurs. In addition to this, units that have caused an adverse transfusion reaction are also returned to the blood bank and are discarded (Table-4.5).

Table 4.5 Issued Blood Returned to the Blood Bank Year-2003-2004

SN	Department	Component	Number of Units
1	OT	WB	34
2	CTVS OT	PC	55
	CTVS OT	FFP	11
	CTVS OT	PRP	2
3	Medical ward	WB	16
4	Medical emergency	WB	2
5	Pediatrics	FFP	2
6	Paed Surgery	PC	2
7	Nursing home	WB	12

8	Dialysis	WB	9
9	ICU	WB	2
10	Ortho	WB	8
11	Neurosurgery	WB	7
12	Burn	WB	2
13	Orthopedics	WB	2

The record of blood and components returned after issue was poorly maintained but the table gives some idea of the returned units from the different users. Table-4.5 shows that, most of the blood units are returned from the operation theatres because many surgeons start the procedure only after blood is issued to them. In case transfusion is not required unused units are then returned to the blood bank. Units returned after adverse incidents are often not recorded properly because of improper communication from the clinicians. Some units are discarded in the wards itself, which was a major deviation from the standard procedures. Hence it is likely that the actual number of units returned/discarded could be much higher.

Documentation

As per requirements of the drug controller, standard operating procedures (SOPS) for every process and activity conducted in the blood bank have to be in place. These records have to be preserved for a minimum period of five years. This is to ensure traceability of positive results and is also considered an important step in ensuring quality in blood banks. Further, in case of litigation proper documentation helps in tracing the implicated unit to the donor. Information is entered manually in registers.

Some of the records maintained by the blood bank are : Test worksheets, reader print-outs , test reports, control charts, reagent name and batch number; expiry date, date tests were performed, operator identity & signature, results of controls and specimens, calculations ,interpretation of results and donor and patient details.

There are a total of 18 registers in the blood bank, namely: master register, stock register, cross match register, issue register, donor grouping register for outdoor and indoor patients, voluntary donor register, quality control of antisera, daily temperature record, donor register, donor refreshment register, component register, quality control of component register, TTI lab register's for each of the five infectious diseases are some of the important documents that are being maintained since late 1980's.

Adverse incident register is not maintained properly because there is improper communication from the clinicians. Mild adverse reactions even go unnoticed and unrecognized. Only when transfusion is urgently needed, the implicated unit is returned to the blood bank, to get another in exchange.

A detailed record for equipments is maintained at the blood bank and contain the following information: instructions for use, calibration status, calibration worksheet, equipment identification ,date of calibration, operator, calculations, outcome, calibration certificate ,routine maintenance / monitoring forms, demonstrate achievement of quality standards and effective operation of quality systems, enable each staff member to be consistent in performance as laid down in SOP, identification of sources of error or variability in performance of procedures.

In summary, the blood bank is located in a 1000 bedded public sector tertiary hospital in Delhi, one of the three belonging to the central government. The hospital caters to a large number of outstation patients referred from neighboring states and most services are free of cost. It has several super specialty departments like Nephrology, Urology, Neurosurgery, Paediatric Surgery and the newly established department of CTVS. A large proportion of transfusions are ordered by these departments as the conditions treated by them are blood intensive. In addition, it caters to all the broad specialties also.

The blood bank licensed in 1983 is one of the best equipped in Delhi and also a regional training center for the blood bank staff. It depends mostly on replacement donation as a source of blood

supply. Component separation was started in the year 2001 with government support as part of the modernization program, by way of provision of equipment, manpower and training.

The description above is that of the setting in which the study was conducted the details of which are dealt with in the subsequent chapters.

The next chapter looks at the transfusion prescribing practices by the various specialties, before and after components became available in the hospital blood bank.

CHAPTER-5

Audit of Blood and Component Use: Transfusion Prescribing Practices (1997-2003)

Trends in blood and component use at the hospital were studied retrospectively for over a period of seven years, through an examination of the request forms for blood and blood components received at the blood bank. A 50 percent systematic sample of blood request forms, received at the blood bank, for the years, 1997, 2000 and 2003, were studied to analyze the trends in blood transfusion practices over this period. The year1997 was taken as the baseline, five years after the blood safety initiative began in 1992 with Phase-1 of the World Bank funded project. This period was considered to be sufficient for information regarding the blood safety guidelines, to reach the provider level and for its effects to be observed. To study the pattern of demands after the availability of component separation unit, in the hospital, 2000 was taken as the year immediately *before* the component separation unit was installed and the year 2003, two years *after* component separation started. Thus a total number of 3188, 3845 and 4946, request forms for the years 1997, 2000, 2003 respectively amounting to 3939, 4852, 8644 component units, were included in the study.

Evidence available at the time shows that there was over ordering and inappropriate use of blood and blood components in India even after years of the launch of the blood safety program. NACO estimated that 30 percent of the transfusions were inappropriate (Document on Rational Use of Blood NACO 1996). The data presented in this chapter allows us to study the impact of changes in transfusion medicine and hospital services on transfusion practice in the study hospital.

Trends in Service Indicators and Transfusions in the Hospital-Before and After Setting up of Component Separation Unit: 1997-2000 and 2000-2003

Over the study period there was a minimal increase in beds and admissions, with some increase in surgeries, but there was a major increase in blood units requested as well as total patients transfused as can be seen in table-5.1. Demands for the newly started CABG (Coronary Artery

Bypass Graft) surgeries by the department of CTVS that require several units of blood and component transfusions per patient, could have added to the total units. For one patient undergoing CABG, a total of 18 units-six each of packed cells, platelets and fresh frozen plasma were demanded per request form, whereas the other departments usually asked for one or two units only.

The component separation unit was established in the year 2001.The only components available in the year 1997 and 2000 at the hospital blood bank were whole blood and plasma. Packed cells were prepared manually, by gravitational method, where the bags were hanged on a stand, red cells being heavier settled at the bottom. The supernatant plasma was separated into another bag. Platelets when needed were procured from the Indian Red Cross Society. But in the year 2003, packed cells, platelets and fresh frozen plasma were available at the blood bank after the component separation unit was installed in the year 2001.

Table 5.1 Trends in Service Indicators and Transfusions 1997-2003

SN	**Service Parameters**	**Percentage Increase (%)**	
		2000 over 1997	**2003 over 2000**
1	Total Beds	4.69	1.93
2	Total Admissions	10.54	5.71
3	Total Major surgeries	13.16	14.75
4	Total Blood Donations	25.14	33.54
5	Total Patients Transfused (Request Forms Received)	8.74	58.14
6.	Total Component Units Transfused(Components	**33.35**	**64.55**

	Requested)		

Trends in Component Units Requested in the Three Study Years (Table-5.2)

Table-5.2 shows the proportion of component units requested per patient. Between the year1997 and 2000, whole blood use was approximately 89 percent then it declined sharply in 2003.Between 1997 and 2000, packed cell use declined by approximately 2 percent and between 2000 to 2003, it increased by approximately11 percent. A decrease in the number of thalassemia patients in 2000 could be a possible reason for decline of packed cell use in this year as the department of Pediatrics was the chief user. As for use of fresh frozen plasma, it was almost same between1997 and 2000 with a sharp increase of approximately 15 percent between 2000 and 2003.Platelet use increased marginally between1997 and 2000,but between 2000 and 2003 it increased by approximately 8 percent.

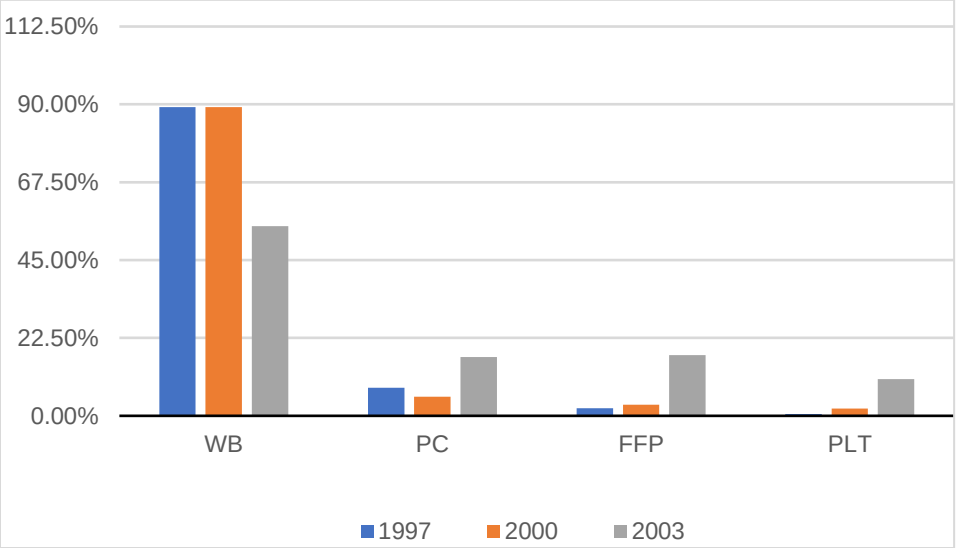
In summary, over the study period, whole blood use had decreased, while component use increased. Packed cell use showed a decrease in 2000 from 1997 and then a steep rise in 2003. Fresh frozen plasma and platelet use showed an upward trend. Both fresh frozen plasma and platelet use showed a slight increase in 2000 from 1997, but a marked increase in 2003.

Table 5.2 Trends in Component Requests in the Three Study Years

Year	WB%	PC%	FFP%	PLT%	Total
1997	89.18	8.07	2.20	0.53	100
2000	89.20	5.54	3.17	2.08	100
2003	54.81	17.01	17.57	10.59	100

Note: Component Separation Unit set up in 2001

Figure 5.1 Trends in Component Requests in the Three Study Years



Trends in Component Requests in the Three Study Years

Trends in Components Requested by Specialty: 1997, 2000 and 2003 (Table-5.3)

Over this period of seven years, new departments were established in the hospital, resulting in an increase in the number of beds. In the year 1997, the number of beds was 937, with two well established super specialty departments of Neurosurgery and department of Burns and Plastic Surgery. The other super specialty departments of Pediatric Surgery, Nephrology, Urology and Neurology were in the initial stages of establishment. The total number of departments that were transfusing blood or components was 12 in the year 1997. In the year 2000 the total number of beds had increased to 981. The department of CTVS was also established in this year, increasing the total number of departments that ordered for transfusions to 13. Between 2000 and 2003, the number of beds was increased to 1000, the increase being mainly due to addition of 20 beds earmarked for disaster cases. The disaster beds were utilized mainly in the event of mass casualties therefore this increase would not bring about much difference in the usual pattern of demand.

In 1997 and 2000 the highest proportion of requests (indicating patients transfused) excluding CTVS, were received from the department of general surgery, the second highest was from the department of Medicine, with the department of Obstetrics and Gynecology being in the third place. In the year 2003 the only change was the department of medicine showing highest proportion of requests, with surgery at a close second place, which was due to redistribution of demands among other newly formed surgical specialties.

The total number of components units transfused was higher than the number of requests indicating that in some cases multiple transfusions were given per patient. The massive increase in component units transfused by almost 30 percent, could have been due to, change in services at the hospital, size of departments and admissions or due to changes in prescribing practices.

Table 5.3 Trends in Components Requested by Specialty: 1997, 2000 and 2003

SN	Departments	1997(%)	2000(%)	2003(%)
1	Burn	3.70	1.93	4.61
2	ENT	0.60	0.28	0.56
3	Obstetrics and Gynecology	12.94	11.64	8.37
4	Medicine	22.54	23.90	19.89
5	Neurology	0.03	0.02	0.04
6	Nephrology	0.22	3.09	1.01
7	Neuro Surgery	9.01	7.68	5.32
8	Orthopedics	11.75	13.04	6.64

9	Pediatrics	8.60	4.61	5.88
10	Pediatric Surgery	0.40	0.43	0.17
11	General Surgery	30.13	27.86	19.22
12	Urology	0.05	1.87	1.31
13	CTVS	X	3.60	27.05
14	Total	100	100	100

Transfusion per Bed: W.H.O. Norms for Estimation of Requirement

WHO calculation for transfusion requirement takes all hospital beds into account irrespective of transfusions. Depending upon the type of medical care it could vary between 7-15 units per bed per year. For specialized institutions giving hematological and oncology care it could be 25-30 units.

Component units requested per all hospital beds was approximately, 4.2 per bed in 1997, 5 per bed in 2000 and 9 per bed in 2003. Similarly component units requested per patient from only those departments that transfused blood and components was at 6 per bed in 1997, 8 per bed in 2000 and 11 per bed in 2003.

Department wise Trends in Component Units Requested Per 100 Admissions over the 7 year Study Period: (Table-5.4)

The analysis was done taking into account the component units ordered by each department per 100 admissions.

Whereas transfusion rate per bed is indicative of variations due to size of the department, of greater relevance is the influence of number of patients admitted to use the beds, since the

patients using these beds will vary across departments and with changing patient management practices overtime.

In the year 1997, department of Burn and Plastic Surgery had the highest rate of transfusions per 100 admissions at approximately 29, followed by orthopedics at approximately 21 and General Surgery at 12.

In the year 2000, CTVS, Nephrology, Urology were the highest three users of components at approximately192, 147 and 41 per 100 admissions respectively.

In the year 2003 the three highest users per 100 admissions were CTVS, Burn Plastic Surgery and Urology at 815, 59 and 34 respectively.

Department of Obstetrics and Gynecology, Medicine, Neuro Surgery, General Surgery and CTVS, showed a rising trend in transfusion rate per admission during this period. Component use in the department of Nephrology, Paediatric Surgery and Urology showed a declining trend. Transfusion rate for the departments of Burn, E.N.T. Neurosurgery and Paediatrics did not show a uniform trend.

Department wise Trends in Components Requested per 100 Beds over the 7 year Study Period:(Table-5.5)

Department of Neurosurgery was the highest user of component transfusions per 100 beds in the year 1997 at approximately 1109 followed by Obstetrics/Gynecology at 1063 and General Surgery at 970.

In the year 2000, CTVS, Urology, Nephrology, were the highest three users of components at 8750, 4746 and 3033 per 100 beds respectively.

In the year 2003 the three highest users were CTVS, Urology and Burn at approximately 12994, 1900 and 1535 respectively.

Comparative Analysis of Department wise Trends in Components Requested per 100 Admissions, 100 Beds and Component use over the 7-year Study Period (Tables-5.4, 5.5, 5.6, 5.7, 5.8)

Burn and Plastic Surgery

Proportion of demands from the department of Burn and Plastic Surgery was variable in the three study years. It dipped in the year 2000 (Table-5.1).

Component units transfused per 100 *admissions* was approximately 29, 18 and 59 respectively (Table-5.4), showing less component use in 2000.

Component units transfused per 100 *beds* was approximately 562, 362, 1535 respectively for the three years (Table-5.5)

The department used whole blood and plasma in all the three years but did not use platelets for transfusions (Tables-5.6, 5.7, 5.8).

E.N.T

Demands from ENT remained the same, being at approximately less than 1percent of all requests (Table-5.1).

Component units transfused per 100 *admissions* were approximately 2, 1 and 5 respectively (Table-5.4).

Components transfused per 100 *beds* were approximately 93, 54 and 204 (Table-5.5).

The department used whole blood and packed cells in the years 1997 and 2000 and used whole blood and platelet in 2003. No plasma was used by this department (Tables-5.6, 5.7, 5.8).

Obstetrics and Gynecology

The requests showed a declining trend from 13 percent to 8 percent.

Rate of component transfusion per 100 admissions were approximately 10, 10, 15 in the years 1997, 2000, 2003 respectively (Table-5.4).

Components transfused per 100 beds were approximately 1063, 1027 and 1316 (Table-5.5)

In 1997 and 2000, whole blood, packed cells and fresh frozen plasma were used. In the year 2003 all the components were used (Tables-5.6, 5.7, 5.8).

Medicine

The demands from Medicine department remained at a little over 20 percent of all requests in the three study years (Table -5.3).

Component transfusions per 100 admissions were approximately 8, 10, 13 respectively (Table 5.4) indicating increased use of components during this period.

Component transfused per 100 beds were approximately 513, 921 and 761 (Table-5.5)

Department of Medicine used all four components in all four years, with 21 percent of whole blood, 37 percent of packed cells, 13 percent of plasma and 81percent of platelets being used in 1997. Packed cell use remained the same in 2000 and proportion of plasma and platelets used were at50 percent and 43 percent each. In 2003 whole blood use remained at 22 percent but packed cells, fresh frozen plasma and platelets decreased in proportion to other departments to approximately 20 percent of the total (Tables-5.6,5.7,5.8).

Neurology

This department used less than 1percent of all transfusions.

Nephrology

Requests received from the department of Nephrology showed an increase in 2000.

Component units transfused per 100 admissions were approximately 147 and 15 in the year 2000 and 2003 (Table-5.4).

Components transfused per 100 beds were approximately 2500 and 629 in 2000 and 2003 (Table -5.5)

Nephrology used mostly whole blood in all the three years, though in 2000 packed cells and fresh frozen plasma were also used which was approx. 2-3 percent of all requests (Tables-5.6,5.7,5.8)

Neurosurgery

A declining trend in the proportion of request for transfusion was seen in the three study years (Table-5.3).

Component Transfusion per 100 admissions were approximately 11, 21 and 27 respectively (Table-5.4), indicating a high rate of transfusion per patient.

Components transfused per 100 beds were approximately 1109, 4746 and 920 (Table 5.5)

In the year 1997 components used were whole blood and packed cells. In the year 2000 all components were used, whereas, in 2003 whole blood, packed cells and fresh frozen plasma were used.

Requests for whole blood in the three years were 8-10 percent of total requests for whole blood (Tables-5.6, 5.7, 5.8).

Orthopedics

The requests from the department of Orthopedics did not show a uniform trend (Table-5.3).

Component transfusion per 100 admissions was approximately 21, 28 and 26 for the three study years (Table-5.4).

Components transfused per 100 beds were approximately 747, 1097, 973 (Table-5.5)

Whole blood was used in the years 1997 and 2000. However whole blood use dropped in the year 2003 and was replaced by packed cell demands (Tables-5.6,5.7,5.8).

Pediatrics

No uniform trend was observed in the study years (Table-5.3).

Component units transfused per 100 admissions were approximately 7, 4 and 8 (Table-5.4).

Components transfused per 100 beds were approximately 440 and 220 and 389 (Table-5.5)

All components were used in all the three years whole blood demands ranged from 3-5 percent, packed cells demands decreased over the study period. More packed cell transfusions were used in comparison to whole blood, and all four components were used in the study years. In 2000, 25 percent of the platelets was used by the pediatrics department (Tables-5.6, 5.7, 5.8).

Pediatric Surgery

A decline in proportion of requests was seen in 2003 (Table-5.3).

Component Transfusion per 100 admissions was approximately 6 and 5 in the years 2000 and 2003 respectively (Table-5.4).

Components transfused per 100 beds were approximately 160, 100 and 107 (Table-5.5)

Components used were whole blood and fresh frozen plasma in 2000 and 2003.

Proportion of all components utilized was less than 1 percent of total, except fresh frozen plasma that was 3 percent in the year 2000 (Tables-5.6, 5.7, 5.8).

General Surgery

There was a gradual decline in the proportion of demands over this period. However, throughout the study period the proportion of demands from general surgery continued to be the highest, in comparison to the other departments. The reason for decline could be distribution of demands among the newer surgical super specialties (Table-5.3).

Rate of component transfusion per 100 admissions were approximately 12, 15 and 16 respectively (Table-5.4)

Components transfused per 100 beds were approximately 970, 1001, 1039 (Table-5.5).

All components were used in all three years. Highest proportion of plasma was used in 1997 at 55 percent but declined subsequently, similarly platelet used declined over the study period. Whole blood use also declined but packed cell use increased over this period (Tables-5.6, 5.7, 5.8).

Urology

Proportion of demands in the study years was approximately 0.05 percent, 2 percent and 1 percent respectively.

Component units transfused per 100 admissions were approximately 41 and 34 respectively for the two years (Table-5.4).

Components transfused per 100 beds were approximately 3033, 1900 for the years 2000 and 2003 respectively (Table-5.5).

Urology used only whole blood in 1997 and 2003, but all components were transfused in 2000. The proportion of component used was between 1-2 percent (Tables-5.6, 5.7, 5.8).

CTVS

The proportion of component requests increased 9 times between 2000 and 2003 from approximately 4 percent to 27 percent (Table-5.3).

Component units transfused per 100 admissions were approximately 192 and 815 (Table-5.4).

Components transfused per 100 beds were approximately 8750, 12994 for the years 2000 and 2003 (Table-5.5).

In the year 2000 few whole blood units were used i.e. only approximately 2 percent of the total whole blood was used. However, packed cell was 17 percent, 23 percent and platelet were 18 percent, where as it was the highest consumer of components i.e., packed cells, fresh frozen plasma and platelets in 2003 at 51 percent, 49 percent and 81 percent (Tables-5.6, 5.7, 5.8).

Table 5.4 Component Units Requested per 100 Admissions

S N	Specialty	Adm 1997	Comp. Units 1997	Comp Req/ 100 Adm	Adm 2000	Comp. Units 2000	Comp Req/ 100 Adm	Adm 2003	Comp. Units 2003	Comp Req/ 100 Adm
1	Burn	510	146	**28.62**	510	94	**18.43**	678	399	**58.84**
2	ENT	1199	24	**2.00**	1059	14	**1.32**	963	49	**5.08**
3	Obg Gynae	5085	510	**10.02**	5525	565	**10.22**	4779	724	**15.14**
4	Med	10746	888	**8.26**	11206	1160	**10.35**	12814	1720	**13.42**
5	Nephro	+	9	**-**	102	150	**147.05**	568	88	**15.49**
6	Neuro Sur	3260	355	**10.88**	1798	373	**20.74**	1685	460	**27.29**
7	Ortho	2242	463	**20.65**	2265	633	**27.94**	2186	574	**26.25**
8	Paed	4777	339	**7.09**	6345	224	**3.53**	6113	509	**8.32**
9	Paed Sur	*	16	**-**	368	21	**5.70**	303	15	**4.95**
10	Surgery	9884	1187	**12.00**	9148	1352	**14.77**	10157	1662	**16.36**
11	Urology	+	2	**-**	221	91	**41.17**	333	114	**34.23**
12	CTVS	+			91	175	**192.30**	287	2339	**814.9**
13	Neurology				206			141		

14	Cardio	**								
15	Endo	+			6			40		
16	Gastro	+			32			118		
17	T Adm	37703			41104			43386		
18	T Comp Units		3939			4852			8644	

Table 5.5 Components Requested per 100 Beds

SN	**Specialty**	**Beds 1997**	C. Units 97	**Per 100 beds**	**Beds 2000**	C. Units 2000	**Per 100 beds 2000**	**Beds 2003**	C. Units 2003	**Per 100 beds**
1	Burn	26	146	**561.5**	26	94	**361.53**	26	399	**1534.61**
2	ENT	26	24	**93.3**	26	14	**53.84**	24	49	**204.16**
3	Obg Gynae	48	510	**1062.5**	55	565	**1027.27**	55	724	**1316.36**
4	Medicine	173	888	**513.29**	126	1160	**920.63**	226	1720	**761.06**
5	Nephrology	+	9		6	150	**2500**	14	88	**628.57**

6	Neuro Sur	32	355	**1109.37**	50	373	**4746**	50	460	**920**
7	Ortho	62	463	**746.77**	58	633	**1096.55**	59	574	**972.88**
8	Paed	77	339	**440.25**	102	224	**219.60**	131	509	**388.54**
9	Paed Sur	10	16	**160**	21	21	**100**	14	15	**107.14**
10	Surgery	122	1184	**970.49**	135	1352	**1001.48**	160	1662	**1038.75**
11	Urology	+	2	**-**	3	91	**3033.33**	6	114	**1900**
12	CTVS	+	X		2	175	**8750**	18	2339	**12994.44**
13	Neurology				6			6		
14	Cardio	**								
15	Endo	+								
16	Gastro	+								
17	Total Beds Transfused	576			616			789		
18	Total Hospital Beds	937			981			1000		
19	Total Comp		3939			4852			8644	

	Units									

Table 5.6 Department wise Breakup of Component Requests for 1997

SN	Department	WB%	PC%	FFP%	PLT%	Total
1	Burn	3.58		22.98		
2	ENT	0.65	0.31			
3	Obg Gynae	14.34	0.62	4.59		
4	Medicine	21.09	37.10	13.79	80.95	
5	Nephro	0.25				
6	Neuro Sur	10.01	0.94			
7	Ortho	13.17				
8	Paed	4.29	57.86	3.44	4.76	
9	Paed Sur	0.45				
10	Surgery	32.05	3.14	55.17	14.28	
11	Urology	0.05				

12	CTVS	X	x	X	X	
13	Total Requests					3939

Figure 5.2. Department wise Breakup of Component Requests for 1997

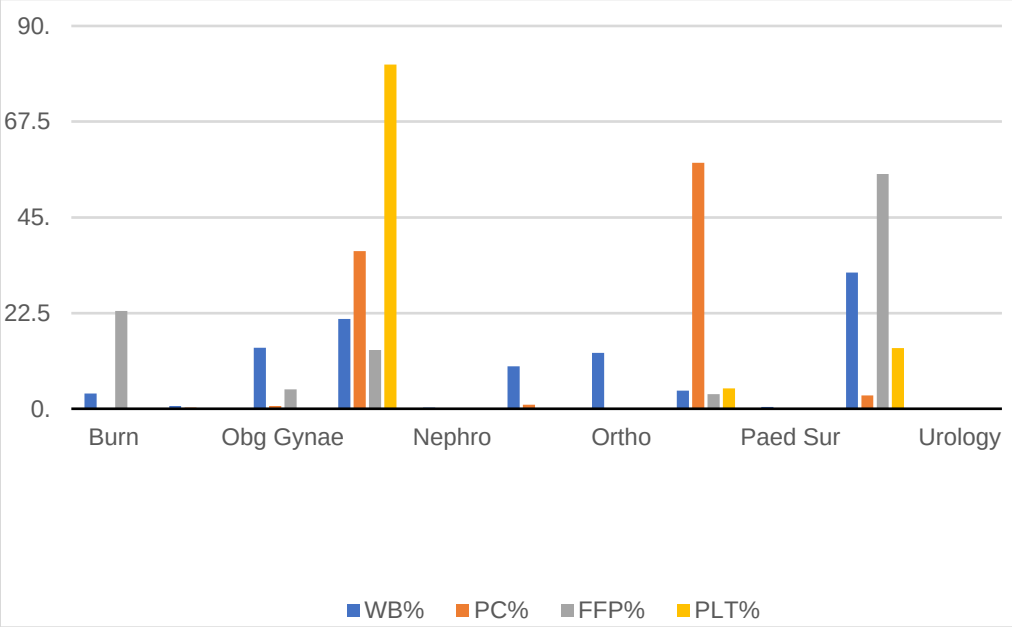


Table 5.7 Department wise Breakup of Component Requests for 2000						
SN	**Department**	**WB%**	**PC%**	**FFP%**	**PLT%**	**Total**
1	Burn	1.98	2.60	0.64		

2	ENT	0.32	x	X	X	
3	Obs Gynae	12.91	1.48	1.29		
4	Medicine	21.88	33.82	50.64	43.56	
5	Nephrology	3.18	2.60	3.24	X	
6	Neuro Sur	8.34	1.85	2.59	2.97	
7	Orthopaedics	14.62	x	X	X	
8	Paeds	2.19	32.34	10.38	25.74	
9	Paed Sur	0.32	0.37	3.24	0.99	
10	Surgery	30.66	5.20	3.89	4.95	
11	Urology	1.84	2.23	1.29	2.97	
12	CTVS	1.70	17.47	22.72	18.81	
	Total Requests					4852

Figure 5.3 Department wise Breakup of Component Requests for 2000

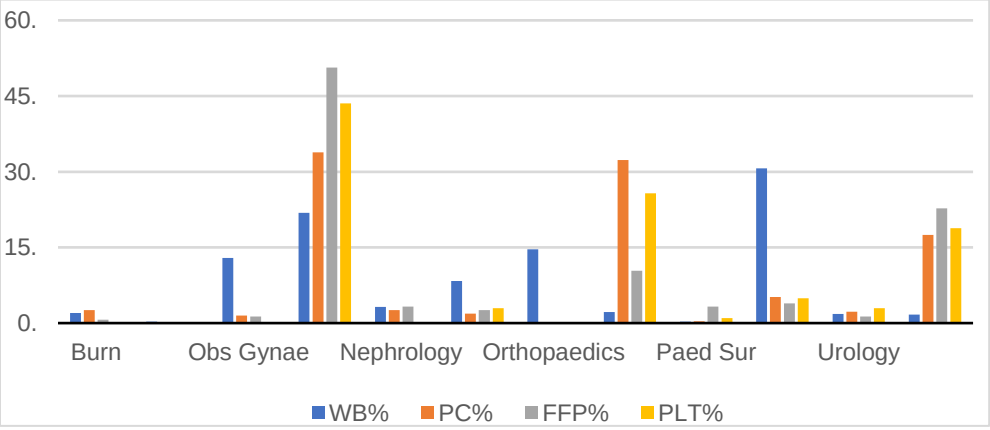
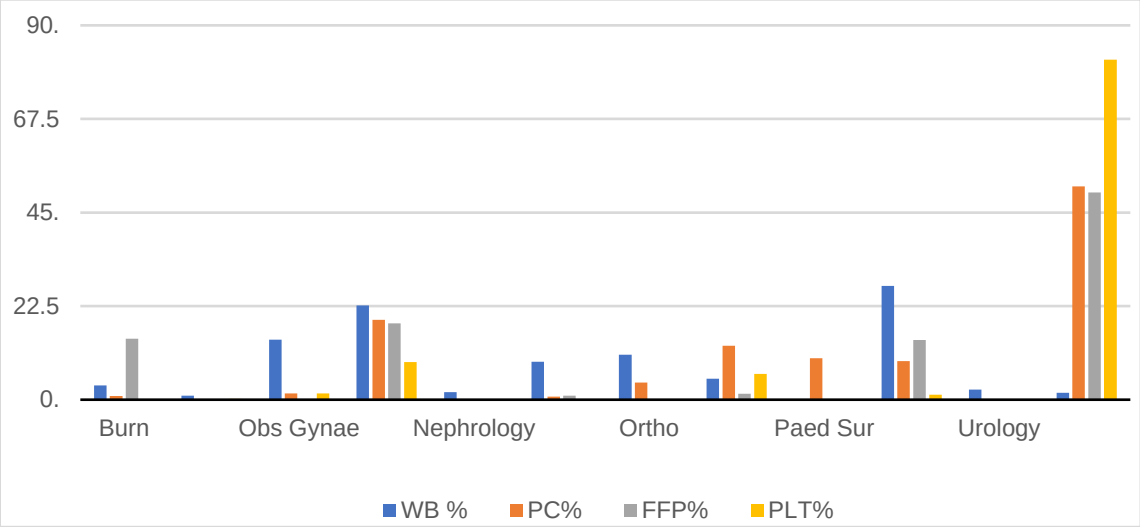


Table 5.8 Department wise Breakup of Component Requests for 2003						
S N	**Department**	**WB %**	**PC%**	**FFP%**	**PLT%**	**Total**
1	Burn	3.4	0.88	14.68	X	
2	ENT	0.99	x	X	0.21	
3	Obs Gynae	14.47	1.49	0.13	1.52	
4	Medicine	22.7	19.17	18.36	9.06	
5	Nephrology	1.85	x	X	X	
6	Neuro Surgery	9.15	0.74	0.98	X	
7	Ortho	10.78	4.14	0.13	X	
8	Paeds	5.04	12.998	1.44	6.22	
9	Paed Sur	0.10	10	0.06	X	
10	Surgery	27.35	9.31	14.35	1.20	
11	Urology	2.40	x	X	X	
12	CTVS	1.66	51.25	49.83	81.76	
13	Total Requests					8644

Figure 5.4 Department wise Breakup of Component Requests for 2003



Trend in Demands by Number of Units of Whole Blood/Components per Request over the Study Period

For all the years and for all the components, the maximum numbers of demands were for single units. In the year 2003 however, the maximum demand for platelets was for 6 units (53.91percent), which came from the department of CTVS.

Single unit whole blood demands show a declining trend over this period. There was an increase in double unit demand, but it still remained second to single units.

In case of packed cells also the demand for single units showed a decline with a corresponding rise in demand for double unit packed cells.

Fresh frozen plasma demands did not follow a uniform pattern for either single units or double units.

A decline of single unit platelets was seen over the years, however as mentioned earlier the demand for 6 units was the maximum in the year 2003 and came from CTVS.

Single unit demands could be due to scarcity of donors, or inadequate knowledge of transfusion guidelines.

Table 5.9 Proportion by Number of Units of Whole Blood per Request over the Study Period

Units	**1997(%)**	**2000 (%)**	**2003(%)**
<1	4%	1.4%	0.8%
1	76.46%	75%	69.455
2	20.19%	21.67%	27.34%
3	1.87%	2.06%	1.97%
4	1.10%	1.16%	1.00%
5	0.11%	0.02%	0.05%
6	0.25%	0.02%	0.17%

Figure 5.5 Number of Units of Whole Blood per Request over the Study Period

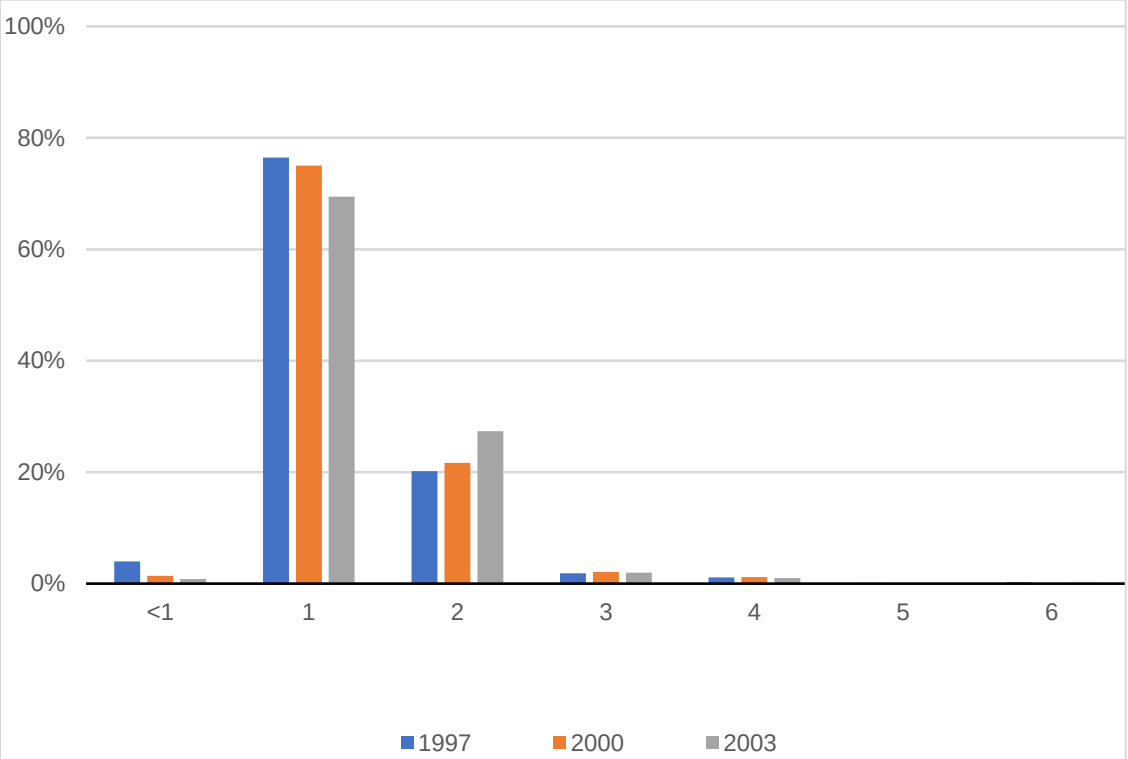


Table 5.10 Proportion by Number of Units of Packed cells per Request over the Study Period			
Units	**1997(%)**	**2000(%)**	**2003(%)**
<1	3.9	7	6.1
1	85.34	77.10	26.23
2	12.82	21.02	36.29

3	1.83	0.93	5.52
4	0	0.93	8.28
5	0	0	0.39
6	0	0	23.27

Figure 5.6. Number of Units of Packed Cells Requested over the Study Period

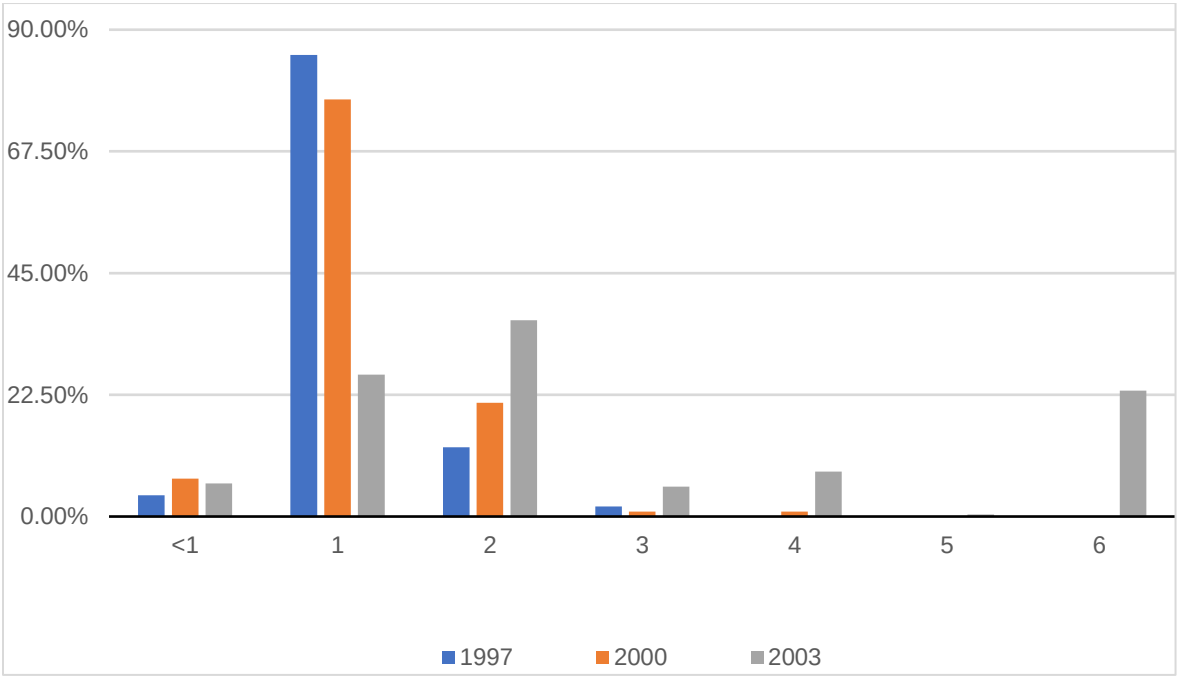
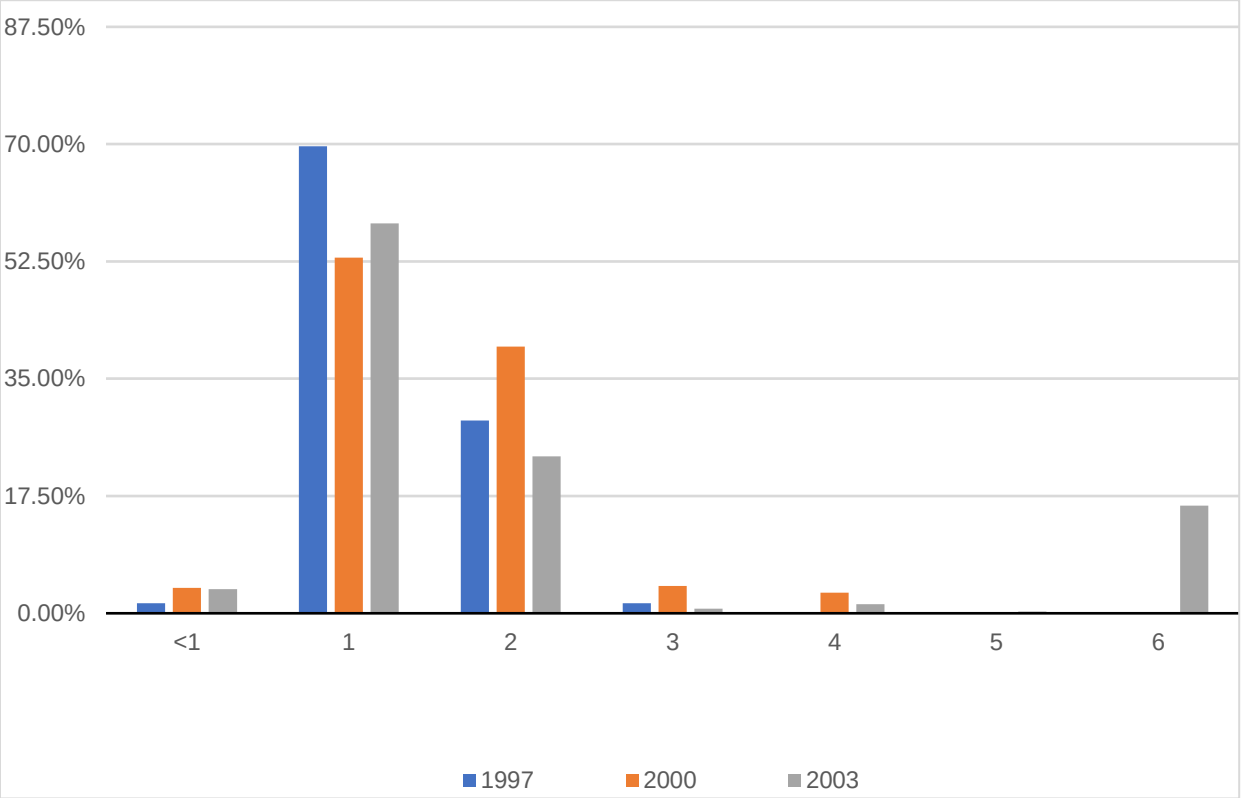


Table 5.11 Proportion by Number of Units of FFP per Request over the Study Period

Units	1997(%)	2000(%)	2003(%)
<1	1.5	3.8	3.6
1	69.69	53.06	58.17
2	28.78	39.79	23.40
3	1.51	4.08	0.69
4	0	3.06	1.38
5	0	0	0.27
6	0	0	16.06

Figure 5.7 Number of Units of Fresh



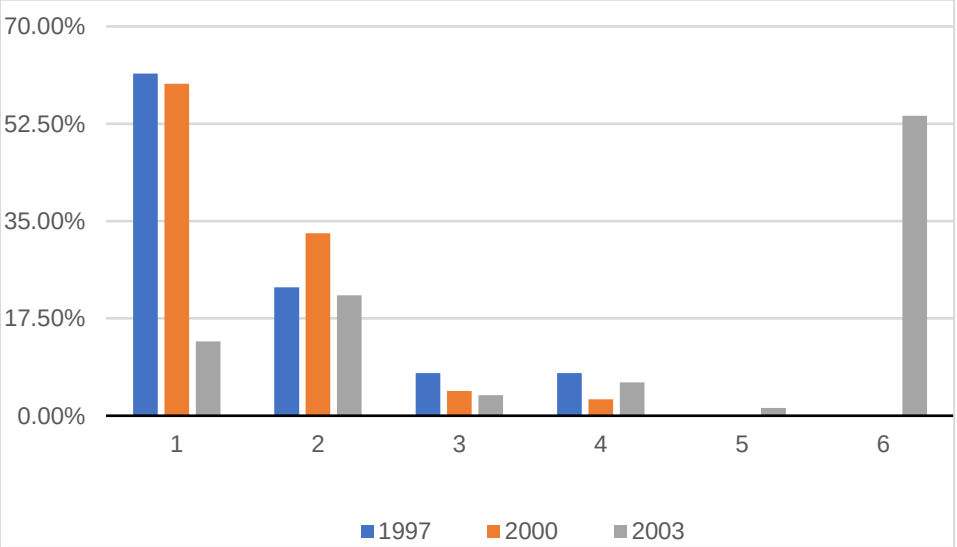
Frozen Plasma per Request over the Study Period

Table 5.12 Proportion of Number of Units of Platelets per Request over the Study Period

Units	1997(%)	2000 (%)	2003(%)
1	61.50	59.70	13.36
2	23.07	32.83	21.65
3	7.69	4.47	3.68
4	7.69	2.98	5.99

5	0	0	1.38
6	0	0	53.91

Figure 5.8. Number of Units of Platelets per Request over the Study Period



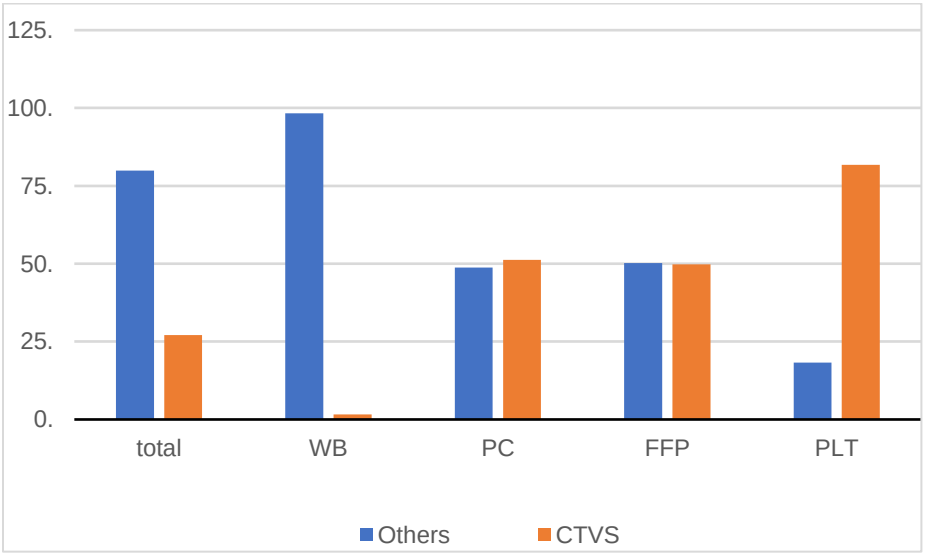
Analysis of Component Requests from CTVS in Comparison with other Departments (2003) (Table-5.13)

In the year 2003, approximately 27 percent of component requests came from the department of CTVS. Out of all requests, proportion of whole blood was 2 percent packed cell was 51 percent, fresh frozen plasma was 50 percent and PLT was 82 percent (Table-5.13). This indicated that the chief user of components was the department of CTVS.

Table 5.13 Comparison of Component Requests from CTVS with all Other Departments (Year 2003)

SN	Requests	Units	%	WB	%	PC	%	FFP	%	PLT	%
1	Others	6305	72.94	4659	98.34	717	48.75	762	50.17	167	18.24
2	**CTVS**	**2339**	**27.05**	**79**	**1.66**	**754**	**51.25**	**757**	**49.83**	**749**	**81.76**
3	All	8644		4738		1471		1519		916	

Figure 5.9. Comparison of Component Requests from CTVS vs Others (Year-2003)



Demographic Characteristics of Patients over the Study Period (1997-2003)

Mean Hemoglobin

The mean hemoglobin at which transfusion was requested was the same in all the three study years (Table-5.14).

In the year 1997, the mean hemoglobin at which transfusions were requested was 10.46gm percent (Range2.5 percent-16.5 percent, Standard deviation-3.03).

In the year2000, the mean hemoglobin at which transfusions were requested was 10.57gm percent (Range2-17 gm percent, Standard deviation-2.75).

In the year 2003 the mean hemoglobin at which transfusions were requested was10.41 percent, (Range2-16.5 gm percent, Standard deviation-2.87).

Table 5.14 Hemoglobin levels at which Requests were made

SN	Year	N	Mean Hb gm%	Range gm%	S.D.
1	1997	2723	10.46	2.5-16.5	3.03
2	2000	3097	10.57	2-17	2.75
3	2003	3691	10.41	2-16	2.87

Breakdown of the Transfusion Requests by Age of Patients (Table 5.15)

Patients were divided into the following five age categories: 0-15, 16-30, 31-45, 46-60 and above 60 years.

For all the three study years pattern of transfusion among the various age categories was similar**.** The most frequently transfused age group was, 16-30 years, the next most frequent being 30-45 years. Together these two age categories accounted for 50 percent of all transfusions.

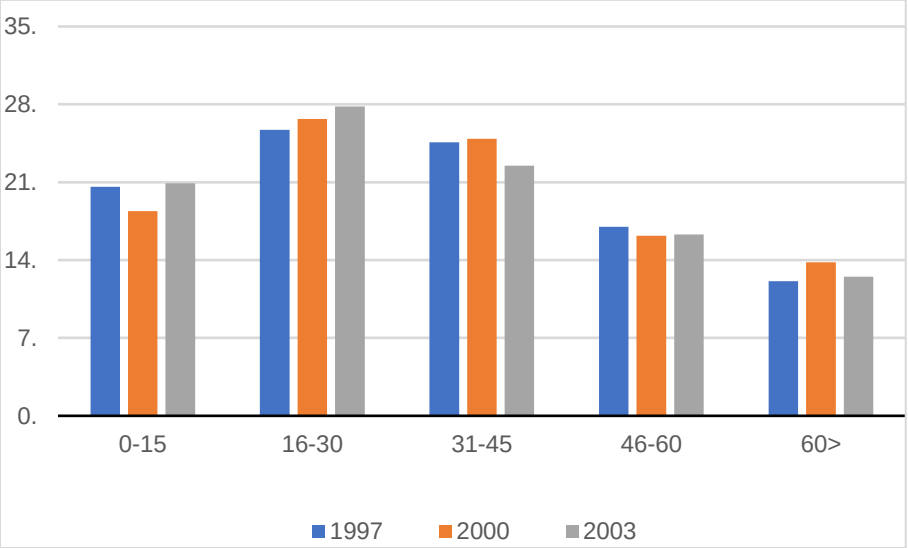
The age group between 0-15 years received approximately 20 percent of transfusions.

The age group of 46-60 years received approximately 16 percent of all. The age group 60 years and above received the least i.e., approximately 12 percent of all transfusions.

Table 5.15 Transfusion Requests by Age of Patients

Age	**1997(%)**	**2000(%)**	**2003(%)**
0-15	20.6	18.4	20.9
16-30	25.7	26.7	27.8
31-45	24.6	24.9	22.5
46-60	17	16.2	16.3
60>	12.1	13.8	12.5

Figure 5.10 Transfusion Requests by Age of Patients



Sex distribution of Patients Transfused (Table 5.16)

Transfusion demands were almost equally distributed between the two sexes, approximately 50 percent for each group in the three years. The study hospital treated only a limited number of Obstetrics and Gynecology cases that were entitled for nursing home admission.

Table 5.16 Sex Distribution of Patients Transfused

Sex	1997 (%)	2000 (%)	2003 (%)
Female	50.20	53.60	46.80
Male	49.80	46.40	53.20

Units matched/Units issued

A strong correlation was found between units issued and units demanded, in all the three years indicating that most of the units requested were transfused.

The ‘Cross Match to Transfusion Ratio’ (CTR) in all the three years was below 2.5 indicating that component units were not blocked in excess by cross matching which could create an artificial shortage .

In the year 1997, Pearson coefficient of correlation was 0.715 and the cross match to transfusion ratio was (CTR) 1.26,

In the year 2000, Pearson coefficient of correlation was 0.896 and the CTR was 1.30.

In the year 2003, Pearson coefficient of correlation is 0.883 and the CTR was 1.40.

Component Use by Common Indications

In all the three study years’ whole blood was used for all types of Indications.

The department of pediatrics used the maximum number of packed cell units, the difference in demands from other departments was statistically significant ($p<0.05$). In the year 2003, however a large proportion of packed cells were also used for CTVS cases.

Fresh frozen plasma was used for perforation peritonitis, burn, hematemesis or malena in alcoholic liver disease, or DIC (Disseminated intravascular coagulation) and CTVS.

Platelets were used for aplastic anemia with thrombocytopenia or pancytopenia and DIC. In the year 2003, platelets were also used by CTVS (Table-5.17).

Table 5.17 Component use by Common Indications

Year	Whole Blood	Packed Cells	Fresh Frozen Plasma	Platelets

1997	All diseases	1.Severe Anemia 2.Thalassemia 3.Paediatric Anaemia	1.Perforation Peritonitis 2.Burn 3.Alcoholic Liver Disease/Upper Gastrointestinal Bleeding 4.Disseminated Intravascular Coagulation	1.Aplastic Anemia/ Thrombocytopenia Pancytopenia 2.Disseminated Intravascular Coagulation
2000	All diseases	1.Severe Anemia 2.Thalassemia 3.Paediatric Anemia	1.Perforation Peritonitis 2.Burn 3.Alcoholic Liver Disease/Upper Gastrointestinal Bleeding 4.Disseminated Intravascular Coagulation 5 Factor VIII deficiency	1.Aplastic Anemia/ Thrombocytopenia Pancytopenia 2.Disseminated Intravascular Coagulation
2003	All diseases	1.Severe Anemia 2.Thalassemia 3.PaediatricAnaemia 4.CTVS	1.Perforation Peritonitis 2.Burn 3.Alcoholic Liver Disease/Upper Gastrointestinal Bleeding 4.CTVS	1.Aplastic Anemia/ Thrombocytopenia Pancytopenia 2.Disseminated Intravascular Coagulation 3.CTVS

Top Ten Causes of Transfusion

Ten most frequently transfused diagnosis categories were selected to study the changes in transfusion pattern over this period. They were severe anemia (primary or secondary to another underlying condition), perforation peritonitis/intestinal obstruction, total abdominal hysterectomy, vaginal hysterectomy, fracture femur, cholecystectomy, upper gastrointestinal tract bleeding, head injury, thalassemia, burn cases and CTVS (Table-5.18).

Severe anaemia: remained on top for all the three years, at approximately 5 percent, 8 percent, 9 percent.

Intestinal obstruction: Demands for intestinal obstruction cases that require laparotomy were the second most transfused group among the ten categories and showed a rise in the study period. This category requested the highest proportion of transfusions among all General Surgery patients.

Fractures: Cases of fractures showed a gradual rise, from approximately 3 percent in 1997, to 4 percent in 2000 and 5 percent, in the year 2003

Cholecystitis: Demands for transfusions for cholecystectomy cases remained the same in this period, at about 3 percent of the total demands.

Hematemesis: Cases of hematemesis increased considerably from approximately 3 percent of the total transfusions to 5 percent of all in the year 2000 and remained at 5 percent in 2003.

Head Injury: Transfusion for head injury showed variations across the years without indicating any pattern.

Thalassemia: Thalassemia transfusions dipped in the year 2000 because of fewer patients coming to this hospital for transfusions.

Burn and Plastic Surgery: Transfusions for burn and plastic cases was similar for the three years

Vaginal Hysterectomy: was the least transfused.

CTVS: The department of CTVS was established in 2000.Proportion of transfusions in the years 2000 and 2003 showed a rapidly increasing trend.

Table 5.18 Top Ten Causes for Transfusion

SN	Indication	1997(%)	2000 (%)	2003 (%)
1	Severe Anaemia	9.49	7.59	9.42
2	Perforation Peritonitis	6.46	5.84	7.42
3	Thalassemia	5.39	1.96t	4.36
4	Abdominal Hysterectomy	4.97	5.97	3.92
5	Burn	3.67	2.88	2.87
6	Fracture Femur	3.41	3.82	4.54
7	Head Injury	3.38	3.9	2.12
8	Hemetemesis	3.21	5.19	4.89
9	Cholecystectomy	3.05	3.39	3.07
10	Vaginal Hysterectomy	2.08	3.12	1.51

11	CTVS	X	1.06	3.90

Summary of Important Findings

Whole blood was the predominant form of transfusion across all specialties and across all the study years, excluding the department of CTVS which used most components. The difference was statistically significant ($p<0.05$). The department of Paediatrics used the maximum number of packed cell units, difference was statistically significant ($p<0.05$).

There was a definite increase in component use over this period, but the predominant demand was for whole blood except for CTVS. There was also a change in trend in the number of units of fresh frozen plasma and platelets ordered per request, showing an increase in 2,3,4,6 unit demands. Most of this change could be explained by the high number of component requests per patient from the department of Cardio Thoracic Vascular Surgery. The department of CTVS utilised most of the components in the year 2003.

A uniform trend of highest proportion of transfusion requests was seen from General Surgery for all the three years except for 2003 when it was a close second to Medicine. This was because in the year 2003 a large proportion of requests, approximately 27 percent was from the department of CTVS.

Trends show that approximately 60 percent of the requests came from the surgical disciplines excluding CTVS, in the years 1997 and 2000 and was 40 percent in 2003.

Of the total whole blood and packed cell requests approximately 77 percent were single unit requests in 1997, 75 percent in 2000 and 64 percent in 2003, out of which, all surgical departments put together contributed to 44 percent,44 percent and 35 percent, respectively for the three years. Single unit transfusions for elective surgery could have been avoided by better patient preparation. Whether these single unit transfusions were used rationally or were unnecessary could not be judged by this data alone.

This increase or decrease in the rate of transfusions per 100 admissions could either be due to an increase in the number of patients requiring transfusions or an increase in the number of patients with conditions that require multiple transfusions or due to change in prescribing practices. Since there has not been an unusual increase in the number of patients admitted in the year 2003 (approximately 11 percent between 1997-2000 and approximately 6 percent between 2000 and 2003), it appears that multiple component demands per patient for blood intensive surgeries, like CABG, or medical conditions requiring multiple transfusions could have led to the steep rise. Whereas one or two units were requested for elective surgical cases, 18 units or more of components were ordered per case, 6 each of packed cells, platelets, fresh frozen plasma, for cardiac surgery, as reflected by more than a quarter of component units requests (27 percent), in the year 2003.

Mean haemoglobin at which transfusions were demanded was 10.5 gm percent. Age groups of 16-30 years and 31-45 years, together accounted for 50 percent of all the demands, in all the three study years.

The indications or disease categories for which transfusions were demanded remained almost the same in the three study years with the only addition of CTVS in years 2000 and 2003.

CHAPTER-6

Clinicians' Awareness of Prescribing Guidelines, Perceptions of Blood Safety and Transfusion Prescribing Practices

All available literature and studies give prime importance to ignorance of clinicians about transfusion medicine. In order to find out the reasons for their prescribing practices and changes in them over the study period, multiple methods were used.

The reasons for prescribing practices for transfusions by clinicians in the various departments of the study hospital were explored using the data presented in the previous chapter on demands for blood and blood products. This chapter presents the general awareness and opinion of clinicians about transfusion medicine and its safety.

Schedule-based interviews were carried out with 97 senior clinicians from the departments of Anesthesia, Surgery, Medicine, Pediatrics, ENT, Neurosurgery, Nephrology, Obstetrics and Gynecology, Burns and Plastic Surgery, Urology, Pediatric Surgery, between the years 2003-2005, to ascertain their knowledge and opinions related to prevailing transfusion practices. The most important criterion for inclusion was that the clinician should have had at least 10 years experience. Junior residents were excluded from the sample since their learning and practices are largely influenced by the practices' of their consultants and there is little exposure to transfusion medicine practices in the medical undergraduate course.

The schedule based interview consisted of questions on knowledge of guidelines for transfusion and the current practice followed, hindrances to and suggestions for improvement in the present transfusion practices, availability of components in the hospital, perceptions about blood safety, perceptions about blood donation and transfusion among donors and recipients, problems faced in arranging blood and problems with the blood bank (Annexure-4).

The responses of these clinicians showed that prescription practice was based on individual clinical experience and lacked uniformity even amongst clinicians of the same specialty. Knowledge of transfusion guidelines among the clinicians was inadequate. Although most respondents did not perceive the presence of non-clinical factors in transfusion decisions, very few admitted that structural constraints in the hospital, difficulty in donor motivation, and

socioeconomic factors sometimes also played a role in decision making when prescribing for transfusions.

Awareness and Perceptions Regarding Clinical Considerations

Awareness of Component Availability in the Hospital

The prescribers' responses reflected that "Blood Transfusion" largely meant Whole blood or packed Cells for them. When asked about the indication for transfusion, most enumerated the indication for whole blood and red cells. Very few mentioned the indications for fresh frozen plasma or platelets.

90 percent of the respondents were aware of availability of components in the hospital blood bank and 6 percent were unaware of any availability of blood components in the hospital. The remaining 4 percent were not sure whether the components supplied were prepared in the hospital or came from another blood bank.

Awareness of Safety Concerns of Blood Transfusion

Awareness of TTIs and other hazards was low among the clinicians. A total of 38 percent of the respondents felt that blood and components were absolutely safe for transfusion after being tested.

Of the 62 percent who considered blood to be potentially hazardous, window period transfusion risk was the main concern. In comparison to surgeons, physicians had a better understanding of transmission of infections by blood and blood components during the window period. *'Every blood unit should have the details of the tests done at the blood bank written on it. This would help create awareness about TTIs.'*

Only one respondent had concerns for emerging viruses and some presently unknown transmissible disease that could surface in the future.

Perceptions Regarding Common Adverse Effects of Transfusion

Most of the respondents considered transfusion of blood and components to be a safe treatment option as they had never encountered any major problems in their practice.

The commonly encountered adverse effects were febrile reactions, rigors and rashes, which could be easily managed at the bedside. ABO incompatibility was encountered very rarely and most of these were due to clerical errors. Only one surgeon had seen a fatal hemolytic transfusion reaction in his practice. Therefore, the general perception among clinicians was that transfusion was a safe procedure. Delayed transfusion reaction was not encountered by any of the respondents and most did not know about it.

Most surgeons were concerned about the immediate outcome of surgery rather than the long term hazards of transfusion, *"We are happy with a good surgery, no post operative complications-we don't give much importance to problems of blood transfusion."*

In their opinion it was the job of the blood bank to ensure that blood supply was safe. *'It' is the blood bank's responsibility to provide safe blood; we have a lot of faith in the blood bank.'*

'The blood bank should ensure that blood is safe for transfusion, I think if they do their job well there would be no transfusion transmitted infections'.

Some respondents voiced more faith in the government blood banks in comparison to private blood banks.

Perceptions about Common Conditions Requiring Blood and Product Transfusion

Conditions for which blood transfusions were commonly prescribed in surgical departments were listed by respondents as per- operative/intra- operative bleeding, emergency surgery for perforation peritonitis, trauma, pelvic injury, burns, pre-operatively for patients with borderline anemia, awaiting surgery and post-operatively for complications like septicemia. One respondent explained the reason of development of anemia in Burn patients. '*In patients with burns, several factors contribute to the development of anemia. The most important is loss of superficial blood vessels that are burnt along with skin. Bleeding from wounds during dressing of intensive burns further aggravates anemia. In addition, stress-induced gastric ulcers result in decreased food*

intake and improper absorption. The resulting nutritional deficiency leads to bone marrow depression'.

Medical conditions commonly requiring blood transfusions listed by respondents were acute and chronic anemia, acute blood loss due to hematemesis and malena resulting from liver disease; drug induced peptic ulcers, disseminated intravascular coagulation (DIC), etc. Study of transfusion request forms corroborated that transfusion requests were largely made for the conditions listed by the respondents.

As evident from the responses, "blood transfusion" meant transfusion of whole blood and packed Red cells to the majority of clinicians. They did not think of components like platelets and fresh frozen plasma. Hence indications cited by most were for transfusion of red cells only.

Perceived Changes in the Type of Cases Requiring Transfusion

Respondents said that over the years, there had also been a change in the type of cases and the number of cases requiring transfusions. It was observed that cases of aplastic anemia, pancytopenia and thalassemia were on the rise. The increase in trauma cases over the years has in fact led to increased need for transfusions. Also there had been an addition of newer specialties that were blood intensive. Among the surgical specialties, cardio thoracic vascular surgery (CTVS), a relatively new specialty in the hospital required a large number of units for each patient.

At the same time, with refinement of surgical techniques and better methods of homeostasis fewer transfusions were required for surgeries, like cholecystectomy.

'There has been a lot of change in transfusion practice over the years. Lesser transfusions are being used. Many surgeries like cholecystectomy that required transfusions earlier, do not need now.'

While the perception of decrease in older forms of surgery is corroborated by changing practice, the escalation in requirement of transfusion in the study period due to new technology had gone unnoticed by the clinicians.

Perception Regarding Criteria for Transfusion (When to Transfuse and How Much)

Transfusion decisions were made on the basis of clinical judgment supported by laboratory criteria. Most physicians agreed that they were guided by a transfusion trigger for hemoglobin level i.e., a cut off level of hemoglobin below which transfusions were given. However, the cut-off varied widely in their responses, ranging from, less than 2.5 mg percent to less than10.0 gm percent, the median being 6 gm percent. According to WHO guidelines, there is no cut off level below which red cell transfusions are to be given. The decision should be made based on a careful assessment of the clinical criteria along with the laboratory criteria. However data from the previous chapter, from analysis of request forms showed that, blood transfusion was often done with hemoglobin of 10.0 gm percent and above, the mean being about 10.5, 10.6 and 10.4 for 1997, 2000 and 2003 respectively.

From the responses it was evident that in routine practice, any patient posted for elective surgery was declared fit by the anesthetist, only when the hemoglobin was at 10.0 gm percent. If the patient required surgery urgently, this level was achieved by transfusions prior to surgery.

There were variable replies as to how the quantity of transfusion was decided. There was a general agreement that surgical blood loss estimation in operation theatres was easier, than bedside estimation in medical cases. There are several tools that guide the anesthetist and the surgeon in accurately assessing intra-operative blood loss. These include volume of blood collected in the suction machine and the number/ weight of soaked gauze pieces. But there was no clarity among the respondents on, after how much blood loss, transfusion should be started. Some replaced one unit of blood for each unit lost; some put the figure at ‘after more than 500 ml.’ of loss and others at ‘after more than1000 ml’. The WHO guidelines however state that up to a loss of 1000 ml of blood, colloids and crystalloids are sufficient for its management. Transfusion is required only if blood loss exceeds this amount.

Surgeons and gynecologists differed on the question of who actually made the transfusion decision in the operation theatre (O.T.). Most surgeons were of the opinion that it was the anesthetist who was in command, whereas most gynecologists felt that it was a joint decision. The general surgeons said they rarely required more than two units of blood except in surgeries on highly vascular organs or when some complication arose in routine surgeries.

Difference of Opinion Among Colleagues

Overall, 66 percent of the respondents said that there was a difference of opinion, among colleagues when deciding for transfusions. The remaining 34 percent said that there was no question of having a difference of opinion in transfusion decision making, as it was the decision of the senior doctor or anesthetist that had to be complied with, indicating that the junior doctors had a limited role in prescribing transfusions.

We divided our study sample into two broad groups- out of which 65 percent were surgeons and 30 percent were physicians.

Disagreement was rarely seen among surgeons because they largely depended on the anesthetist's assessment for transfusion.

Among physicians, disagreements were common, especially in cases where the hemoglobin value was borderline or fell in the "grey zone" which was 6 or 7 gm percent according to them. Assessment of blood loss was also difficult for medical conditions, where the overall clinical condition of the patient had to be taken into consideration. In complicated cases or presence of co morbidities like diabetes and hypertension decision making was even more complex.

Clinical versus Laboratory Criteria

Most respondents agreed that decision-making was the result of an assessment made on the basis of a combination of laboratory and clinical criteria. However, laboratory reports were often unreliable and did not match the clinical condition of the patient. Commonly reports showed high hemoglobin level when the patient was clinically pale, but the reverse was also true

sometimes. *'Laboratory reports can't always be trusted, so we use clinical judgment to assess transfusion requirements. Judging transfusion needs in such situations is difficult.'*

In cases of acute blood loss, the general tendency was to replace the amount lost with the same volume of blood. In such cases, the cause and also the volume of blood loss was an important factor in determining the time and quantity of transfusion. Most respondents said that when blood loss was acute, e.g., due to trauma, then the patient was transfused aggressively, because delaying transfusion could risk his life. *'In developed countries, as lab investigations are automated and reliable, assessment of blood loss was accurate; with all required details available promptly at the click of a button. Such facility is not available here, decision-making in emergency situations becomes difficult.'* Similarly, difficulty in decision making was also encountered in patients with complications and those at extremes of age.

Table 6.1 Summary of Findings

Questions	Yes (%)	No (%)	Not Sure/Cannot Say (%)
Difference of opinion in prescribing	56	34	10
Problems with blood bank functioning	36	58	6
Experienced difficulty in finding donors	84	12	4
Awareness of risk and safety after testing	38	62	-
Scope for reduction of transfusion	62	30	8

Awareness of guidelines	44	56	-
Awareness of availability of components in hospital	90	6	4

Perception and Awareness about Social Dimensions of Transfusion

Responses to Effect of Factors other than 'Clinical' on Transfusion Decision-Making

Questions were posed to the respondents in order to understand whether factors like the socio-economic condition of the patient, cultural beliefs, institutional factors, cost of treatment etc., affected decision making.

The vast majority of the respondents, (92.6 percent) felt that socioeconomic condition of the patient or factors like limited resources did not influence transfusion decisions. '*Need for transfusion would be the same for the poor or the rich alike.'* They had difficulty in relating socioeconomic factors to medical science and did not appreciate the role of factors other than clinical in "rational scientific" practice. *'Socioeconomic factors predispose the patients to anemia but do not guide treatment decisions. Decisions are based on scientific principles.'*

They argued that socio economic factors like poor hygiene, sanitation, ignorance, poverty and illiteracy could be predisposing factors for anaemia, but would not guide transfusion decisions. However, on further probing and explaining with examples, a few clinicians did acknowledge the presence of such factors.

They conceded that physicians sometimes considered transfusions for patients who were old, poor, would not be properly cared for at home or patients from remote areas who could not come for regular check-ups. Some patients were given transfusions to achieve a basic minimum hemoglobin level before being discharged on prescriptions for oral hematinics. Similarly,

surgeons widely believed that a low hemoglobin level delayed post-operative recovery so many borderline anemic cases were transfused before discharge.

Most prescribers were of the opinion that transfusion was not the ideal course of treatment, and were aware that transfusions were not a substitute for nutritional deficiencies. The guidelines also indicate that oral hematinic should be prescribed to correct borderline anemia without any other concomitant illness.

An example of guidelines not being followed for reasons of economy was that of plasma transfusion. '*It is common to find patients with burns having hypo-albuminemia. Plasma was preferred to commercial albumin preparations for its low cost. Using albumin for all burn patients would significantly increase the hospital expenditure as the price of one bottle (100 ml) of albumin was Rs 2840'*. There was also a perception among most clinicians that plasma was a by-product of component preparation and is available in surplus quantity with the blood bank. *'Albumin is costly. For the burns patients, we routinely need transfusions to build up proteins, so we transfuse fresh frozen plasma (FFP) instead of albumin. Fresh frozen plasma is always available in the blood bank and donation is not insisted upon for this product.'*

The effect of social class in transfusion decision-making was more pronounced among the well-connected VIP patients admitted in the nursing home and special wards of the hospital. The experience with such patients was same across all specialties. Doctors did not want to take any risk with this group of patients, so they were transfused liberally. *'When it's a V.I.P. patient, we don't want to take any chance'*.

In the emergency wards, where high patient load hindered adequate monitoring of patients, transfusions were given at the slightest indication. This was to avoid a crisis situation, as repeated monitoring of patients was difficult.

Lack of proper institutional support like inadequate laboratory support in the emergency hours resulted in more number of transfusions because decision was made on the basis of the clinical signs and symptoms alone. Limited number of ICU beds and non- availability of emergency operation theatre on time, due to high patient load, also sometimes led to aggressive treatment and unnecessary transfusions. This happened specially in situations where a bleeding patient had

to wait for his turn. The doctors did not want to take any risk as acute blood loss was a rapidly changing situation.

While influence of such factors on decision making was acknowledged by the respondents only after probing with specific examples, these appear to be considerations for the benefit of patients under resource constrained conditions of the patients and of the hospital. Therefore they were not considered as influences of 'Non-clinical' or 'socio-economic' in nature by the prescribing doctors. The prescribers were coping with these issues on a daily basis and it had unknowingly become a routine affair for them.

Perceived Role of Transfusion among the Recipients' and their Attendants

Lack of awareness of the hazards of transfusion was common among the patients.

'People do not think that blood transfusion can transmit diseases, they only think that it saves life.' According to one prescriber, the common perception among the public was that transfusion was very important for patients' well being and any blood loss should be replaced immediately.

'*In fact they panic at the mere sight of blood, as they consider bleeding is an indication of patients deteriorating condition.'*

The common perception among people was that blood transfusion improves the general wellbeing of the patient and helps in a rapid recovery. Often, parents of children from poor socio-economic backgrounds wanted to 'buy' blood as it was perceived as a 'tonic' and expected to improve the general condition.

'The poor, who don't even have enough money for treatment, are ready to pay for blood, as they think that blood transfusion works like a tonic.'

Blood donation for patients with anemia was made without much coercion. But if later on in the course of treatment, transfusion was not required and then the patients' relatives questioned the doctors' intention. Though some with better education did understand the situation, most felt that the patient was not given proper treatment, if transfusion was withheld. Sometimes the donors

also went to the blood bank to enquire about what would happen to the donation which was not transfused to their patient.

'There is pressure from the relatives to transfuse when the patient is acutely bleeding, but we generally don't succumb to these pressures.

Few educated relatives were aware about transfusion hazards. It was this group that also requested for "directed donations" i.e., the donation from a family member reserved for their patient. "*A known donor is safer than an unknown donor*".

'The educated want more information about disease transmission via blood.'

When asked about taking consent for transfusion, the treating doctors felt that in the present scenario, it would be very time-consuming and unnecessary.

'Confusion will be created if the patient is asked for consent for transfusion as they are illiterate. The final decision in any case lies with the treating doctors'.

'Consent is not necessary as being in government service we have protection from the Consumer Protection Act (CPA)'.

Perceptions about Ways of Improving Transfusion Prescribing Practices

Knowledge of W.H.O. Guidelines

The majority of respondents (56 percent) were not aware of the WHO or national guidelines. *'We don't remember the guidelines, but we can make a clinical judgment by experience.'*

44 percent of the respondents knew about the guidelines, but only 18 percent followed them.

Anesthetists followed the guidelines because it was an integral part of their training and did not feel the need for any other guidelines. Surgeons were dependent on the anesthetists for decisions taken at the time of surgery, *'As surgeons we depend on the anesthetists' for transfusion decisions'.*

Most respondents felt that the blood bank doctors should be more proactive in disseminating the guidelines among the practitioners.

'Yes, I have heard of transfusion guidelines, but not on tips, we should have regular continuing medical education (C.M.E.s) for doctors of the hospital.'

As far as modification of the guidelines is concerned, most were of the view that the already laid down guidelines must be followed first, before adaptation is considered. A few respondents felt that a transfusion policy should be in place- *"Similar to 'Antibiotic policy', we should have a transfusion policy for the hospital."*

Physicians did not feel the need to consult the blood bank doctors, but surgeons said that they sometimes consulted the blood bank doctors, about the dose or type of blood-component to be transfused. *"We sometimes feel the need to discuss the indications for transfusion with the blood bank officers.'*

Scope for Reduction in Transfusions

62 percent of the respondents acknowledged that there was over prescription of blood. They were of the opinion that between 10 percent-30 percent transfusions could be avoided but that it was difficult under the given conditions.

'Guidelines are of no use in emergency conditions. We cannot wait when the patient is serious and over transfusion is bound to take place in such situations because our primary concern is to save the life of the patients come what may.'

30 percent of the respondents felt that there was no scope for reduction in transfusions, as they were aware of the hazards and were already restricted in their practice. These respondents were also the ones who did not want to acknowledge that any deviations from prescribed procedures took place in scientific medical practice.

Of all, 8 percent of the respondents thought that over- transfusion was rare.

'Many times transfusions are given even when they can be avoided because doctors want to keep themselves safe, do not want to get unnecessarily involved in medico legal problems- want no 'lafda'(problems).

Many surgeons (mostly males) felt that the maximum scope of reduction in transfusions was from the gynecologists (mostly females) who are very prone to over- transfuse patients. '*The*

(male) surgeons are daring, can take risks and more skilled in the procedures, hence use less transfusions.'

The surgeons were over-cautious when children or old patients were being treated.

'When we operate on children or old patients, we take no chance." The anesthetists also are cautious with children and old patients.

Most felt that better communication between the blood bank staff and the users could solve some of the problems and help in minimizing transfusions.

'Some of the inappropriate transfusions can be cut down if we are assured that blood would be available as soon as it is required. Then we would not be in a hurry to get the blood released in advance.'

'Sometimes blood bank staff does not take matters seriously leading to delays.'

A few senior surgeons were of the opinion that blood was only requisitioned when absolutely necessary and there was no over transfusion. *"We only place requests when it is absolutely necessary"*

Opinion about Suggestion to Document Indications of Transfusion for Improving Transfusion Practice

Asked whether proper documentation of the indications by clinicians would act as a check and lead to more conscious transfusion practice, 18 percent respondents felt that judgment of transfusion is made on the basis of both laboratory results and assessment of the clinical condition of the patients, which are already documented on the case sheets, in the form of daily records. They felt that separate documentation was not required as it would lead to duplication of work and add to the already existing workload on the residents. It would also divert them from other important patient care activities.

However some conceded that *'Transfusions can be restricted, if we write the indications for transfusions on the case sheets, before ordering',* agreeing that documenting the rationale for

transfusion of blood and components would serve as a check and curb casual requests for transfusion.

Problem with Donors

Arranging for blood was experienced as a major problem, as the system of sourcing of blood was dependent on 'replacement donations'. To motivate a relative or attendant for donation was very difficult and time consuming for the clinicians as the onus of replacement was on them. *'Many people refuse to have blood drawn even for a sample (testing); it is difficult to expect them to donate."*

The respondents felt that this was due to several myths and misconceptions about blood donation that abound among the general public. The commonest myth is that blood donation causes weakness and impotence among males. *'First spread public awareness through IEC, ensure availability of blood and components… the rest will fall in line.'*

Arranging donors for patients who came from outside Delhi was even more difficult and getting them to bring people for more than one unit was almost impossible, as most did not have more than one attendant. The available attendant burdened by the task of looking after the patient was usually tired, overworked and hesitant to donate. The clinicians observed that, often, relatives who volunteered to donate were either anemic or underweight and declared 'unfit' by blood bank doctors.

Some respondents were of the opinion that most patients came to the government hospital for free treatment because they were poor. *'Patients think everything in the hospital should be supplied free-even blood transfusion.'*

The current trend of nuclear families and children staying away from parents too made it difficult to provide replacement. Similar problems were seen among migrant laborers who leave their families behind in the villages making it difficult to find a next of kin to donate. The only help came from fellow laborers who were sometimes hesitant, or were unfit. A respondent observed, *'the educated and well connected patients can 'get away' without donating; it is the poor patients who are forced to make replacement donations.'*

The respondents also observed that the female members of the family were commonly very protective about their husbands and feared that the male members who are the bread earners would become weak after donating.

The Experience of Interaction with the Blood Bank

Most of the clinicians acknowledged that there have been major improvements in blood banking in the last few years; mostly in the form of technology for testing and component separation. Also blood shortages were rare with better availability of blood and blood components. Earlier they often had to depend on the Red Cross blood bank for rare blood groups and blood components.

There were mixed responses regarding the functioning of the blood bank. 58 percent had no problems, 36 percent voiced some problems, while 6 percent were unable to give a clear opinion. Generally the prescribers felt that there was no problem in getting blood issued from the blood bank when a donor card was available. However, difficulties were occasionally encountered especially when negative blood groups were required.

'Blood bank services are by and large satisfactory. Sometimes there are problems with availability of negative groups.'

'There are problems on both sides, sometimes residents make mistakes, forms not properly filled up or submitted in time, seniors have to intervene then problems are resolved.'

'Technicians often refuse to issue blood in the evening and night shifts, if no replacement donors are available '.

Most surgeons said that they encountered no problems in planned elective surgeries. In the evening and night shifts, however, clinicians faced problems like scarcity of donors which were generally resolved after telephonic requests. *'If we speak to the staff personally they issue blood even when there are no replacement donors'.* In their experience sometimes there was delay in issue in evening and night shifts.

Some had problems with the timings of donations at the blood bank. '*We in the department of Plastic Surgery, run OPD clinics in the afternoon, so relatives are available in the evenings for*

donation. The blood bank staff asks the donors to come in the morning causing inconvenience to donors."

The Problem with Pediatric Transfusion

Some pediatricians had difficulty with the volume of blood that was issued to them. Since the requested volume of transfusion was calculated by the weight of the child, blood collected in the adult size bags had to be divided. The blood bank staff separated it manually and the measurement was approximate. The clinicians proposed the use of pediatric bags where aliquots of the volume required for a particular transfusion could be made in the blood bank. The procedure being followed at present was transferring half of the blood unit into another bag, which made it difficult to assess the exact amount to be transfused.

Summary of Findings

Component use was still not a common practice even though only about 10 percent respondents were not aware of the availability of components in the hospital blood bank.

The results of the schedule based interview clearly showed that there was inadequate knowledge of indications for blood and component use among the clinicians. The dose and indications for component use were not known to approximately 65 percent of the respondents. It was also found that 56 percent of the clinicians were not aware that transfusion guidelines existed.

The responses also indicated that transfusion prescribing decisions could also be influenced by cases of medical dilemmas and grey-zone situations, the clinicians positive and negative experiences of transfusions and non- clinical factors like the problems in arranging for replacement donors, availability of blood/and components, high patient load and lack of certain basic facilities also affected decisions.

An example of institutional policy on cost containment influencing transfusion decisions was seen in burn patients with hypoalbuminemia where fresh frozen plasma was generally preferred to commercial albumin because of its high cost, ignoring safety issues. The guidelines on the other hand recommended use of fresh frozen plasma for coagulation factor deficiencies.

The perception of transfusion-associated risks was found to be low, since very few had encountered serious transfusion reactions. Moreover more than one-third of the respondents, i.e., 38 percent thought that tested blood was absolutely safe for transfusion and were not aware of the problems of window period donations. Future problems due to risks of transfusion-transmitted infections were not taken seriously as the clinicians were concerned with the immediate results of treatment.

Most respondents faced a lot of problems in motivating patients' attendants for replacement donations. Overall, the experience of the respondents with blood bank services was largely positive and felt that better communication between clinicians and blood bank could improve services further. They suggested that the blood bank doctors should play a pro-active role in dissemination of guidelines.

Thus, the explanation for changes in transfusion prescribing practices, in the study hospital that can be inferred from the clinicians' responses is a combination of:

low knowledge of guidelines, clinical conditions necessitating deviation from guidelines, health service conditions necessitating deviation from guidelines and blood donor and banking system issues

The clinicians' perceptions also imply that overuse of transfusion of components is likely to continue until, safety concerns are highlighted, blood banking and access to blood in time is ensured to all patients and clinicians are capacitated to think critically before prescribing transfusion.

In order to elicit more specifically the reasons for transfusion prescription as practiced by the clinicians, specific patients' records were discussed with the prescribing doctors, the findings of which is being presented in the next chapter.

CHAPTER-7

'Inappropriate' by W.H.O. Guidelines: Prescribers' Rationale for Their Transfusion Practices

W.H.O. guidelines provide indications for transfusing the right component, at the right time, in the right dose. An in depth enquiry into the reasons for transfusions considered inappropriate by W.H.O. guidelines and the circumstances under which these decisions were made, was undertaken for 80 current cases in the year 2007 with the following objectives:

a) To understand the clinicians' rationale for transfusions,

b) To identify the circumstances, under which the transfusions were ordered.

The 80 cases identified as inappropriate transfusions as per guidelines laid down by WHO, were selected from among the requests received in the blood bank for acute blood loss, elective gynecological surgery, elective general surgery and anemia, using the following criteria:

(a) Transfusion of whole blood/packed cells for elective surgery in patients with hemoglobin more than 10 gm percent.

(b) Transfusion in anaemia with haemoglobin between 7 gm percent and 10 gm percent.

(c) Transfusion of fresh frozen plasma or platelets in inappropriate doses or when not indicated.

(d) Transfusion of single unit of whole blood/packed cells to patients of elective surgery.

Case records were then obtained and examined, followed by in depth discussion with the prescribing clinicians.

With the findings from this in-depth enquiry, a Focus Group Discussion was conducted with the prescribers with the following objectives:

(1) To get feedback from the study group on the results of the previous two parts of the study, especially on the problems identified.

(2) To reach a consensus on what could be the best possible way of transfusion prescribing practice in the given circumstances.

(3) To identify changes required in the blood bank practices.

Based on comparison of the prescribing practice with the WHO guidelines and with consideration of the justification given by them in the given context of the hospital and its users, both through individual interviews and through FGDs at departmental level, the case studies were further classified into four categories:

1) Appeared to be rational by WHO guidelines on detailed scrutiny

2) Clearly irrational (inadequate knowledge of guidelines)

3) Differed from guidelines but had a reasonable justification (adapting to context)

4) Differed from guidelines and difficult to judge as rational or irrational, (as had elements of both 2 and 3).

Categorization by Prescriber's Rationale of Cases Considered Irrational by WHO Guidelines

Of the 80 cases selected as "Irrational" from the request forms received at the blood bank for in depth study, 15 percent were found to be rational on detailed scrutiny by WHO criteria. The request forms have limited information therefore appeared to be irrational on first screening. When more information became available from the case records and interviews, they were found to be rational by application of WHO criteria.

Out of all, 37.5 percent more could also be considered "Rational" when rationality according

to the context was considered to ensure proper treatment and in the best interest of the

patient. Here, rationality according to the context meant dealing with problems in decision

making at the individual clinical case level, such as with proper estimation of blood loss, or

due to institutional limitations that hindered practice according to prescribed guidelines. This was especially seen with cases that fell in the 'grey zone'.

Therefore categories (1) and (3) i.e., 52 percent of the total cases can be considered rational prescribing; If we remove category (1) from the 'rational by W.H.O.' then 68 cases remain. Out of the 68, give the number were then 'rational'.

Category (2) was of those cases found to be clearly irrational after detailed scrutiny because it was found that inappropriate transfusion was the result of low levels of knowledge of guidelines and comprised of 26.25 percent of the total 80 (or 30.88 percent of the 68). In this category transfusion was given either for wrong indications or in wrong dosage and the prescribing clinician did not provide adequate rational basis for it.

The 21.25 percent (or 25 percent of the 68 cases) that fell in category (4) were difficult to place clearly as either rational or irrational. They had elements of both (2) and (3) as it was found that both health service system problems and inadequate knowledge of guidelines were responsible for transfusion decisions in these cases indicating that problems in this group need to be further analyzed and discussed to make any judgement (Table-7.1).

Table 7.1 Categorization by Prescriber's Rationale of Cases of Transfusions Considered Irrational by WHO Guidelines

SN	Categories	1.Rational even by WHO on detailed scrutiny	2.Clearly irrational	3.Differed but had reasonable justification	4. Differed but difficult to judge as rational or irrational	Total
A	Acute Blood Loss	2	4	9	5	20
B	Anemia	3	3	11	3	20
C	Surgery	2	8	5	5	20

D	Obstetrics and Gynecology	5	6	5	4	20
E	Total	12(15%)	21(26.25 %)	30(37.50%)	17(21.25 %)	**80**
F	Cases Irrational by WHO%		30.88	44.11	25	**68**

Description of Case Studies

Analysis of the case records and discussion with the prescribers again showed that transfusion practice was affected by several factors, which can be broadly described as clinical factors, socioeconomic factors, institutional factors and health service system factors.

These factors become clearer by the examples of specific case studies discussed below. The case studies are illustrative of the categorization shown in table-7.1. As will be evident, the criteria of categorization were (1) concordance with WHO guidelines, and (2) deviation from WHO guidelines for rationale that was considered valid from the point of view of patient benefit.

A. ACUTE BLOOD LOSS

Twenty cases of inappropriate transfusions with the primary symptom of acute blood loss were selected. The age group of these patients ranged between 27 to 60 years and their hemoglobin ranged between 7-12.4 gm percent. There were seven cases of active hematemesis, five cases of excessive intra operative blood loss, 2 cases of trauma/road traffic accident, two cases of bleeding per rectum, two cases of hemoptysis and two cases of ruptured ectopic pregnancy. Whole blood and fresh frozen plasma were transfused in these patients with acute blood loss.

Illustration of Category 1: Rational Transfusion

Trans Urethral Resection of Prostrate

A 60 year old male with complaints of urinary problem was diagnosed as having enlarged prostate and transurethral resection was planned. His pre-operative hemoglobin was 12.1gm percent and post-operative hemoglobin was11 gm percent. He was transfused 4 units of whole blood intra operatively.

Questions:

A. There is minimal loss of blood in TURP why was 4 units of whole blood transfused when the preoperative hemoglobin was 12.1 gm percent.

Prescriber's rationale: In this case, blood loss was more than expected which could be controlled with difficulty. It was suspected to be an arterial bleed. Transfusion was given on the advice of the anesthetist.

What do the guidelines say:

Guidelines say that when the blood loss is up to 1000 ml there is no need for transfusion as transfusion of crystalloids and colloids can take care of the loss. However, this seems to be a case of rational transfusion given to make up for the massive unexpected blood loss. The post-operative hemoglobin was 11 gm percent in spite of transfusion of four units, which indirectly shows that there was considerable intra operative blood loss.

Illustration of Category 2: Clearly Irrational

Hematemesis Requiring Liver Biopsy

A 53-year male with complains of hematemesis for 7 days, was admitted as a suspected case of chronic alcoholic liver disease with portal hypertension. He had hemoglobin of 8.5gm percent and deranged coagulation parameters. To establish the diagnosis, a liver biopsy was required. In preparation the patient was transfused two units of whole blood to correct anemia and one unit of fresh frozen plasma.

Question: Why was only one unit of fresh frozen plasma, which is inadequate dose, transfused to this patient?

Prescriber's rationale: Fresh frozen plasma was transfused to prevent bleeding during liver biopsy.

What do the guidelines say:

Fresh Frozen Plasma should be transfused when the International Normalized Ratio (INR)[7] is more than 1.5, suggesting a deranged coagulation profile. Usually the dose of fresh frozen plasma is 15 ml per kg body weight, which means 4-5 units, but may vary according to the clinical condition of the patient. Therefore, one unit of fresh frozen plasma is inadequate in dose for the desired clinical effect.

Illustration of Category (3): Differed from Guidelines but had a Reasonable Justification

Hematemesis

A 55-year-old male with complaints of bouts of bleeding for 3 days and restlessness reported to the emergency and was diagnosed as a case of chronic alcoholic liver disease. The patient was not in cardiac failure. The hemoglobin was found to be 10 gm percent. Two units of Whole blood and one unit of fresh frozen plasma were transfused.

Questions: Why were two units whole blood transfused at 11 gm percent when the patient was not in failure? Why transfusion of fresh frozen plasma as a single unit which is an inadequate dose was given.

Prescribers' rationale: Laboratory reports are sometimes unreliable. The patient looked clinically anemic and since he was having hemoptysis for the last three days and his deteriorating clinical condition, whole blood transfusion was given. Coagulation profile could not be done as tests were done only twice a week. As patients with alcoholic liver disease are known to have

[7] International normalized ratio (INR) is a calculation made to standardize prothrombin time. INR is based on the ratio of the patient's prothrombin time and the normal mean prothrombin time. Prothrombin time is a test to learn how fast the blood clots in patients receiving oral anticoagulant medication. This test may be used in patients with prosthetic heart valves, venous thrombo embolism, or anti phospholipid syndrome.

deranged coagulation profile, fresh frozen plasma was transfused. But since only three donors were available at that time, only three units could be obtained from the blood bank.

What do the guidelines say:

Ideally, when the hemoglobin is more than 10 gm percent, transfusion of red cells is not required, since the body can compensate for mild anemia.

Fresh frozen plasma should be transfused when the International Normalized Ratio (INR) is more than 1.5, suggesting a deranged coagulation profile and 4-5 units are required.

Transfusion of whole blood was given because of clinical judgement of anemia in spite of the fact that the laboratory reports showed hemoglobin of 11 gm percent. Laboratory investigation for coagulation profile was not possible so fresh frozen plasma was transfused in anticipation of bleeding. Thus the decisions were made because of inadequate laboratory support, unreliability of laboratory results and the non-availability of replacement donors.

Illustration of Category (4): Differed from Guidelines but Difficult to Judge as Rational or Irrational

Road Traffic Accident

A 32 year male was brought to the emergency with fracture of right tibia after road traffic accident. He was also suspected to be having intra-abdominal bleeding. His hemoglobin was 9.5 gm percent. This patient was transfused 2 units of whole blood and 2 units of fresh frozen plasma.

Questions: Why was whole blood transfused when the hemoglobin was borderline?

Why was fresh frozen plasma transfused in this case?

Prescriber's rationale: The laboratory reports showed borderline anemia. The treating doctors were of the opinion that in cases of active bleeding the hemoglobin level is not a true indicator of anemia and may show a falsely high reading, as more loss could have occurred by the time the reports came in. Since the patient needed operative intervention, transfusion was given as a

precaution. In the emergency ward sometimes close monitoring for blood loss is not possible because of high patient load. Fresh frozen plasma was given to correct for volume loss.

What do the guidelines say:

Guidelines say that in cases of acute blood loss, an approximate assessment of proportion of blood loss can be made by close monitoring of vitals. Hypovolemia has been categorized in four classes on this basis. class1 hypovolemia-when the blood loss is up to 15 percent, class 2 hypovolemia-when loss is between 15 percent to30 percent class3-when the blood loss is 30 percent to 40 percent and class 4 when the blood loss is more than 40 percent. Transfusion is indicated when hypovolemia falls in category -2, with 15 to 30 percent of blood loss. For class-1 hypovolemia transfusion of colloids and crystalloids should suffice. WHO guidelines say that fresh frozen plasma should not be used for correction of fluid imbalance. Instead infusion of colloids and crystalloids which is a safer option should be used to correct volume loss. Therefore fresh frozen plasma use here was unjustified.

Discussion with Prescribers

The chief reason for deviation from guidelines in this group of cases was disparity in the clinical condition of the patient and the laboratory results, high patient load especially in the emergency wards that hindered close monitoring and dealing with anxious relatives.

The prescribers felt that laboratory reports cannot be always relied upon. When asked about mismatch between laboratory reports and the clinical picture, they were of the opinion that '*the clinical picture helps in correct assessment, instead of waiting for laboratory reports which may sometimes lead to delay in treatment. Moreover, disparity has been found even in reports from the same laboratory."*

Pressure from relatives also built up when there was delay in the availability of emergency operation theatres. Active intervention from the doctors was expected until the operation theatre became available. In these situations, frequent monitoring was necessary, to manage the patient appropriately. Relatives feel satisfied when they *"see"* their patient being treated with IV infusion fluids or transfusions in active bleeding cases. "*In such times verbal reassurances alone don't help*". The doctors in the absence of proper institutional support were forced to 'give in' to

requests for transfusion. This problem was aggravated by the negative image of government hospitals among the people. Many relatives felt that in government hospitals the treatment given is *"too little too late", "and no one cares"*. This perception sometimes led to aggressive behavior of the relatives. *"The patients are often in a critical condition either because they have initially gone to private practitioners or are referred to us when the condition has worsened"*

In the FGDs, the residents agreed that sometimes the guidelines could not be followed, especially in the emergency wards where the workload is high, close monitoring is often not possible and there is pressure to act fast. As they are the first line of contact with the patients, they were answerable and had to be extremely cautious, so they preferred to be liberal with transfusions. They agreed with most of the factors listed by me as the findings from analysis of cases and said that sometimes it was very difficult to work in such situations.

Discussions also revealed that, in acute blood loss, since the situation was a rapidly changing one, there was panic and transfusions were given as a precaution to stop the patient's condition from deteriorating. However as per guidelines up to a loss of 1000 ml, blood transfusion is not required, only colloids and crystalloids suffice. Though intravenous fluid infusions are started routinely in profusely bleeding patients, blood transfusion is generally given as soon as possible until haemostasis is achieved. Since in emergency wards, periodic monitoring of the vitals was not possible due to high patient load, blood loss was treated with caution and withholding transfusion was considered risky.

The prescribers were of the opinion that excessive intra operative blood loss could result from multiple factors like delay in hemostasis, high blood pressure, surgeons' skills etc. The anesthetists felt that in difficult situations such as these their primary concern was control of bleeding and making the patient hemodynamically stable.

When the prescribers were questioned about why fresh frozen plasma transfusion was given in case of hematemesis with liver failure, without waiting for the results of coagulation profile, they cited problems with the laboratory as the reason. *"Coagulation factor assessment is an expensive investigation when ordered from outside laboratories. Our hospital runs the test only twice a week. Since the coagulation profile is invariably deranged in liver failure and bleeding is unpredictable, we transfuse fresh frozen plasma at the earliest as a precaution."*

Summary of Rationale for 'Irrational' Transfusion in Acute Blood Loss Given by the Prescribers

Acute blood loss results in a hemodynamically unstable condition since it is a rapidly changing situation. Hence assessment of blood loss becomes difficult in such cases. Further hemoglobin level in cases of acute blood loss is not a reliable indicator of anemia. Such patients need close supervision and constant monitoring of clinical parameters and assessment of ongoing blood loss which was not possible due to a high patient load and understaffed emergency wards, resulting in transfusions that could ideally be avoided.

Transfusions were also given as a precaution in cases where hemostasis requires surgical intervention and there was a delay in arranging emergency OT. The prescribers felt that it would be difficult to manage if the patient's condition deteriorated**.**

Visible blood loss is associated with panic resulting is pressure from relatives to act fast and take quick action. In medical cases of acute blood loss as in alcoholic liver disease with hematemesis, fresh frozen plasma transfusions were given without the coagulation profile report because daily testing facility was not available.

B. **ANAEMIA**

A total number of twenty cases of anemia with inappropriate transfusions were selected to understand the circumstances under which transfusion decisions were made. The hemoglobin ranged between 7 to 8.8 gm percent and the age group was between 16-60 years. There were various underlying causes that had resulted in anemia; nutritional (iron deficiency anemia, megaloblastic anemia), anemia secondary to blood loss (hematemesis, malena), or anemia secondary to bone marrow disease (aplastic anemia, pancytopenia), anemia associated with burns, with malaria and with cellulitis. Whole blood, packed cells, fresh frozen plasma and platelets were transfused in this category.

Illustration of Category (1) Rational Transfusion

Anemia with Pregnancy

The patient was a case of anemia with 38 weeks of pregnancy and was in the third trimester, with a hemoglobin of nine-gram percent. The patient was having breathlessness on rest. One unit of whole blood was transfused.

Questions:

Could use of oral hematinic be used for correction of anemia and transfusion be avoided in this case?

Prescriber's rationale:

The obstetrician decided to transfuse whole blood because the due date for child birth was close. Treatment with oral hematinic would take longer for anemia correction. The decision to transfuse was taken after clinical assessment to relieve symptoms of breathlessness.

What do the guidelines say:

To build up the hemoglobin levels in borderline anemia first a trial of oral hematinic should be given. Transfusion is to be considered only when trial of oral drugs fails to correct the anemia.

Since the due date for delivery was close, this was a case of rational transfusion.

Illustration of Category (2) Clearly Irrational

Nutritional Anaemia

A case of nutritional anemia reported with complaints of weakness, tiredness and pallor for 1 month. The patient was in heart failure. The hemoglobin was 7.1 gm percent and the patient was transfused 1 unit of whole blood at admission.

Questions:

Why was transfusion given before investigation for establishment of diagnosis of type of anemia and why was whole blood given instead of packed cells to a patient in failure?

Prescribers rationale:

The treating physician explained that transfusion was indicated because the patient was moderately anemic and that the practice was to transfuse whole blood along with diuretics.

What do the guidelines say:

The patient should be first investigated to establish the diagnosis of the type of anemia. Megaloblastic anemia can be treated by oral medication of vitamin B complex. Packed Red cells should be transfused if the patient is in cardiac failure to avoid overload. Therefore, this was clearly a case of irrational prescription of whole blood transfusion.

Illustration of Category (3): Differed from Guidelines but had a Reasonable Justification

Severe Anaemia

A 29yr female with complaints of weakness and giddiness for one month reported to the emergency. There were no symptoms of acute bleeding, or signs of cardiac failure. Her hemoglobin was 7.5 gm percent. She was diagnosed as a case of severe anemia and transfused two units of whole blood on the day of admission.

Questions: Why was whole blood given instead of packed cells?

Prescriber's rationale: Whole blood was transfused because the patient was symptomatic but not in failure. Whole blood, in addition to red cells contains plasma proteins. Most of the cases encountered are those of nutritional anemia with deficiency of both micronutrients like Iron, B complex and proteins. Albumin infusions indicated for correction of protein deficiency is very costly. Complete investigations would take at least two days as some special investigations are not done by the emergency laboratory.

What do the guidelines say:

In severe anemia packed cells should be given. Whole blood may cause volume overload in an anemic patient. Ideally albumin infusion is indicated to raise plasma protein levels because being commercially manufactured it is free from infections. The decision of the doctor was based on the understanding that giving whole blood could correct protein deficiency along with raising hemoglobin levels. Since transfusion of packed cells would also carry the same risk of exposure to infections as transfusing whole blood and was a cheaper option when compared to commercial albumin.

Illustration of Category (4): Differed from Guidelines but Difficult to Judge as Rational or Irrational

Anemia with 30 percent Burn

A 35-year-old male with 30 percent burns and a hemoglobin of 9.5 gm percent, was transfused one unit of whole blood and two units of plasma.

***Questions*:** Why was whole blood transfused in a borderline anemic patient?

Why were two units of fresh frozen plasma given?

Prescriber's rationale: Correction of anemia improves the general well-being of the patient and helps in recovery. One unit of whole blood was requested, along with two units of fresh frozen plasma. Fresh frozen plasma was transfused to raise albumin levels and could be obtained from the blood bank without a donor. Commercial Albumin is costly and its availability in the hospital is limited whereas plasma is abundantly available, so preferred.

What do the guidelines say:

The objective of red cell transfusion is to increase the oxygen carrying capacity and not to improve the wellbeing of the patient. The WHO indications for fresh frozen plasma say that it should be used only to correct coagulation deficiencies and not to correct protein deficiency. Instead commercial albumin which is safer and does not carry the risk of transmission of diseases should be transfused.

Discussion with Prescribers

An important observation related to the WHO guidelines was made by a senior doctor. *"WHO criteria are only based on the symptoms of anemia as the primary problem. The underlying cause of anemia should be also be given due consideration".* In patients with co-morbidities like cardiac or renal disease, it was difficult to predict how the individual would respond to medical or surgical stress so these were transfused liberally.

There was a striking difference in knowledge of guidelines between specialties. The physicians had a good understanding of the patho-physiology of anemia. The discussions which ensued mainly focused on the problems faced by them in following the guidelines in actual practice.

On pointing out that transfusion for anemia many times is started on the basis of hemoglobin report, without ascertaining the cause of anemia, the physicians were of the opinion that transfusion is given only when the patient looks severely anemic clinically, even if the laboratory reports say otherwise. *'Patients do not report until they are severely anemic, then we don't waste time in the routine investigations, we prefer to transfuse. In our experience anemia is mostly due to nutritional deficiency therefore proteins in the whole blood makes up for the protein deficiency. Moreover, there are difficulties faced in the judgment of transfusion needs of the patient at the individual level'.*

They felt that a patient should be assessed in totality and transfusion decision should take into account the entire picture. Each episode of transfusion could not be seen in isolation and labelled as appropriate or inappropriate. '*The judgment to transfuse or not, is a complex decision depending upon the clinical signs and symptoms, duration of illness and the condition of the patient in its totality'.*

Their clinical experience showed that correction of anemia with transfusion did help in patients' recovery, though a precise level of hemoglobin could not be suggested, as again this would depend on the individual case and the clinical condition. '*When a patient is examined, the primary concern is the main disease and anemia is secondary to that. Moreover, studies show*

that presence of anemia is associated with increased risk of death, therefore correction does help.'

The physicians were of the opinion that transfusion criteria should also take into account the lower BMI of the Indian population. "*The criteria set by WHO is based on the BMI of the western population. Therefore, we must develop our own criteria, be it for transfusion or blood donation."*

Extending the discussion to dengue cases, their observations were informative. The physicians felt that during epidemics, the prescribed cut-off guidelines for platelet transfusion could not be followed and there was every chance of missing small hemorrhages. '*In our set up we cannot wait for platelets to fall to low levels of <20,000/ul. The patient load is very high and panic created by the media makes the situation difficult to handle. During the epidemic, every patient with fever reports to the hospital for a check- up and relatives demand transfusions if the platelet counts are low.'* At such times it is difficult to convince them that transfusions can wait. They suggested that clear cut hospital guidelines should be framed to avoid unnecessary transfusions in dengue epidemics.

'Inpatients with dengue, we monitor the platelet count daily. If a constant downward trend is seen we prefer to transfuse platelets, as once bleeding starts it becomes difficult to control. During the dengue epidemic, the patient load increases many fold and close monitoring of each patient is not possible.'

On the use of fresh frozen plasma in hypo- proteinemia it was pointed out by the clinicians' that albumin is expensive with a shorter half-life and requires multiple transfusions. They felt that results of studies on albumin use were controversial and a better understanding of its role was required. On the other hand, plasma is available free of cost, it is a good source of protein and increases the oncotic pressure, but its dose of administration and indications were not clear. *"Cost is definitely a factor, if we are getting it for free (as a by-product of packed cell preparation) why should the hospital spend? After all you have a surplus of FFP in the blood bank"*

Summary of Rationale for 'Irrational' Transfusion in Anaemia Given by the Prescribers

The prescribers preferred to depend on the clinical diagnosis for decision making as sometimes the laboratory reports were questionable and did not match the clinical condition of the patient. Transfusion was given in these circumstances to prevent impending heart failure as saving patient's life was the primary concern.

In borderline cases there was difficulty in judging the real need for transfusions but to be on the safe side the doctors prescribed transfusions. Moderate to severe anemia due to nutritional deficiency was mostly seen in those from low socioeconomic group. In such cases doctors were of the opinion that nutritional anemia is generally dimorphic and transfusion of protein in whole blood would correct the protein deficiency also.

Commercial albumin is expensive, costing about Rs 3000 for 100 ml bottle and was restricted in supply. Therefore, fresh frozen plasma is transfused for burn patients as a substitute for proteins in spite of the fact that guidelines say otherwise.

When the patient was brought to the emergency, the patient's attendants were not satisfied with treatment with oral iron & B complex. Instead there was expectation of active intervention which created a pressure on the doctors to transfuse. Many times, in spite of the fact that the actual requirement was for two units, only one could be given because of non-availability of donors.

C. ELECTIVE GENERAL SURGERY

Twenty surgical cases which had received inappropriate transfusions were selected to understand their rationale. These included cases from General Surgery, Orthopedic Surgery, and Neurosurgery. Out of these, eight were laparotomy for perforation peritonitis or intestinal obstruction, two were cholecystectomy, two with breast carcinoma, one was a right sub trochanteric fracture, one was fracture shaft tibia, one of colloid goiter, two were operated for subdural hematoma/head injury, two cases of renal calculus and one was operated for prostatectomy.

The age groups of these patients varied between 16-50 years and the hemoglobin was between 8 and 14.5 gm percent. The components transfused for these cases were whole blood and fresh frozen plasma.

Illustration of Category (1): Rational Transfusion

Cholecystectomy

Laparoscopic cholecystectomy was planned for a patient diagnosed with cholelithiasis. Due to uncontrolled bleeding, abdominal incision had to be made. Two units of whole blood were transfused. hemoglobin before surgery was 11.0 gm percent. Post-operative hemoglobin was not documented.

Question:

Why was transfusion given in laparoscopic cholecystectomy which is a minimally invasive procedure with little blood loss?

Prescriber's rationale:

No transfusion is required for laparoscopic cholecystectomy, but since bleeding could not be controlled, conventional abdominal incision had to be made to fasten the bleeders. Transfusion was given to make up for excessive blood loss. Amount of blood loss and the post-operative hemoglobin was not documented in the case sheet.

What do the guidelines say:

Blood loss less than 1000ml should be managed by colloids and crystalloids.

Illustration of Category (2) : Clearly Irrational

Perinephric Abscess

A 45year old male with drained perinephric abscess with a hemoglobin of 10 gm percent was transfused one unit of packed cells in the post-operative period.

Question:

Why was transfusion given in the post-operative period when the hemoglobin was 10 gm percent?

Prescribers' rationale:

Transfusion was given for improving general condition and better wound healing as the patient's general condition was very poor.

What do the guidelines say:

Packed cell transfusion should not be given for wound healing or to improve the general wellbeing. Building up the patient with diet and oral supplements in the post-operative period would be the ideal line of management.

Illustration of Category (3): Differed from Guidelines but had a Reasonable Justification

Perforation Peritonitis

A 17 years old male patient with complaints of severe pain abdomen and vomiting was diagnosed as a case of perforation peritonitis and was posted for exploratory laparotomy. His hemoglobin was 9 gm percent and was transfused one unit of whole blood intraoperatively.

Questions:

Why was 1 unit of whole blood transfusion given in this case? It could have been avoided when the preoperative Hb was 9 gm percent.

Prescriber's rationale:

The patient was clinically pale on physical examination. Laboratory reports from the emergency are not reliable and don't match the clinical assessment. Actually two units of transfusion was planned, but only one unit was transfused because only one donor was available at that time.

What do the guidelines say:

Transfusions should be avoided in patients with borderline anemia. However, the unreliable laboratory report, patient's poor condition and unavailability of donors are valid reasons for the decision taken.

Illustration of category (4) Differed from Guidelines but Difficult to Judge as Rational or Irrational

Intestinal Obstruction

A 27years old male patient with complaints of vomiting and severe pain in the abdomen reported to the emergency. He was diagnosed as a case of intestinal obstruction, with suspected perforation peritonitis, requiring immediate laparotomy. His hemoglobin was 9.5 gm percent. He was transfused one unit of whole blood and one unit of fresh frozen plasma.

Questions:

Could this whole blood transfusion be avoided?

What was the indication for transfusion of Fresh Frozen plasma?

Prescriber's Rationale:

Anaesthetist wanted to have blood ready in the operation theatre as the patient was operated upon in the emergency hours. Since the patient's relative had donated we preferred to transfuse it. One unit of fresh frozen plasma was transfused to make up for the volume loss, because a lot of fluid is lost during peritoneal lavage. Further, Fresh frozen plasma is easily available without having to provide for replacement donors. In this case deviation of guidelines was both due to non-availability of donors and inadequate knowledge of fresh frozen plasma use.

What the guidelines say:

Guidelines say that packed red cells are indicated for oxygen carriage in surgical blood loss. Transfusions should be avoided because a small volume loss can be taken care of by IV fluids alone. Fresh frozen plasma should be used only to correct coagulation factor deficiency and not to replace plasma volume. Colloids and crystalloids should be used for volume correction.

Discussion with Prescribers

Surgeons and anesthetists estimated blood loss differently and both groups agreed to this observation. The anesthetists generally over-estimated blood loss and were liberal with transfusions as compared to the surgeons. The anesthetists were very open in accepting that the guidelines were difficult to follow because the patients' transfusion needs were determined by several factors and varied on a case-to-case basis. They were very forthright in accepting the problems faced in assessment of blood loss in the operation theatres. They said that it was difficult to assess the amount of blood loss even in the operation theatres though it was easier than that in the wards. Tools for blood loss estimation were inaccurate e.g., counting of gauze pieces that could be fully or partially soaked in blood. The gauze pieces were washed and squeezed in a saline bath to estimate the volume of blood loss which was a crude method. Ideally, specialized weighing machines for weighing the gauze pieces before and after soakage should be used but were not available in the OT's.

Most surgeons believed that anemia hindered wound healing, but they also agreed that it was not a problem in borderline anemia. There was no clarity on the levels of hemoglobin below which transfusion would help in wound healing. *"The general condition and nutritional status of the patients we deal with is poor as they belong to low socioeconomic strata. Our patients cannot be compared to patients in western countries."*

'Usually transfusion is not given for wound-healing, but in anemic patients with poor general condition, experience shows that there is better recovery'.

The guidelines however said that, transfusion is rarely indicated for Hb > 10 g/dl and is almost always indicated for Hb<6 g/dl (particularly when the anemia is of acute onset). Guidelines also said that transfusion decisions should be made after assessment of the clinical signs and symptoms, particularly those of hemodynamic instability, co morbidity and the risk of further blood loss.

The predominant concern among the surgeons was inadequate knowledge of transfusion guidelines. They felt that many problems could be sorted out by educating the doctors. '*Proper knowledge of guidelines will instill greater confidence among doctors and help them handle emergency situations with ease'.* They were also of the opinion that the blood bank should be

more proactive in disseminating guidelines to the clinicians and should organize regular CME's. *"Why don't you people start taking classes for us?"*

Some surgeons felt that infections transmitted by transfusions were clearly not an issue as their only concern was *"immediate relief from symptoms*" for the patient and an *"uneventful post-operative period"*. They were not aware of the 'window period' infections and felt that tested blood should be safe for transfusion. "*If you blood bankers do your job well why should we worry about the safety of blood?"*

Some surgeons said that, '*many anesthetists do not start surgery until blood is released from the blood bank'*. '*Once released it is invariably transfused*'. They were of the opinion that the real solution of this problem lies with the blood bank. They believed that if the problem of delays is sorted out, then many unnecessary transfusions could be minimized. '*We have to be cautious when we are performing a surgical procedure especially when considerable blood loss is expected'.*

When asked about transfusion of issued units even when not needed, the anesthetists' said that this happened rarely. '*If a surgery is uneventful, surgeons take the credit, but if anything goes wrong intra- operatively, the anesthetists are 'blamed*'. Therefore, they did not risk waiting till the need for transfusion arose, instead preferred availability in advance. "*In any case, if we do not transfuse, the surgeons will almost always transfuse post operatively"*. The anesthetists also felt that the blood bank needs to address delays in issue of blood and components. '*We cannot cope with delays especially when the patient is bleeding during surgery.'*

Another issue which was strongly raised by the anesthetists was that of coordination between them and the surgeons/ gynecologists in the planning phase, which was necessary for optimization of blood use. "*The patient is dealt with in a "piecemeal approach"; the anesthetist gets to see the patient only at the time of pre- anesthetic check-up. Thereafter, it is the responsibility of the treating doctor to look after the patient till he is taken up for surgery. Similarly, after the patient is wheeled out of the O.T., anesthetists are not given any feedback about the patient, unless a major complication arises."*

Like the other specialties, even anesthetists thought that proper laboratory support is not available- "point of care" testing would help in better decision making, these are being used in some centers intra- operatively for coagulation profile testing.

Many prescribers complained about the behavior of the blood bank staff especially in the evening and night shifts. They said that routine donations (those for elective surgeries) were not taken in the evening shifts, causing a lot of difficulty and inconvenience to the donors. "*We have to spend a lot of time in convincing the donors but do not get support from the blood bank. Most donors are free in the evening and are willing to donate".*

The surgeons were of the opinion that the guidelines were based on evidence from the western countries; some would not be applicable to the Indian situation. For example, as anemia is widespread in India, the capacity to cope with anemia would also be different from other populations. Therefore, studies are required for better understanding of these aspects, as '*clinical experience is sometimes different from what the guidelines suggest'.*

The problem of pressure from relatives for transfusion, once blood had been donated was discussed. The surgeons found that this problem occurred frequently because in most situations the relatives were coerced to bring replacement donors. It was a common practice that the patient is posted for surgery only after the blood donations had been made. Also, the relatives kept count of the units released since they were made to transport units from the blood bank, a practice followed because of a shortage of nursing orderlies. The surgeons said that explaining why the transfusion was not required sometimes helped in convincing the relatives, but it required a lot of effort *"Who has the time? We are already so overloaded with work".*

The residents from general surgery agreed to most of the problems but some senior surgeons felt that instances of guidelines not being followed were rare and transfusion practice was by and large appropriate. Some did not want to acknowledge the problems out rightly and were uncomfortable with the issue of inappropriate practice. They however agreed that in emergency situations over prescription of transfusions due to 'panic' does take place.

There was serious discussion on documentation issues in which the juniors actively participated. Most of them agreed that documentation of the reasons for transfusion would curb unnecessary transfusion but would also increase the existing workload on the already overburdened residents. The residents working in the emergency wards observed that, '*the patients generally come to the*

hospital emergency after their condition has worsened and are serious'. Few options are available in such situations.

Summary of Rationale for 'Irrational' Transfusions in Elective Surgery Cases Given by the Prescribers

Many surgeons thought that transfusion helped in wound healing. Whole blood was used in surgical bleeding cases because they felt that the plasma in the whole blood made up for volume loss too. Many unnecessary transfusions were given because anesthetists' wanted blood in readiness in OT before the start of surgery. The usual practice followed was to invariably transfuse once blood was released. There were instances of under transfusion also where actually two units were required, but only one unit of whole blood could be given because of non-availability of donors. Non availability of donors also led to the transfusion of fresh frozen plasma because blood bank did not insist for replacement when fresh frozen plasma was demanded. Sometimes transfusions were given to build up hemoglobin for improving the general condition for future treatment like chemotherapy. Similarly, in tubercular intestinal obstruction where patients generally came from low socioeconomic groups were found to be anemic. The immediate concern of the surgeons was a healthy wound, relief from symptoms and no post-operative complications. TTI's (transfusion transmissible infections) were not of major concern to them.

D. ELECTIVE GYNAECOLOGICAL SURGERY

Twenty operated cases of elective gynecological surgery with deviations from guidelines were studied retrospectively for their rationale. They consisted of ten cases of total abdominal hysterectomy, eight cases of vaginal hysterectomy, one case of ovarian cystectomy and one of modified Shirodkar's stitch. The age group of patients ranged between thirty and fifty 55 years and the haemoglobin ranged between 8.5 gm percent and 14.2 gm percent. In this group the component used was whole blood and between one and three units were transfused. Transfusions were made in the preoperative, intra-operative or in the post-operative period.

Illustration of Category (1) Rational Transfusion

Uterovaginal Prolapse

A 40 year old female with 3rd degree of uterovaginal prolapse, underwent vaginal hysterectomy. Her preoperative hemoglobin was 10.8gm percent and post-operative hemoglobin was 9 gm percent. One unit whole blood was transfused.

Question: Why was one unit of blood transfused when the preoperative hemoglobin was 10.8gm percent?

***Prescribers' rationale*:** There was excessive blood loss during tissue dissection with much bleeding, so one unit of whole blood was transfused.

What the guidelines say: Transfusion of red cells is only indicated when the blood loss is more than 1000 ml. This could be labelled as a case of rational transfusion as the postoperative hemoglobin was less than preoperative hemoglobin indicating more than normal blood loss.

Illustration of category (2) : Clearly Irrational

Fibroid Uterus for Total Abdominal Hysterectomy

A 47 year old female, with complaints of excessive menstrual bleeding and weakness for a period of one year, diagnosed as fibroid uterus, was advised total abdominal hysterectomy. Her hemoglobin at the time of admission was 11.7 gm percent. She was transfused one unit of whole blood preoperatively.

Questions:

(A) As per guidelines packed cells and not whole blood should have been transfused?

(B)Transfusion of a single unit could have been avoided because only about 500-700 ml loss occurs in total abdominal hysterectomy, which according to guidelines could have been replaced by colloids and crystalloids alone?

Prescriber's rationale:

Whole blood is routinely transfused for surgical bleeding because it makes up for volume loss too. Menstrual bleeding of long duration results in low reserves; transfusion was given to improve the general condition of the patient.

What the guidelines say:

Packed cells must be transfused to increase the oxygen carrying capacity during surgical procedures. Volume deficit should be made up with the transfusion of colloids and crystalloids. Transfusion of packed cells/red cells should be considered only when blood loss is more than 1000 ml. For bleeding less than this amount colloids and crystalloids alone suffice. Red cell transfusion should not be used to improve the general condition of the patient. Therefore, transfusion was unnecessary in this case.

Illustration of category (3): Differed from Guidelines but had a Reasonable Justification

Total Abdominal Hysterectomy

A patient with negative blood group (B negative) and hemoglobin of 10 gm percent was transfused one unit of whole blood.

Question: It is unlikely that blood loss would have been more than 1000 ml in total abdominal hysterectomy, so why was whole blood transfused?

Prescriber's Rationale:

Uncertainty of availability in times of need, as negative group donors are rare was the reason for transfusion. In case transfusion was required later, it would be difficult to arrange a negative group immediately.

What the guidelines say:

Transfusion should be considered when blood loss is more than 1000 ml after proper assessment and not given in anticipation of bleeding.

Illustration of Category (4) Differed from Guidelines but Difficult to Judge as Rational or Irrational

Ovarian Cystectomy

A 40 year old female, with symptoms of burning micturition for one year, was diagnosed with right ovarian cyst and was advised ovarian cystectomy. The preoperative hemoglobin was 12.1 gm percent and one unit of whole blood was transfused post operatively.

Question: Blood transfusion is not indicated in ovarian cystectomy as there is minimal blood loss in surgery.

Prescribers Rationale: The anesthetist had kept one unit in readiness in the operation theatre, which was not used intra operatively. Ideally unused units should be returned to the blood bank. The patient looked pale and developed tachycardia postoperatively. Moreover, the laboratory reports are always not reliable, so decision for transfusion was made on clinical judgement.

What the guidelines say:

Blood transfusion is not indicated up to a loss of 1000 ml and can be managed with infusion of colloids and crystalloids. Transfusions should be avoided if the hemoglobin is above 10 gm percent.

Discussion with Prescribers

Inadequate knowledge of guidelines was discussed at length with the gynecologists where deviations were pointed out, citing examples from the case studies. Most senior doctors were of the opinion that the blood bank should play a more proactive role in disseminating transfusion guidelines to the clinicians an opinion similar to the surgeons. They said they were very busy and found little time to read and update themselves with latest developments even in their own specialties. "*Finding time for other subjects is extremely difficult."* They proposed that regular CME's should be held on the recent advancements in transfusion medicine. '*We are very busy*

with clinical work and cannot be expected to read so much and remember it. The blood bank should distribute the guidelines and organize regular CME's to update us.' An important observation was made with regard to transfusion prescription. They pointed out that many of the prescribers incorrectly ordered "whole blood" when they actually meant 'packed cells', which was done out of sheer habit.

The gynecologists had a clear opinion on the issue of raising hemoglobin to 10 gm percent before surgery. A trial of oral and injectable hematinic was given first to correct anemia. Transfusions were considered only when there was severe menorrhagia with an indication for urgent surgery. Gynecologists also agreed to the problem of accurate assessment of blood loss in the OT. The Gynecologists were also not clear on the guidelines for large volume loss or massive transfusions.

They felt very strongly that maintaining an adequate stock of blood should be the responsibility of the blood bank. This should be done by increasing voluntary donation and gradually phasing out the system of replacement donation. With an adequate stock, some problems like pressure from the relatives to transfuse blood would not arise. The blood bank should also provide for those who do not have donors. It is often seen that family members do not volunteer to donate for women patients.

All felt that motivating the relatives for donation is a hard task and many times elective surgeries had to be postponed to build pressure on them to arrange for donors. In desperation some approached the touts and paid for donors. *'The blood bank should hold more voluntary blood donation camps and provide blood for all patients, arranging donors is very difficult and we waste a lot of precious time that otherwise could have been used for patient care."*

Another issue that they strongly felt about was that the reason for deferral of donor should be communicated in writing to the treating doctor.

Like the surgeons, the Gynecologists were also of the opinion that 'anxious' relatives could be handled by proper communication. The doctors, by virtue of their position could explain the actual position to the patients' relatives hence proper communication was essential.

The gynecologists did not encounter any problems with a surgical blood loss of up to 500 ml, but they became cautious with any blood loss exceeding this amount. Regarding over-transfusion they were of the opinion that it is of rare occurrence. '*We critically assess the situation after transfusion of one unit has been made'.*

The experience of the gynecologists with the laboratory was similar to the other prescribers. "*The laboratory does not always give accurate reports; hence many assessments for transfusion requirement are made on clinical parameters alone".* Their experience showed that if the patient developed tachycardia along with anemia in the post- operative period, transfusion helped to relieve the symptoms resulting in improved patient outcomes. A routine practice that was followed was assessment of anemia on the third post- operative day. Such practices helped in proper assessment of transfusion needs.

Regarding the issue that once released, transfusions were invariably given even when not required, elicited intense reactions. The gynecologists out rightly denied it. *"First keep a record of the units that we have sent back to the blood bank, because we only transfuse when necessary. When not required, blood is returned to the blood bank".*

"*An account of how many units of blood were requested and how much was returned from the OT, when released in advance should also be maintained by the blood bank and disseminated among the users."*

'*The blood bank needs to improve and assure us that blood will be released within 10 minutes. This would minimize the units of blood being issued to the OTs' in advance.'*

Some senior doctors also felt that a modified request form to serve as a checklist and a reminder should be introduced immediately. They also suggested that a retrospective review of the transfused cases with the blood bank experts is necessary, to understand the specific situations under which the transfusions were ordered.

Summary of Rationale for 'Irrational' Transfusions in Gynecological Surgery Cases Given by the Prescribers

Transfusions were given because of excessive bleeding during tissue dissection when there was more than expected loss and proper assessment of loss was difficult during surgery was a commonly given argument. Some post-operative transfusions were given for fear of loss to

follow up, when the patients were from far off places and could not come back for regular check-up**.**

Some gynecologists also found that there was better postoperative recovery and clinical improvement after transfusion. A specific example given by them was reduction in heart and post-operative tachycardia after transfusion. Transfusions were also given in situations where the laboratory reports showed normal hemoglobin but the patients were clinically pale. These transfusions according to them were rational in patients coming from low socioeconomic background and in a social context where women's health is given low priority.

Summary of Focus Group Discussions (Annexure-5)

On analyzing the prescribers' rationale for transfusion, it was found that many times a combination of factors played a role in transfusion decision making.

Knowledge of Guidelines and Professionalism

Knowledge of guidelines was inadequate, as seen by the results of the interview and analysis of case studies. It was found that whole blood and components like fresh frozen plasma and platelets were sometimes used for wrong indications or in improper doses.

Clinical experience of the prescribers and their skills (deftness with surgical techniques) has a significant role to play in treatment decisions. It also impacts patient management. With advancement in knowledge and technology, hemostasis can be achieved both surgically and medically with fewer blood transfusions. Also, personal experience with transfusion, either positive or negative, shapes the prescribers' attitude toward blood safety. Peer influence, prescribers' attitude towards availability of blood, their faith in the blood bank and the capabilities of the staff also affected decision making. Prescribers' Attitudes towards blood safety, knowledge of window period infections had an influence on practice.

In addition, there were several other clinical, organizational, institutional and socioeconomic factors, (like donor related issues, problems with blood bank, improper lab support, high work

load and costs) that hindered practice according to prescribed guidelines and made deviation from them ‘rational’ from the point of view of benefit to patient.

The hospital laboratory services were deficient in manpower, with improper laboratory support and unreliable laboratory reports.

Considerations for Rationality Outside WHO Guidelines: Clinical Factors

There were problems in decision making at the individual case level, especially those that fell in the ‘grey zone’ (moderate anemia not in failure) and issues with proper estimation of blood loss.

Patient factors like clinical condition of the patient and the cause of anemia requires different management modalities. Acute blood loss requires constant patient monitoring and may sometimes lead to liberal transfusion decisions. Clinicians also had to take into account individual variations before prescribing transfusions. Decision making was particularly difficult in complicated cases with existing co morbidities and grey areas where it was difficult to predict the response of patient under stress.

Between different categories of cases explanation for transfusion decisions varied considerably because of the biological differences in the development of anemia. However, some of the factors affecting transfusion decision were quite similar in the two surgical specialties of surgery and gynecology.

In acute blood loss, it was not routine practice to make a prior estimation of the amount of blood lost and to document it. Clinical parameters like, pulse, BP, though mostly documented were not used as a guide for estimating the amount of blood loss or an indication for transfusion. Since an accurate estimation was difficult to make, most estimates were approximate.

Cases taken up for surgery in emergency hours or those with complications were transfused liberally as surgeons did not want to take any chance. There was a general notion that transfusion helped wound healing and wellbeing. Rarely documentation of the quantity of blood loss during surgery was made in the operation theatre notes. There was no uniform method of estimation of blood loss or requirement of transfusion. Calculation was done arbitrarily. An approximate

estimation was made from the amount of blood collected in the suction machine, drain, mops (approximately 150ml per large mop) and supported by visual estimation.

Common practice among most anesthetists was that they wanted blood and components ready in the operation theatre, at the start of the surgery. Once released from the blood bank, it was invariably transfused. Sometimes it was also sent to the ward along with the patient to be given in the post-operative period. Indications for postoperative transfusion were also not mentioned in the case sheets. So in the absence of proper documentation, while scrutinizing the case sheets for this study, a rough estimate of the amount of blood loss was made by comparing the pre-operative and post-operative hemoglobin levels.

Blood Banking System: Organizational Factors

System of sourcing from replacement donors, leading to uncertainty of getting blood in time of need, was a major barrier to rational practice, sometimes leading to under transfusion and at others to over transfusion. As each blood bank works in isolation a poor system of blood sharing exists between them. The responsibility of arranging for donors lies on the patients' relatives, aggravating problems faced by them, eroding their faith in the health system. Sometimes blood is ordered depending on the number of donors available; if one is available only one unit is ordered. Hence due to non-availability of donors, a few cases could be actually under transfused.

Since blood was donated by relatives, sometimes after much coercion, there was expectation and even pressure for transfusion.

Delay in issue of blood and components by the blood bank also led to problems in rational prescription. There were problems in procuring blood from the blood bank in evening shifts in the absence of senior blood bank officers. Extending donation facilities to late evening hours would help, as those employed could not donate during office hours.

Institutional Limitations

It was found that Institutional factors like high patient load, availability of beds**,** OT facilities**,** laboratory facilities**,** blood bank facilities**,** logistics had a direct influence on the prescribing practice.

Prescribers' perception of risk and need for precaution within the given hospital facilities led to many transfusions that could be avoided.

Blood bank working also led to problems in smooth functioning of the services at the hospital. Since the blood bank had fixed timing of bleeding the donors, it caused inconvenience to some donors who could not manage a day off.

Communication between blood bank staff and doctors was lacking with respect to feedback on donor fitness. Lack of an active hospital transfusion committee for review and audit of transfusion practice also affected proper dialogue between the users and the blood bank.

High patient load and overworked doctors led to, 'irrational' transfusions because of inadequate institutional support at the right time. Shortage of staff, doctors, nursing staff and orderlies was a barrier to prompt provision of service.

The hospital laboratory services were deficient in manpower resulting in improper laboratory support and unreliable laboratory reports. Faulty and inadequate laboratory support made decision making difficult, leading to liberal transfusion practices.

Non availability of operation theatres in urgent need, more waiting time and shortage of beds, were major problems.

It was also found that fresh frozen plasma a cheaper option was preferred to commercial albumin preparations which were costly. Deviations from guidelines were made when cost was a concern.

Health Service System Factors

The blood banking system has developed on the pattern of the general health service system. The services are fragmented with different kinds of blood banks having different sources of funding along with multiplicity of regulatory authorities. The charges for blood and components were

also not regulated leading to blood sharing between them practically impossible. There was also no uniform mechanism of sharing of information related to stock position and availability**.**

Blood was sourced mostly from replacement donors, resulting in problems of availability and safety.

Attitudes of the donors towards the health services and expectations from the blood banking services and the attitudes of the patients and their expectations from the health services also affect the functioning of the blood banking services and transfusion practice.

Socio-Economic Factors

The fragmented nature of health services and the blood banking system is an outcome of the larger socio-political context and policy-making. The dual structure of society is also reflected in the low socio-economic background of the majority of patients availing services of the study hospital and the smaller number of VIP patients who come from the better-off and the powerful sections.

Decisions to transfuse are influenced by the clinical experience of doctors with treating poor patients, patients coming to the capital for treatment from far flung parts of the country and patients living with gender discrimination. Given the levels of under nutrition, reflected in high anaemia prevalence and low body weights, the clinicians prefer to err on the side of being liberal with transfusions to improve post-operative healing and recovery and in giving whole blood instead of packed cells.

With VIP's the clinicians do not want to be seen as being negligent or not providing full services and so undertake aggressive intervention, including transfusions

Perceptions of Clinicians and Patients

Blood is perceived as a vital force. Therefore, blood loss results in a panic reaction. Myths and misconceptions about blood donation are also the result of these perceptions among the public at

large. Expectation of proper service from the doctors, sometimes leads to pressure on the doctors to transfuse.

Each patient /relative expect immediate attention and action. But there is also a perception of lack of attention and negligence unless there is some form of pressure on the doctors and other staff, given the over-crowding and the preferential attention to VIP's.

Whole Blood and Component Use

The clinicians generally perceive transfusion as whole blood and packed cells. Fresh frozen plasma is viewed as a plasma expander and used also for correction of protein deficiency, while platelets are essential in treatment of specific diseases affecting coagulation, such as dengue and in CTVS.

In the period 1997 to 2000, there was small shift to component use except use of platelet, despite the focus on use of blood components for blood economy and educational messages to clinicians about it. However, after 2001 after a fractionation unit was installed, there was shift to component use by about 28 percent, with most marked increase in use of fresh frozen plasma and to a lesser extent of packed cells and platelets. A major proportion of packed cells and Platelet were used for CTVS and therefore does not indicate any major shift in prescribing of components by other disciplines.

Education of guidelines would be able to address issues of approximately 30 percent of the cases i.e., those falling into category (2). The awareness and implementation of guidelines strictly as they are, however, may lead to some changes in prescribing behavior of the other categories, but whether that is desirable from patients' benefit point of view needs serious consideration. Ignoring of contextual factors, as in category (3) or (4) would actually harm the patient instead of benefitting them if universal guidelines were followed too strictly.

Clinicians' Suggestions for Improving Transfusion Practice

(1) Education of guidelines: The blood bank should play a more proactive role in dissemination of transfusion guidelines. In addition to this, clinicians should be trained in development of clinical skills and proper assessment of blood loss.

(2) Both physicians and surgeons suggested that proper documentation of indications for transfusions would cut down the number of irrational transfusions. A modified request form in the form of a check list could serve as a reminder at the time of prescribing. However, some felt that it would be difficult to fill up these forms due to high workload.

(3) Periodic Audits i.e., retrospective review of the cases with blood bank specialists would help understand specific situations under which transfusions were ordered.

(4) In view of delays and less responsive staff at the blood bank, it was suggested that prompt service from blood bank could minimize unnecessary transfusions.

(5) Blood banks should also keep a record of the returned units and give feedback to clinical departments and units.

(6) Increasing voluntary donation would assure adequate supply and save time spent in motivating relatives to donate and also ease pressure on patients' relatives.

(7) Improving communication between providers and relatives, would build trust, allay fears and prevent panic. Improving communication between the prescribers and the blood bank, to sort out problem and build trust. Blood bank should send a written communication to the prescribers when donors are deferred.

(8) Since laboratory results are not considered reliable, especially in emergency hours, they suggested that a doctor must be posted in emergency laboratory to ensure quality.

(9) Interaction and dialogue on contextual issues would help in consensus development and formulation of locally relevant guidelines, where the 'Hospital Transfusion Committee' would play an important role.

(10) Anesthetists suggested that a proper workup of the patient and plan for transfusions in advance after discussion with the prescriber would help in rational blood and component usage.

CHAPTER-8

Costing: Epidemiological and Economic Rationale

Interventions for blood safety include screening donors, testing for TTIs and limiting transfusions, thereby limiting the probability of exposure to infections. Costs have increased because of the TTI testing and processing, but expected to decrease due to blood economy by more rational use of blood and components. Cost effectiveness of an intervention is not the same in all contexts, since costs can vary requiring different inputs, where the clinicians' context of safety and rationality of use are necessary considerations. In addition, liability, politics, public opinion and commercial interests, are also important influences in policy formulation and resource allocation (Grosse et al., 2007). Many experts feel that economic analysis plays a limited role in blood safety as 'Blood is Different' and the blood banks want to achieve maximum safety regardless of the cost (Custer & Hoch, 2009).Since decisions in this area do not seem to have been based on critical evidence, there is an opportunity for evidence based principles to have a greater role in blood safety (Treloar et al., 2001).

As has been found in this study there has been an increase in the prescribing of transfusion per 100 admissions over the study period which is contrary to the promotion of blood economy. However a greater increase is seen in the phase after the component separation unit was set up in the hospital. During this period there has simultaneously been a 35 percent decrease in proportion of whole blood use as compared to component use.

In order to understand the relative cost of component separation to rationalize future collection and use, an analysis was undertaken to:

(i) Estimate the cost of laboratory resources needed to provide a unit of whole blood and

(ii) Do a comparative costing of ways in which the essential fractions could be supplied and the rationale for establishing separation unit in the hospital.

(iii) Do a comparative costing if there was no CTVS department.

(iv)Use estimates from this study to provide a rationale, for policy on component separation for different levels of health care in the Indian context.

Principles/Assumptions for Costing

The calculation was based on the costing tools provided by the Blood Safety unit of W.H.O. (1998). The unit of output was the cost of a single unit of blood or blood component and it was assumed that all components had equivalent costs.

- The capital and recurring costs were enumerated separately. The cost of building and maintenance were not included in the capital cost as the blood bank was part of a large public hospital. Also, a large number of other resources like, electricity and administrative support that are provided by the hospital were not included. Only the cost of equipment and their maintenance was included in the capital cost.
- Maintenance was calculated as 3 percent of the total equipment cost, annually. The recurring expenditure included staff salaries, consumables and miscellaneous items.
- As the supply depended on replacement donors and blood was utilized within the hospital, costs incurred by the activities of recruitment and distribution were not included.
- Cost of collection, processing and storage were included in the calculation.

Method

- The expenditure for equipment, salaries and consumables for the year 2008 was listed.
- The total collection in 2008 was 9586 units, with 50 percent of the collection being separated into components. Therefore the total number of whole blood and component units that were prepared was 17,116.
- The total number of units actually used was 16,452.
- Economic costs of equipment on an ‘annualized’ (cost per year) basis, was used to estimate the annual cost of equipments. It took into account the current value, useful life of the equipment and a discount rate of 10 percent fixed by the World Bank, to calculate the annualization factor. Annualization factor of 3.791 was used for calculation (discount rate of 10 percent and average life of the equipment was taken as 5 years- from the chart provided in the WHO costing guidelines). The cost of the equipment divided by the annualization factor gave the annual economic cost of the equipment.
- The annual expenditure on salaries and consumables (recurrent cost) were then added to the annual economic capital cost and annual maintenance cost.

- Lastly the total annual expenditure was then divided by the total number of blood and components prepared/used in the year 2008. This represented the 'investment' per unit of blood and component produced/used in the year.
- Calculations involving the cost of blood components assumed an equivalent cost for all blood and component units.

Cost was Calculated in the Following Ways

[A] Cost of each unit of whole blood and components prepared in 2008 (with approximately 50 percent component separation) = **17,116 UNITS** (Table-8.4)

[B] Cost of each unit by fractions actually used in 2008 (with approximately 50 percent component separation) = **16,452 UNITS** (Table-8.5)

[C] Cost of each unit of whole blood if no fractions were made in 2008 = **9,586 UNITS** (Table-8.6)

[D] Cost of each unit of whole blood at basic mandatory functioning of the blood bank (minimal automation) = **9586 UNITS** (Table-8.7)

[E] Cost of each unit after component separation if there had been no CTVS-(subtracting units used by CTVS from the denominator and expense for CTVS from the numerator) (Table-8.8).

Table 8.1 Calculation of Cost per Unit

SN		Fractions	No. of units	Cost per unit
A	Cost of each unit of WB and components-prepared	WB+50 % components	17,116 units	Rs 996.63

B	Cost of each unit of WB and components-actually utilized	WB+50 % components	16,452 units	Rs 1036.86
C	Cost of each unit of WB without Component separation	None	9,586 Units	Rs 1412.18
D	Cost of each unit of WB at Basic Mandatory Functioning of Blood Bank (minimal automation)	None	9,586 Units	Rs 1162.30
E	Cost of each unit after Component separation if there had been no CTVS	WB+25%components (subtracting 25 % CTVS)	12,644 Units	Rs 1311.99

Component Units Used in the Year 2008

In the year 2008, out of the total components used in the study hospital, proportion of whole blood used was approximately 30 percent, proportion of packed cells was 38 percent, proportion of fresh frozen plasma was approximately 17 percent and proportion of platelets used was approximately16 percent out of total components issued (table 8.2).

Table 8.2 Component Utilisation in 2008				
	WB (%)	**PC (%)**	**FFP (%)**	**PLT (%)**
TOTAL	29.32	38.02	16.84	15.80

Specialty Wise Component Utilisation in 2008

The highest users of components were the departments of CTVS, Medicine and Pediatrics.

CTVS used 24.14 percent of all units out of which approximately 3 percent of all whole blood, 22 percent of all packed cells, 43 percent of all fresh frozen plasma and 45 percent of all platelets was utilized by CTVS (table-8.3).

Table 8.3 Specialty wise Component Utilization 2008					
SN	**Departments**	**Whole Blood (%)**	**Packed cells (%)**	**FFP (%)**	**Platelets (%)**
1	Burn	4.08	1.16	<1	<1
2	ENT	1.59	0.67	<1	<1
3	Obstetrics and Gynaecology	7.31	2.07	<1	<1
4	Medicine	19.35	19.67	28.28	38.14

5	Nephrology	6.75	7.04	1.15	1
6	Neuro Surgery	14.71	5.96	2.9	1.73
7	Orthopaedics	12.14	3.02	<1	<1
8	Paediatrics	2.67	19.93	5.91	4.61
9	General Surgery	23.4	12.97	8.3	3.30
10	Urology	2.81	1.66	1.5	2.03
11	CTVS	2.59	22.17	43.4	45.46
12	Anaesthesia	2.63	3.62	6.60	5.42
13	Total	100	100	100	100

Epidemiologic and Economic Rationale for Setting up a Component Separation Unit

A. In a tertiary hospital with facility for cardiothoracic surgery (CTVS), the cost of one unit of whole blood or component was Rs 996. Data for the year 2008 showed that approximately 20 percent of fresh frozen plasma was not utilized and approximately 30 percent of the platelets were discarded**.** After subtracting the wastage, the cost of units actually utilized were factored into the calculation. The cost then increased to Rs 1036 from Rs 996, meaning Rs 40 more per unit. Hence in tertiary centers with CTVS facility, blood sharing with other hospitals would be a more cost-effective option and would prevent wastage of components.

B. Cost of a unit was also calculated after excluding the expenditure involved in CTVS which used almost 25percent of transfusions and most of the components. This was done to ascertain cost effectiveness of setting up component separation unit in tertiary hospitals without facility for CTVS. In addition to CTVS other departments, like medicine and pediatrics, along with the super specialty departments of Nephrology, Urology and Neurosurgery put together, used 50 percent of packed cells, 50 percent of fresh frozen plasma and 20 percent of platelets (table-3). It was found that setting up a component separation unit for use of components in departments other than CTVS, increased the price of one unit markedly to Rs 1312, with a difference of Rs 316 per unit (Rs1312 minus Rs 996) and hence was not a cost effective option. However, if 50 percent component separation was done and cost kept to 996/- there would be a wastage of approximately 20 percent of fresh frozen plasma and 30 percent platelets.

Conditions that required component transfusion were analyzed from 2003 data with the assumption that the pattern of patients had not changed in 2008 and remained similar to 2003. It was seen that aplastic anemia/thrombocytopenia/pancytopenia and disseminated intravascular coagulation were the other conditions in addition to CTVS that required components, the proportion of which was very small. Analysis of 2003 data showed that proportion of requests for cases of anemia was approximately10 percent of all, hematemesis with liver disease and thalassemia both were 5 percent of all requests for transfusion. The coagulation factors are deranged in hematemesis which is generally associated with liver disease and requires transfusion of fresh frozen plasma to correct the coagulation factor deficiency. In thalassemia, multiple transfusions are required for life, (on an average two transfusions per month), in which packed cells is the treatment of choice. Further since the process of component separation removes most leucocytes, transfusion reactions associated with multiple transfusions in such patients is minimized. Transfusion of components is justified and necessary in these conditions and would best be treated in tertiary centers where facility for component separation is available. The other important transfusions were related to surgery.

Our study showed that in a tertiary hospital just using whole blood and not having a component separation unit is not a cost effective option. Using whole blood alone in large centers increased the price of one unit by Rs 416, i.e., from Rs 996 to Rs 1412. Hence component use would be essential in tertiary centers with super specialty facilities like CTVS.

Further, if such facilities functioned as centralized units and supplied components to other blood banks and medical institutions, wastage and cost would come down and the cost would decrease proportionately to the scale of operation. Therefore wherever there is CTVS, or other super specialties, component separation with sharing would be the best option.

C. With basic functioning following mandatory regulations to maintain quality and safety of the blood banks, i.e., without high end equipments and minimal automation the cost was Rs 1162 i.e., the cost saved was Rs 250 per unit (Rs 1412 minus Rs 1162). Therefore this would be a good option for situations where no component separation facility is required.

In the context of India, because malnutrition and anemia is high in the general population, whole blood could be used to treat anemia unless the patient was in cardiac failure where packed cells are indicated to lower the load on the heart. Using whole blood for anemia would provide proteins in addition to raising the hemoglobin because most of the cases of anemia result from nutritional deficiency. Similarly, in case of elective surgery with surgical or acute blood loss, whole blood and other cheaper options of colloids and crystalloids can be used. Since the District level hospitals with no super specialty departments, mostly treat these kinds of patients, component separation is not desirable both epidemiologically and by cost effectiveness criteria. In cases of anaemia with cardiac failure proper training to make packed cells by gravitational or other low cost centrifugation method should be imparted. Research should be undertaken to optimize this technology which requires less infrastructure and fewer machines and find better ways to do it and develop low cost technology in our context.

Table 8.4(A) Cost of Whole Blood and Components Prepared in 2008

SN	Item	Rs
1	Equipment cost a	51,49,000

2	Equipment cost b	59,88,308
3	Total equipment cost	1,11,37,308
4	Annual economic cost	29,37,828
5	Annual equipment maintenance 3%	3,34,119
6	Annual staff salary	92,28,000
7	Consumable-a	26,95,280
8	Consumable-b	13,95,550
9	Consumable-c	1,57,250
10	Consumable-d	50,227
11	Consumable-e	1,47,082
12	Consumable-f	1,13,144
13	Total consumable cost	45,58,533
14	Grand total	1,70,58,480
15	Grand total divided by number of units prepared	17116
16	Cost per unit(17116 units)	**Rs 996.63**

Table 8.5(B) Cost of Component Units Actually Utilized in 2008		
SN	**Item**	**Cost (Rs)**
1	Equipment cost a	51,49,000
2	Equipment cost b	59,88,308
3	Total equipment cost a+b	1,11,37,308
4	Total annual economic cost	29,37,828
5	Equipment maintenence-3%	3,34,119
6	Total annual staff salary	92,28,000
7	Consumable- a	26,95,280
8	Consumable-b	13,95,550
9	Consumable-c	1,57,250
10	Consumable-d	50,227
11	Consumable-e	1,47,082
12	Consumable-f	1,13,144

13	Total consumable cost	45,58,533
14	Grand total	1,70,58,480
15	Units actually used-16452 units	16452
16	Unit cost	**Rs 1036.86**

Table 8.6(C) Cost of Whole Blood if No Components were Prepared in 2008

SN	**Item**	**Cost (Rs)**
1	Total capital cost	5,14,900
2	Total annual economic cost	13,58,216
3	Annual equipment maintenance 3%	1,54,470
4	Total annual staff salary	88,68,000
5	Consumable-a (75% Antisera)	25,70,528 minus 1,15,650 = 24,54,878
6	Consumable-b	2,33,960
7	Consumable-c	1,57,250

8	Consumable-d	50,227
9	Consumable-e	1,47,082
10	Consumable-f	1,13,144
11	Total annual cost of consumables	32,72,191
12	Grand total	1,36,52,877minus 1,15,650=1,35,37,227
13	Grand total divided by units collected	9,586
14	Cost per unit of whole blood	Rs 1412.18

Table 8.7 (D) Cost of Whole Blood at Basic Mandatory Functioning in 2008

SN	**Item**	**Cost (Rs)**
1	Equipment cost a	42,09,000
2	Annual economic cost	11,10,261
3	Annual equipment maintenance 3 %	33,307
4	Annual staff salary	88,68,000(Same as C)

5	Consumable-a	3,96,760
6	Consumable-b	3,32,900
7	Consumable-c	1,57,250
8	Consumable-d	50,732
9	Consumable-e	1,45,898
10	Consumable- f	46,054
11	Total consumable cost	11,72,136
12	Grand total	1,11,41,844
13	No of donors	9586
14	Cost per unit	Rs1162.30

Table 8.8 (E) WB+Components Minus CTVS (25 Anti sera & 25 percent Quadruple Bags Used for CTVS)-2008		
SN	**Item**	**Cost (Rs)**
1	Equipment cost a	51,49,000
2	Equipment cost b	59,88,308
3	Total equipment cost	1,11,37,308
4	Annual economic cost	29,37,828
5	Annual equipment maintenance (3%)	3,34,119
6	Annual staff salary	92,28,000
7	Consumable-a (minus 25 % antisera)	26,95,280-38,550=26,56,730
8	Consumable-b (minus 25 % quadruple bags)	13,95,550-5,08,200=887350
9	Consumable-c	1,57,250
10	Consumable-d	50,227
11	Consumable-e	1,47,082
12	Consumable-f	1,13,144
13	Total consumable cost	45,58,533

14	Grand total	1,70,58,480 minus 4,69,650 =1,65,88,830
15	Grand total divided by the number of units prepared(without CTVS)	12,644
16	Cost per unit	Rs 1,311.99

Differential Pricing by Various Categories of Blood Banks in Delhi

The Blood banks of Delhi fall under different categories hence their sources of funding vary widely and the pricing policy is largely unregulated. The blood banks in the government hospitals provide blood and components free of cost, to the patients admitted in the government hospitals. The categories were, central government, Delhi government, MCD, NGO, private hospitals based and stand-alone blood banks. There has been a gradual increase of private blood banks in Delhi in the 10 years from 1996 to 2007(Table-8.9).

Table 8.9 Various Categories of Blood Banks in Delhi-(1996-2007)

Year	TOTAL	CG	DG	MCD	%	NGO	%	Pvt Hosp	%	SA	%
2007	54	8	8	3	35.18	3	5.55	24	44.44	8	14.81

2006	53	8	8	3	35.84	3	5.66	23	43.39	8	15.09
2005	53	8	8	3	35.84	3	5.66	23	43.39	8	15.09
2004	47	8	8	3	40.42	2	4.25	18	38.29	8	17.02
2003	44	8	8	3	43.18	2	4.54	16	36.36	8	18.18
2002	42	8	8	3	45.23	2	4.76	15	35.71	7	16.66
2001	42	8	6	3	40.47	2	4.76	15	35.71	8	19.04
2000	38	8	4	3	39.47	1	2.63	14	36.84	8	21.05
1999	36	8	4	3	41.66	1	2.77	12	33.33	8	22.22
1998	35	8	4	3	42.85	1	2.85	11	31.42	8	22.85
1997	34	8	4	3	44.11	1	2.94	11	32.35	7	20.58
1996	33	7	4	3	31.81	1	3.03	11	33.33	7	21.21

Source: Drug Controller Office Delhi

Category of Blood Banks, Source of Funding and Available Technology

The hospitals were categorized into four groups, depending upon the facilities available and their source of funding, as follows (Table-8.10)

A-facility for basic testing, component separation and apheresis

B-facility for basic testing and component separation

C-facility for basic testing

A1-facility for NAT

Table 8.10 Category of Blood Banks, Source of Funding and Available Technology-2006

SN	BB Delhi	ORG	Funding	Level of Technology*	Charge Govt	Charge Others
1	AIIMS	AIIMS	AIIMS+DSACS	A	NIL	YES
2	CNC	AIIMS	AIIMS+DSACS	B	NIL	X
3	AFTC	Army	Army+DSACS	A1	NIL	YES
4	N.Railway	Railway	Railway+DSACS	C	NIL	YES
5	ESIC	ESIC	ESIC	A	NIL	X
6	Safdarjung	Cent Govt	C.Govt+DSACS	A	NIL	X
7	DR RMLH	Cent Govt	C.Govt+DSACS	A	NIL	X
8	Lady Harding	Cent Govt	C.Govt+DSACS	B	NIL	X

9	Delhi Govt	Delhi Govt	D. Govt+DSACS	A,B,C	NIL	YES
10	MCD	MCD	MCD+DSACS	A	NIL	YES
11	Pvt Hosp BB	Pvt Hosp	Self	A,B,C	YES	YES
	Pvt Hosp Apollo	Apollo	Self	A1	YES	YES
12	NGO/Trust	IRCS	Self+NACO+DSACS	A	NIL	YES
	NGO/Trust	Rotary	Self+DSACS	A	YES	YES
	NGO/Trust	Lions	Self	A	YES	YES
13	Stand Alone	Pvt Commercial	Self	ABC	YES	YES
	*A-facility for basic Testing, Component separation and Apheresis					
	*B-facility for basic testing and Component separation					
	*C-facility for basic testing					
	A1-facility for NAT					

Source: DSACS

Charges of Blood and Components of Blood Banks of Delhi-2007

To compare the cost of blood from other hospitals of Delhi, information on charges for various components was obtained from the reception of the respective hospitals. There was a wide variability in the charges among government and private blood banks and even among the blood banks within the private sector. The government has no control over pricing. The charges are much higher where NAT testing facilities are available (Table-8.11).

Table 8.11 Charges of Blood and Components of Blood Banks of Delhi-2007

SN	Name	Whole blood (Rs)	Packed cells (Rs)	FFP (Rs)	Platelets (Rs)
1	Kalra Hospital	1200	1200	1100	1000
2	Sant Parmanand	1350	1350	1200	1200
3	Maharaj Agrasen	850	850	800	750
4	Jaipur golden	1200	1200	1100	1000
5	Action Balaji	1300	1300	1200	1200
6	Apollo (NAT)	X	4400	2000	2000
7	Artemis (NAT)	X	5000		

8	Ganga Ram	X	3500(Nursing Home) 2800(Gen Ward-Free)	1000	1500
9	Medicity (NAT)	X	3400	1800	1700
10	IRCS	850	850	400	400
11	Rotary blood bank	1350	1350	1200	1200
12	Lions	1350/1750/2200		1200	1200
13	Railway hospital	925		X	X
14	DDU (DG)	850	850	400	400
15	GTB (DG)	850		400	400

(Charges obtained from the hospital enquiries)

CHAPTER-9

Update- 2018

Introduction

This chapter was included because there was a break in my thesis writing due to personal and professional reasons and I returned to completing the task in 2018. Though in the intervening period the nature of health services has changed somewhat, the issues with prescribing for transfusion outside guidelines still remains as pertinent as before. The technology of component separation has added a different kind of irrationality as being witnessed in view of increased availability of components in the study hospital. More availability has meant more prescriptions but its appropriateness as assessed by guidelines is still questionable. Over this period the health service context remains much the same and the socio economic condition of the patients also has not changed much. Therefore there is continuing relevance for understanding the rationale of the prescribers and adapting guidelines to local, social and health service context.

In this chapter updated data on some policy decisions at the national level, the changes in blood banking system of Delhi, changes in service conditions in the study hospital, results from audit of request forms and costing of blood unit for the year 2018 is being presented.

The methodology for analysis was the same as that of the main study presented in the previous chapters.

The National Scenario

Total number of licensed blood bank in India was 2760, out of which NACO supported blood banks were 1161.Among the NACO supported blood banks there were 304 blood component separation units, 34 model blood banks, 210 major blood banks and 613 district blood banks. Out of all districts, 72 districts did not have blood banks, most are of these were from the north eastern states. Donor sero reactivity among donors in the NACO supported blood banks has declined from 1.2 percent to 0.2 percent in the phase three of the program (Annual Report 2015-2016).

Major Policy Decisions in Recent Years

Initiation of Counseling Services

Although it was recognized early in the program that counseling of donors about TTI's, self deferral for window period infections, leading a healthy life style for becoming a repeat voluntary donor was important for blood safety and also dispelling myths about blood donation, counseling services were not formally started until 2009. The primary focus of the blood safety program right from its inception was to test each donated unit for TTIs. In the year 2009, a post for counselor was created for each government blood bank and donor counseling was given due importance. The understanding that window period infections could be minimized by proper counseling of donors and weeding out of high risk cases led to the engagement of counselors. Before this period pre donation counseling was done by the doctors or nurses posted in the blood banks for which no formal training was imparted**.**

National Plasma Policy

A "National Policy for Access to Plasma Derived Medicinal Products from Human Plasma for Clinical/Therapeutic use: Addendum to National Blood Policy 2003" was formulated in the year 2014, which enabled surplus plasma from blood banks to be mobilized to the plasma fractionators. Donor consent form was revised to incorporate this clause. This decision was taken to meet the huge demand that existed for the 'Plasma Derived Medicinal Products' (PDMPs) in the country, the raw material for which i.e., plasma was being imported. The PDMPs which are life saving drugs are, Albumin, Immunoglobulins, Factor VIII and hyper immune products like hepatitis B immunoglobulin, tetanus immunoglobulin etc.

"There were five objectives in the policy,

(a) Government would facilitate availability of adequate quantity of safe plasma derived products for clinical use

(b) Make available resources for mobilization of plasma throughout the country,

(c) Will take adequate regulatory and legislative steps for monitoring of activities related to plasma derived products,

(d) Will encourage research & development in this field,

(e) Will strengthen quality systems in blood transfusion services for plasma collection, transportation, processing, production and distribution of PDMPs."

NACO/NBTC fixed the exchange rate of plasma at Rs 1600 per liter and directions to this effect were sent to the SBTC's. The directions specified that in exchange for plasma either equipments or PDMPs could be taken by the blood banks. There were two private fractionators available at that time with whom the blood banks were required to sign memorandum of understanding (MOU) under intimation to the SBTC's. Some blood banks misinterpreted the directions and bargained for higher exchange rates of even more than Rs 3000 per liter. A clarification was issued after this practice was brought to the notice of the regulators.

Many government blood banks and most private blood banks of Delhi are giving their surplus plasma to these fractionators.

Hemovigilance Program of India

The Hemovigilance program of India was launched in the year 2012 with 'National Institute of Biologicals' (NIB) as the nodal center. The objective of the program is to collect data on adverse transfusion reactions with voluntary participation of the blood banks. Between 2012 and 2016 a total of 368 centers enrolled for the program. Out of these adverse reaction reports were submitted by 104 centers. A total of 3903 transfusion reactions were reported. The largest proportion was due to febrile non hemolytic transfusion reaction (FNHTR) followed by 'others' category (Bisht et al., 2018).

Minimum Processing Charges Fixed by NACO

Minimum processing charges were fixed by NACO. Due consideration was given to use of advanced technology and additional processing charges were detailed out (table-9.1).

Table 9.1Minimum Processing Charges for Blood and Blood Components			
SN	**Blood Component**	**Government Sector**	**Non-Government Sector**
1	Whole Blood	Rs 1050/- per unit	Rs 1450/-per unit
2	Packed Red Cells	Rs 1050/-per unit	Rs 1450/-per unit
3	Fresh Frozen Plasma	Rs 300/-per unit	Rs 400/-per unit
4	Packed Cells	Rs 300/-per unit	Rs 400/-per unit
5	Cryoprecipitate	Rs 200/-per unit	Rs 250/-per unit

(Source-Annual Report NACO13-14)

Blood Banking in Delhi

Total number of blood banks in Delhi in 2018 were 60 out of which 22, i.e., one thirds are in the government sector and 38, i.e., two thirds are in the private sector demonstrating that the period between 2008 to 2018 has witnessed a considerable increase in private blood banks, when they were approximately 50 percent in each sector(table-9.2). The organizational and regulatory structures however remain the same as that of 2003. The proportion of voluntary donors has increased over the past few years to approximately 50 percent.

Table 9.2 Number of Blood Banks in India and the NCT of Delhi -Dec 2018				
SN		**Public including Government blood banks**	**Private including Charitable/ Trust blood banks**	**Total**
1.	National	1101 (35.42%)	2007 (64.57%)	3018
2.	NCT of Delhi	22 (36.66%)	38 (63.33%)	60

Source: NACO (Unpublished Data)

Changes in Dr. R.M.L. Hospital

Several changes had occurred in the hospital in the last few years, the most significant one being the starting of post graduate teaching in the year 2008. Thus, from being only a service provider, it changed into an academic institution, and the name extended to ABVIMS and Dr. R.M.L. Hospital. The number of departments has increased to 35 with addition of non-clinical departments of Anatomy, Physiology, Pharmacology, Forensic Medicine and Preventive and Social Medicine and some other clinical departments. Teaching faculty was recruited along with induction of postgraduate medical students thus creating an academic environment. However the services have largely remained the same with some expansion of infrastructure and addition of new diagnostic and laboratory tests. The number of patients seen in the OPD, emergency and admissions has increased considerably since 2003.

Hospital Staff

There are presently more than 400 doctors including the teaching faculty, senior residents, junior residents with 350 post graduate students. There has been a reduction in the number of permanent employees with an increase in the category and number of outsourced staff. There are contractual teaching faculty, technicians, clerical staff and data entry operators. Presently the 'Group D' staff comprises of approximately 400 multitask staff, 475 guards and 715 housekeeping staff.

Change in Important Hospital Parameters

In the year 2018 ,total admissions were 94599 total no. of major surgeries were 18,807, total no. of blood donations were 20,748 total request forms received were 41741, total components transfused were 47,769.

There was an increase in beds by 45 percent between 2003 and 2018. Admissions increased by almost 100 percent and total major surgeries have increased by approximately 94 percent in this period. Total blood donation increased by 130 percent and the number of patients transfused/ transfusion episodes have increased by 308 percent in the last 15 years (table-9.3).

Table 9.3 Comparison of Important Hospital Parameters 2003 and 2018

SN	Service Parameters	2003	2018	Increase (%)
1	Total Beds	998	1,447	45
2	Total Admissions	47500	94,599	99
3	Total Major surgeries	9,705	18,807	93.78
4	Total Blood Donations	9026	20,748	130
5	Total Request Forms Received	10,226	41,741	308
6.	Total Component Units Transfused	11,865	47,769	302

Table 9.4 Department-wise Beds and Admissions in 2018			
SN	**Departments Using Transfusions**	**Beds**	**Admissions**
1.	Burn	26	1212
2.	ENT	32	1109
3.	Obstetrics and Gynaecology	94	4727
4.	Medicine	285	27878
5.	Neurology	20	625
6.	Nephrology	26	6076
7.	Neurosurgery	36	2016
8.	Orthopedics	103	4693
9.	Pediatrics	166	7804
10.	Paed Surgery	30	856
11.	General Surgery	174	16048
12.	Urology	30	5954
13.	CTVS	20	737
	Total	1,042	79,735

Expenditure Incurred on Plasma Derived Medicinal Products in Dr. R.M.L. Hospital

The PDMPs used for hospital patients are Albumin, Immunoglobulin and factor VIII. These are restricted items, the utilization of which is monitored and issued on specific demand only. Albumin is given for hypoalbuminemia when the levels fall below 3 gm percent (laboratory report has to be attached with request), Factor VIII for diagnosed cases of Hemophilia and Immunoglobulins for Gullian Barre Syndrome, ITP , Myasthenia Gravis in Crisis, Kawasaki Disease or any other documented illness with therapeutic benefit with the concurrence of respective HODs. It can be seen from table-9.5 that the expenditure on these items is to the tune of several crores annually.

Table 9.5 Details of Consumption and Expenditure on PDMPs (2016-2018)

SN	Item	Year	Quantity utilized	Unit cost	Total Annual Expenditure
1	Factor VIII	2016	100 pcs	2659/-	Rs 2,65,900
		2017	200 pcs	2659/-	Rs 5,31,800
		2018	100 pcs	2659/-	Rs 2,65,900
2	Human Immunoglobulin (5 Gm)	2016	2006 bottles	5990/-	Rs 1,20,15,940
		2017	1971 bottles	5990/-	Rs 1,18,06,290
		2018	2971 bottles	5990/-	Rs 1,77,96,290
3	Human Albumin 20% (100 ml)	2016	3444 bottles	3600/-	Rs 1,23,98,400
		2017	3296 bottles	3600/-	Rs 1,18,65,600

		2018	4787 bottles	3260/-	Rs 1,56,05,620

(Source-Hospital Stores)

Surplus Plasma Data-Blood Bank

Data of 2018 showed that some plasma remained utilized each month. In the month of December, utilization was more than what was produced from the monthly blood collection. Since plasma has a life of one year so it can be stored for a period of one year at minus 80 ˚C hence stored stock was used to make up for the shortfall. Surplus plasma is not being given to the fractionators and a committee is examining the modalities of exchange (table 9.6).

Table 9.6 Surplus Plasma Data -2018

Month	Prepared	Issued	Surplus
January	982	863	119
February	936	740	196
March	1233	998	235
April	1247	1045	202
May	1382	1121	261
June	1546	940	606
July	1511	935	576
August	1431	876	555
September	1596	803	793
October	1248	1182	66

November	1395	1103	292
December	1002	1220	(-) 218
Total	15,509	11,826	3901

Dr. R.M.L. Hospital Blood Bank

In the year 2018, total blood donation was 20,748 out of which 4019 (19.37 percent), units came from voluntary donors and the remaining 16,729 units (80.62 percent), came from replacement donors, showing a considerable increase in voluntary donation from 2003. During the previous study years few blood donation camps were held and few voluntary donors came to the center to donate. In the year 2009, a state of the art blood mobile van and staff was provided to the blood bank by NACO for conducting camps. Since then the number of annual camps and the proportion of voluntary donation has increased. This is also due to increased awareness among the community as a result of campaigns and active involvement of NGO's. A total number of 97 voluntary donation camps were organized in the year 2018. Blood collected from camps is used for outstation patients and has also helped in cutting down on replacement donation.

Total number of units issued including whole blood, packed cells, fresh frozen plasma and platelets in 2018 was 47,069 with 80 percent of the collection being separated into components.

The total number of blood bank staff remained almost the same since the last 10 years in spite of considerable increase in the work load. However, contractual staff had been recruited to fill up vacancies created by permanent retired staff in line with government policy.

The nature of services of the blood bank had remained the same but the workload had increased considerably due to increase in beds, patient load and increased transfusions per patient. Compatibility testing and immunohematology work up was being done using semi-automated equipment, the reagents of which are costly. A total of 88 special cases were done in the year 2018. A specialized test for transfusion transmissible infections, Nucleic Acid Testing (NAT) has been added to the existing battery of tests providing additional layer of safety, to detect

infections missed by ELISA. However, this test has not been universally adopted by all blood banks because of its prohibitive cost, approximately Rs 1200 per test. The expenditure of blood bank had gone up considerably by inclusion of Immunohematology and NAT testing.

In the year 2018, sixty-two platelet pheresis and fifteen therapeutic plasma pheresis were done.

The blood bank has been recognized as a regional training center by NACO to impart training to the blood bank staff from Delhi and other states around Delhi from the year 2007. Since then several batches of Doctors, Technicians, Nurses and Counselors have been trained from different states of North India.

Audit of Request Forms 2018

To examine the current transfusion practice a total number of 3501, 3977 and 3541 forms for the months of April, August and December were analyzed for the year 2018. Since considerable time had elapsed we expected certain changes in the transfusion practice from 2003.

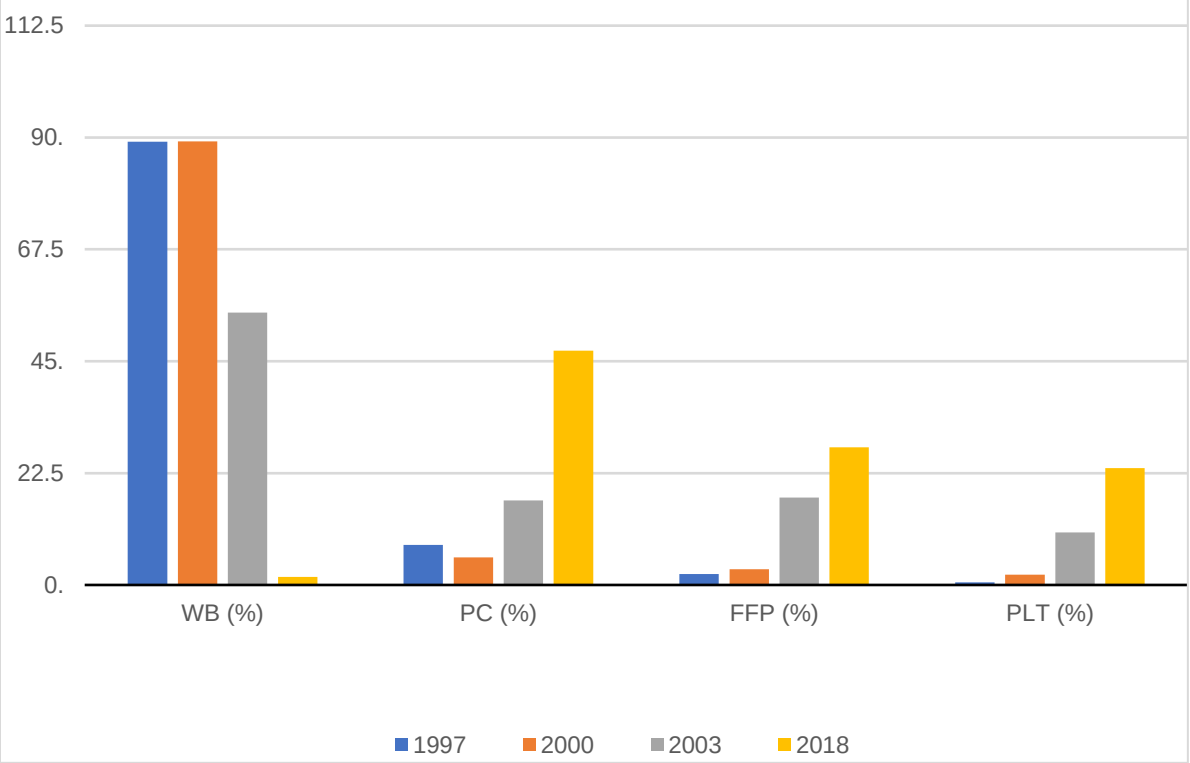
In the year 2018, requests for components increased considerably. Whole blood use had gone down considerably to 2 percent which was a striking change from 2003. Most of the requests were for packed cells. Demand for fresh frozen plasma and platelets were also higher from 2003, indicating increased total demand of components. Increase in component demand could have been due to increased availability, increase in conditions requiring component transfusion and better knowledge of component use as seen by a huge shift from whole blood use to component use (table-9.7).

Table 9.7 Proportion of Component Unit Requests in the Study Years

Year	WB (%)	PC (%)	FFP (%)	PLT (%)	Total (%)
1997	89.18	8.07	2.20	0.53	100

2000	89.20	5.54	3.17	2.08	100
2003	54.81	17.01	17.57	10.59	100
2018	**1.63**	**47.15**	**27.67**	**23.53**	**100**

Fig 9.1 Proportion of Component Unit Requests in the Study Years



Trends in Components Requested by Specialty

The department of Medicine used the highest proportion of requests at 28 % , followed by the department of Pediatrics at approximately 20%.Department of General Surgery was at the third place with 14% of requests. 10% of total demands came from the department of CTVS. Least requests were received from the department of ENT. Proportion of demands increased for the departments of Medicine, Pediatrics, Nephrology, Neurosurgery and Urology from 2003. It had decreased significantly for Burn, Obstetrics and Gynecology, Orthopedics, General Surgery and CTVS (table-9.8). Proportion of component requests by the department of CTVS had decreased in recent years. Component requests per patient had reduced to four units each of packed cells, fresh frozen plasma and platelets from six units per patient in 2003.

Table 9.8 Trends in Components Requested by Specialty

SN	Departments	1997(%)	2000(%)	2003(%)	2018(%)
1	Burn	3.70	1.93	4.61	1.39
2	ENT	0.60	0.28	0.56	0.23
3	Obstetrics and Gynecology	12.94	11.64	8.37	1.27
4	Medicine	22.54	23.90	19.89	28.20
5	Nephrology	0.22	3.09	1.01	5.86
6	Neuro Surgery	9.01	7.68	5.32	8.05
7	Orthopedics	11.75	13.04	6.64	5.78

8	Pediatrics	8.60	4.61	5.88	19.94
9	Pediatric Surgery	0.40	0.43	0.17	1.59
10	General Surgery	30.13	27.86	19.22	14.35
11	Urology	0.05	1.87	1.31	3.03
12	CTVS	X	3.60	27.05	10.25
	TOTAL	100	100	100	100

Component Units Transfused per 100 Admissions in 2018

In the year 2018 the department with highest rate of component transfusion per 100 admissions was CTVS at 165, followed by Neurosurgery at 47 and in the third place was Pediatrics at 30 per 100 admissions. The least transfusions were used by ENT.

Table 9.9 Component Units Transfused per 100 Admissions

SN	Specialty	Admissions 2018	Component Units 2018	Components Transfused per 100 Admission
1	Burn	1212	165	13.61
2	ENT	1109	27	2.43
3	Obstetrics and Gynecology	4727	151	3.19

4	Medicine	27878	3347	12.00
5	Nephrology	6076	695	11.43
6	Neurosurgery	2016	956	47.37
7	Orthopedics	4693	686	14.61
8	Pediatrics	7804	2366	30.31
9	Pediatric Surgery	856	189	22.07
10	General Surgery	16048	1705	10.61
11	Urology	5954	360	6.04
12	CTVS	737	1218	164.99
13	TOTAL	79,735	11,865	-

Highest Rates of Transfusion by Specialty in the Four Study Years-(1997, 2000, 2003, 2018)

The department of CTVS had the highest rate of transfusion in the study years. By and large the rates of transfusion by the super specialty departments like Urology, Nephrology and Neuro Surgery were high. Pediatrics was in the third highest place in 2018, which could have been due to increasing number of thalassemia and hemato oncology patients being treated in the hospital. This signifies that higher rates of transfusion are used by super specialty departments.

Table 9.10 Comparison of the Highest Rates of Transfusion by Specialty in the Four Study Years				
	1997	**2000**	**2003**	**2018**
First	Burn	CTVS	CTVS	CTVS
Second	Orthopedics	Nephrology	Burn	Neuro Surgery
Third	General Surgery	Urology	Urology	Pediatrics

Breakdown of the Transfusion Requests by Age of Patients

Age of patients receiving transfusions showed a change in 2018 from the previous years. Proportion of transfusion requests from the Pediatric age group had increased considerably which was possibly due to increase in the number of aplastic anemia and thalassemia cases after the establishment of pediatric hemato oncology department. This age group received 34% of all transfusions showing an increase of almost 15 % from 2003 data. There was a slight increase in transfusion in the age group of 46-60 yrs. A marked decrease in transfusions among 16-45 years (table-9.11) was seen.

Table 9.11 Transfusion Requests by Age of Patients				
Age	**1997(%)**	**2000(%)**	**2003(%)**	**2018(%)**
0-15	20.6	18.4	20.9	34.11
16-30	25.7	26.7	27.8	21.61

31-45	24.6	24.9	22.5	14.34
46-60	17	16.2	16.3	18.12
60>	12.1	13.8	12.5	11.80

Sex Distribution of Patients Transfused

A much higher proportion of males were transfused in comparison to females at 65 and 35 percent respectively, a markedly different finding from 2003, where transfusion was equally distributed among both the sexes (table-9.12)**.**

Table 9.12 Sex Distribution of Patients Transfused				
Sex	**1997(%)**	**2000(%)**	**2003(%)**	**2018(%)**
Female	50.20	53.60	46.80	34.83
Male	49.80	46.40	53.20	65.16

Top Ten Causes of Transfusion

Severe anemia was the highest followed by aplastic anemia with CTVS in the third place. Thalassemia received 5% of the transfusions. Chronic liver disease and chronic kidney disease were almost equal at 6 % of the transfusions.

9.13 Top Ten Causes of Transfusion		
SN	**Disease Category**	**%**
1	Severe anemia	12.88
2	Aplastic anemia	12.44
3	CTVS	10.25
4	Head injury, Stroke, Brain tumor	6.94
5	Chronic liver disease	5.94
6	Chronic kidney disease	5.82
7	Perforation peritonitis	5.74
8	Burn	5.34
9	Thalassemia	5.30
10	Malignancy	3.51

Severe anemia remained on top which was a finding similar to 2003. A new category of aplastic anemia was in 2nd position; this was because cases of aplastic anemia were being treated in the study hospital. In the earlier years, such cases were referred to other hospitals because of lack of this facility. This could also mean that over this period there has been a rise in the number of aplastic anemia cases. Similar reason can be attributed to increase in brain tumor cases being treated in the study hospital due to availability of trained faculty.

Chronic kidney disease did not figure in the top 10 causes up to the year 2003 because of lack of enough dialysis equipments in the hospital. There was a marked decline in the number of requests from the department of Obstetrics and Gynecology. This also reflected in the sex distribution of the patients transfused which showed a decline in proportion of female patients requiring transfusions as compared to the previous years.

All medical conditions put together accounted for 54.23% of all transfusion requests, whereas requests for all surgical conditions accounted for 45.71 % of all. The reasons could be increase in number of transfusion requests for patients of thalassemia, aplastic anemia, and kidney disease.

Comparison of TTI Rates in the Study Years

Prevalence of TTI rates among donors has gone down from year 2003 possibly because of decrease of prevalence in the general population, more awareness among donors and better counseling leading to self-deferral of the high-risk groups. Only prevalence of HCV among donors showed a slight increase (table-9.14).

Table 9.14 Comparison of TTI Rates

SN	TTIs	2003 (%)	2018(%)
1	HIV	0.34	0.13
2	HBV	1.51	1.10
3	HCV	0.38	0.41
4	VDRL	0.61	0.12

Costing of Blood and Components for the Year 2018

The methodology adopted for calculation of cost was same as that for the previous years. The rise in expenditure between 2008 and 2018 was 219 % on equipment cost, 258 % on staff salary, 833% consumables and 405% on the total expenditure. The highest increase was on consumables.

Table 9.15 Total Expenditure 2018

SN	Category	Total expenditure by category (2008)	Total expenditure by category (2018)	Increase (%)
1	Total Equipment cost	Rs 32,71,947	Rs 1,04,39,166	219
2	Annual Staff salary	Rs 92,28,000	Rs 3,31,24,056	258
3	Total Consumable cost	Rs 45,58,533	Rs 4,25,33,290	833
	Total Expenditure	Rs 1,70,58,480	Rs 8,60,96,513	405

Activity Wise Cost

In addition to expenditure on component separation that was already going on since the start of the study, expenditure on two more activities were included which were NAT testing and outdoor camps on the blood mobile van (table-9.16). Addition of these two activities when factored into the total cost, increased the unit cost considerably.

Table 9.16 Costs Incurred Activity Wise in 2018					
SN	**Activity**	**Equipment Cost**	**Personnel Salaries**	**Consumable Costs**	**Total Expenditure**
1	Expenditure on Component Preparation	Rs 24,11,013	No extra HR required	Rs 58,05,597	Rs 82,16,610
2	Expenditure on NAT	Rs 13,22,022	No extra HR required	Rs 2,56,96,100	Rs 2,70,18,122
3	Expenditure on Camps	Rs 1,30,00,000	Rs 3,53,256	Rs 1,40,000	Rs 1,34,93,256

Comparative Unit Cost of Blood Between 2008 and 2018

The cost of one unit in the year 2018 doubled in comparison to 2008 for both components prepared and components actually utilized. This increase was seen in spite of the fact that the total number of components prepared increased by 2.75 times, which should have actually reduced the unit cost. This was primarily because of increase in total expenditure due to the additional expenditure incurred on NAT testing and the use of blood mobile van for camps. The cost would go up by three times if the all units were used as whole blood and components were not separated.

Table 9.17 Comparative Unit Cost of Blood between 2008 and 2018					
SN		**No. of units 2008**	**Cost per unit 2008**	**No. of units 2018**	**Cost per unit 2018**
A	Cost of each unit of WB and Components-prepared	17,116	Rs 997	47,069	Rs 1830
B	Cost of each unit of WB and Components-utilized (excluding wastage)	16,452	Rs 1037	43,775	Rs 1967
C	Cost of each unit of WB without Component Separation	9,586	Rs 1412	20,748	Rs 4150

Change in Price of Items 2008 over 2018

Prices of all TTI testing kits except HCV showed a decrease in comparison to 2008 except HCV testing kit (table-9.18). Prices of some antisera increased over this period (table-9.19). There was a marked rise in the cost of blood bags of all types except integral blood bags.

Table 9.18 Decrease in Unit Cost of Items between 2008 and 2018			
SN	**ITEM**	**2008 (Rs)**	**2018 (Rs)**
1	VDRL Test kit	3.50	1.50
2	Biovue Cassette	33.00	14.63

3	HBsAg Rapid	9.90	7.00
4	HBsAg ELISA	40.61	32.06
5	Malaria Test Kit	54.00	31.00
6	HCV ELISA Kit	1,225.00	252.00
7	Anti-A1 Antisera	24/ml	15.36/ml
8	Hemocue	32/test	29.7/per test
9	Blood Bag Integral filter	2100.00	730.00

Table 9.19 Increase in Unit Cost of Items between 2008 and 2018

SN	Item	2008 (Rs)	2018(Rs)
1	BLISS Reagent	30.00/ml	33.30/ml
2	HIV Comb	12.58	32.00
3	Anti A Antisera	4.90/ml	6.33/ml
4	Anti B Antisera	4.90/ml	6.33/ml
5	Anti D	15.90/ml	18.70/ml
6	Single Bags	26.99	74.00
7	Double Bags	58.49	110.00

8	Triple Bags	86.00	160.00

Discussion

Between 2003 and 2018 the increase in beds was 45 percent, but there was 100 percent increase in admissions and 90 percent increase in major surgeries with a 300 percent increase in transfusions, indicating more pressure on the already burdened institution. So, in fact the service conditions have worsened resulting in non-clinical contextual factors having multiplied many folds. Hence barriers to rational prescriptions would be amplified due to the influence of these factors, despite awareness about component use within disciplines and knowledge of guidelines likely to have increased, with the hospital becoming a teaching institute.

Change in Prescription of Components

We found that there was significant change in prescribing practice in terms of more component prescriptions and less use of whole blood, leading to judicious use of one unit in several patients. Even the demands for number of fresh frozen plasma and platelets per patients had gone up with reduction in single unit demands for these components, This was due to two reasons, firstly because of more availability of donors and secondly because of improved knowledge of proper dose and indications. It has been explained earlier that over transfusion or transfusion in improper doses would expose the patient to hazards, by increasing the number of exposures without producing desired results. More number of component transfusions also indicated enough availability of these components in the blood bank. But it cannot be said with certainty by the present data that merely demanding more quantity actually meant that it was being used rationally.

Change in Sex Distribution of Patients

It was seen that in comparison to the earlier part of study, the proportion of males transfused increased to 65 percent. This could have been due to actual increase in proportion of males that were transfused or decrease in transfusion of female patients. Since more males are affected with

renal failure requiring dialysis and heart diseases requiring cardiac surgery and these departments have been upgraded, it appears that this could have been the reason for more male transfusions. Data from the department of obstetrics and gynecology showed that despite increase in beds from 55 in 2003 to 94 in 2018, there was a decrease in transfusions which was due to their conservative approach to transfusions.

Increase in Voluntary Donation and Camps

Comparison of TTI positivity Rates in 2003 and 2018 shows that HIV, HBV and VDRL rates had declined whereas HCV remained the same. Since the blood donors represent the general population, this decline would reflect a decline in prevalence of infection rates among the general population. In the year 2003 HIV prevalence among the general population was 0.38 percent (HIV Facts and Figures NACO) and in the year 2017 it was 0.22 percent (NACO Technical report 2017). Our data shows that in the year 2003, TTI reactivity of HIV was the same as the general population at 0.34 percent. In the year 2018 however reactivity among donors reduced to 0.1 percent much lower than the general population which was at 0.22 percent. This indicates that interventions like proper donor screening and counseling helped in self deferral of infected donors. Also sourcing from voluntary donors could have helped to keep the rates lower. Addition of Nucleic Acid Testing over the already existing ELISA has made blood safer, by shortening the window period though at a huge cost. As discussed earlier all the three components of the safety chain complement each other for ensuring blood safety.

Cost of Blood Units

It has been observed that diffusion of technology results in decrease in cost over a period of time. We saw that in these 10 years, prices of several items decreased but also increased for some reagents and blood bags.

Cost of each unit had increased to Rs 1830, almost doubled in 10 years. The increase was due to two reasons 1) price increase of some consumables and addition of NAT, an expensive test and 2) sourcing of blood from outdoor camps from voluntary donors, both measures adopted for increased safety. The additional expenditure on NAT in 2018 was Rs 2,70,18,121 and on outdoor voluntary donor camps was Rs 1,34,93,256.

By the principle of economy of scale unit cost should have gone down as the number of components prepared in 2008 was 17,116 units and in 2018 were 47,069 units which should have actually decreased the cost per unit by one and half times.

Plasma Fractionation

In the year 2018 a major policy decision was taken to give surplus plasma to the fractionators for the production of plasma derived medicinal products. This decision was taken in view of surplus plasma produced by the blood banks and shortage of these products in the Indian markets. An exchange rate of Rs 1600 per liter was fixed by the government. There were two private fractionators in India. But the policy lacks proper regulations for non-profiteering and regulation for sale only in domestic market and not for export. Also, savings for the hospital by such an arrangement should be worked out in detail. Before being given to the fractionators it must also be ensured that fresh frozen plasma is used in the hospital patients as a priority. As seen in table-9.4, the expenditure incurred in procurement of PDMPs was Rs 2,65,900 for factor VIII, Rs 1,77,96,290 for Human IgG and Rs 1,56,05,620 for Human albumin respectively, in the year 2018. Also, a total of 4000 units of plasma (with 80 percent component separation) were unutilized (table-19.5). This would generate revenue of approximately Rs 12, 80,000 annually, if exchanged at a rate of Rs 1600 per liter.

In summary, prescribing practice has changed with technology diffusion and increased awareness of the guidelines leading to increase in component use. Whole blood use has been almost phased out. As seen in the earlier part of the study, whole blood use was considered ‘rational’ by the prescribers for anemic women, who would also benefit from the plasma proteins. In tertiary centres if the government policy of 80 percent component separation is followed surplus plasma would be available that could be exchanged for PDMP’s. This change of policy for universal use of components would not be in patient interest in smaller towns and rural areas where substitute for protein such as albumin is not available.

Unit cost of blood component has almost doubled in 10 years. Price of some items has increased while others have decreased. With diffusion of technology and increased availability the price should have decreased but an opposite trend was seen in this case. However, with addition of newer tests and availability of voluntary donors has increased safety though at a very high price.

A higher proportion of males being transfused than females points to availability of better services for diseases primarily affecting males, like dialysis and cardiac surgery in the tertiary care setting and reduced use of transfusion for hysterectomies.

CHAPTER-10

Discussion, Conclusions and Policy Implications

This study was undertaken when a lot of changes were happening in the blood banking system due to the discovery that blood transfusion was an important source of transmission of HIV. A major change in policy was the screening of each unit of donated blood for HIV before transfusion. In addition, guidelines for the appropriate use of blood were framed and disseminated among clinicians to promote rational use, to prevent adverse effects and its wastage. The main objective of this study was to understand better what shapes transfusion prescribing practices through documenting the effect of these changes on the prescribing practices and to understand the nature of this change in terms of rationality of prescribing practice. Two dimensions of the trends in blood banking that reflect changes resulting from experience of the AIDs pandemic were studied: the need for appropriate prescribing of whole blood transfusions and the use of components prepared from whole blood, as well as the cost-effectiveness of technologies for component separation.

For the rationality of transfusion prescribing practices, the WHO guidelines formed the basis for categorizing ‘appropriate’ and ‘inappropriate’ in the first phase of the study. Then it went on to discuss the rationale of prescribing clinicians within their context for their deviations from the guidelines and the changing understanding of what is ’appropriate’. Hence, this study provides an understanding of the factors that affect transfusion decision making and problems faced by the prescribers in applying the guidelines especially in conditions of resource constraints and to thus inform transfusion policy and its adaptations to suit the given context. Blood economy and component separation to make 3-4 blood products from one unit donated was highly recommended, with component separation units being one of the big expenditures under the blood safety initiative of the AIDS control program. The study examined this technological input for its rationale and cost-effectiveness in the study hospital, understandings from which can be extrapolated for larger policy implications as well. While the thesis was being finalized in 2018, a separate chapter was written to present the changes in the hospital that were relevant to

assess the changes in blood banking and prescribing practices as observed through data available with the blood bank. Updating the data for the blood banking prescribing and technologies in use gave an opportunity to see how diffusion of technology unfolded in this period and how its costs increased or decreased over the years.

Implications of sourcing of blood from replacement donors and the epidemiological assessment of the need for transfusion on prescribing practices as well as the quality and safety of blood banking were also studied.

In this chapter we bring together all the findings presented in the previous chapters and discuss their policy implications.

Uniqueness of the Methodology

This study was conducted in one tertiary hospital and its blood bank in the urban public sector of the capital city of Delhi, covering the period 1997-2008. It was contextualized in the health service system and blood banking system of the metropolis, Delhi, in which it was located. The need to embed this within the country's overall health services was also important for extrapolating findings of the study for wider policy implications.

Several studies from developed and developing countries had concluded that inadequate knowledge of transfusion guidelines was the primary reason for inappropriate transfusion practice. This finding led to introduction of interventions to educate clinicians on guidelines, with the expectation that education would bring about a change in practice behavior. Most of these studies were interventional studies designed to quantitatively measure change in practice, before and after application of educational interventions (Lam et al., 1997).

A randomized controlled trial by Tim Bray (2001) on 'Rational use of blood in India' designed a checklist to be used at the time of placing requests. This intervention to educate the clinicians, found inconsistent results across the four hospitals included in his study. Discussion with key personnel was planned in the initial phase of the study but he later also included qualitative methods like in-depth discussions, semi-structured interviews and group discussions with stake holders. In his analysis, Bray identified some factors which could have contributed to the failure of the intervention: the hospital environment, state of health services and economic issues. Most

educational interventions used by other studies too did not produce desired results indicating that certain 'other' factors could be operating in addition to inadequate knowledge of guidelines.

In this study we attempted to understand the rationality of the prescribers' deviations from the guidelines, not assuming that they are 'inappropriate' while doing so.

Studying Prescribing Practices in a Health Systems Framework

From a review of these existing studies it was concluded that a more comprehensive health systems research framework was required to examine issues such as prescribing practices and their causality. It seemed clear that use of survey methods alone does not allow an in-depth enquiry into the factors that could affect practice. Hence, quantitative survey methods need to be used together with qualitative methods to complement each other (Weber et al., 2005) (Pope et al.,)

Examining the Rationality of Universal Guidelines in Specific Context

This study was conceptualized with the understanding that the approach to merely educate clinicians about transfusion guidelines was based on the premise that the guidelines were universally appropriate and only just required to be put into practice. We hypothesized that transfusion decision making entails a complex procedure and depends upon several factors besides knowledge of guidelines, like those related to the settings in which the prescribers operate. To examine this hypothesis and in an attempt to capture the factors related to the practice environment, a mixed method design was adopted. Four phases of data collection and analysis were undertaken: a blood prescribing audit by analysis of requisition forms over a six-year period after some time of initiation of changes due to the AIDS epidemic; interviews with prescribing clinicians; case studies of 'inappropriate' prescribing with reference to WHO guidelines; focus group discussions with the prescribing clinicians.

First, a quantitative assessment of the transfusion practices over a seven-year period was undertaken, when several changes due to the response to HIV had occurred in the hospital, affecting demand, as well as transfusion practice. Data from transfusion request forms received at the blood bank of the study hospital, between the years 1997 to 2003, was analyzed to get an overall picture of the status and trends in transfusion prescribing practice and to identify it's

inadequacies as against the WHO guidelines. This was five years after the National AIDS Control Program phase-1 and blood banking safety interventions had been instituted. The analysis of trends in prescribing practices included overall hospital and department-wise use of whole blood and components, before and after component separation was started in the hospital.

Using the findings of this phase, the reasons for transfusion prescribing practices were studied employing three sequentially ordered qualitative study methods.

Sequential Qualitative Methods

Awareness and perceptions of the prescribing clinicians were studied first through schedule-based interviews with clinicians of departments that had used blood and components, capturing information on their knowledge of guidelines, attitudes towards blood safety and the transfusion practice they followed.

Next, an in-depth study was conducted of 80 cases identified as ‘inappropriate’ transfusion prescribing by WHO guidelines. Their documents were analyzed along with interviewing the prescribers to classify them by rationality and accounting for problems they faced in translating the guidelines into actual practice. The findings and interpretation from the previous phases of the study were put together by qualitative data triangulation embedded in the background description of the service system in which it was located. This generated a comprehensive interpretation to get a holistic understanding of transfusion prescribing practice in the hospital.

Focus group discussions were then carried out with the clinicians of each department in which the findings and interpretation from the previous steps of the study were shared to elicit their feedback. This feedback was incorporated to further enrich the interpretation of findings and add to the rigor to the qualitative analysis.

Finally, costing estimates were computed of the use of component separation technology to assess the rationality of its adoption in the study hospital and what it could tell us about its rationality in the Indian context.

The Findings

Our study provides evidence that decision making for transfusion of blood and components is a difficult and complex process and is guided by several factors. In addition to inadequate knowledge of transfusion guidelines, there are other factors rooted in the practice environment that affect transfusion decision making. Between 2003 and 2018 the increase in beds was 45 percent, but there was 100 percent increase in admissions and 90 percent increase in major surgeries with a 300 percent increase in transfusions, indicating more burden on infrastructure without a commensurate increase in manpower. So, in fact the service conditions have worsened. Hence there would be chances of irrational prescriptions due to non-clinical factors increasing considerably. On the other hand, knowledge of guidelines would be better with the hospital becoming a teaching institute.

Contextual Issues Affecting Practice

Results from the 'inappropriate transfusion prescribing' case studies showed that **44** were rational because they were adapting to context, **30 percent** were due to inadequate knowledge of guidelines and 25 percent were difficult to categorize into either of two groups as they had elements of both. Deviations from guidelines in **44 percent** of cases seemed to have reasonable justification and were made for the benefit of patients. Transfusion decisions were the result of interaction of multiple factors that forced clinicians to deviate from laid down guidelines. The clinicians worked with the best intention, in patients' interest where saving patient's life was of utmost concern. Since tackling the same problems everyday becomes a habit, they unconsciously covered for all the deficiencies in the system. Therefore, deviations from guidelines where few options were available and where the prime concern was saving patients' life would be justified as rational in the given context. These facts were also corroborated by the FGDs done with the clinicians.

The contextual factors that affected transfusion prescribing practices that were identified by our study included the following:

1. Patient related factors both biomedical and social, clinical condition of the patient, location of residence, socioeconomic status, expectations from the health services, attitudes towards health service system, attitudes towards blood transfusion as a treatment modality.

2. Clinician related factors like--experience, techniques, technology, positive /negative experiences with transfusion, attitudes towards blood safety, towards availability of blood, peer influence.
3. Institutional factors -lab facilities, blood bank facilities, logistics, cost, availability of beds, OT facilities.
4. Organizational factors like, level of development of the health service system and the blood banking system, system of blood sharing between other banks, sourcing of blood-replacement/voluntary donors.

Some of the common examples that illustrate these adaptations to context are discussed in the following sections.

Findings of the Audit of Transfusion Prescribing Practices

The major finding from audit of request forms of the years 1997 to 2003 was the universal use of 'whole blood' across all specialties, in spite of the availability of packed cells and components in the study hospital. Single unit transfusions and inadequate dose of fresh frozen plasma and platelet transfusions were other significant deviations from the WHO guidelines.

Issues in Prescribing of Whole Blood Vs Packed Cells in Anaemia

Anaemia or deficiency of hemoglobin could be acute (as seen in cases with acute blood loss) or chronic, the severe forms of which require transfusions for correction. Guidelines permit the use of whole blood only in case of massive bleeding and in emergency situations when components are not available. The guidelines recommend the use of packed cells that contain RBCs only (without plasma and platelets) that is made by separating whole blood into the different components. Each component is used for specific indications for achieving the therapeutic levels and to promote judicious use of a scare resource. Moreover, component separation helps in removing white blood cells (Leukoreduction) which are known to cause fever in many transfusion recipients.

Our study found that, even in 2003, in spite of the availability of components. whole blood continued to be largely used instead of packed cells. Interviews with the clinicians showed that they had not encountered any major problems with whole blood transfusion in the past and so continued to still prescribe it for correction of anaemia. They also explained their rationale, that since most cases of anaemia resulted from poor nutritional status and did not occur as a selective deficiency of iron or folic acid, plasma proteins present in whole blood would actually help patients who were not in cardiac failure. Secondly, the prescribers also justified transfusion of whole blood in acute blood loss cases because in these cases, plasma proteins helped in maintaining the oncotic pressure. Guidelines prescribe commercial albumin which is a costly substitute. Thus, the continuing use of whole blood in cases of anaemia was 'appropriate', given the socio-economic context and background of patients in a public hospital offering services free of charge.

Prescribing of Blood Components

In the year 2003, Department of CTVS used most components[8]. This is because of the nature of disease and the surgical procedures that are involved for cardio thoracic 'by pass' surgeries. Data showed that out of all the components requests by the department of CTVS only 1.45 percent was for whole blood, 46.49 percent was for packed cells, 44.96 percent for fresh frozen plasma and 73.58 percent was for platelets, indicating more component use by CTVS in comparison with the other departments.

However, in the year 2018, a major shift towards component use was seen by all departments. Only **2.58 percent** of requests were for whole blood, **61.69 percent** was for packed cells, **21.34**

[8] *Components play an important role in the management of cardiothoracic surgery patients. During surgery a considerable number of platelets that are destroyed by the use of the heart lung machine needs simultaneous replacement. These patients are also on anticoagulants causing a deranged coagulation profile and increased bleeding tendency where FFP is indicated. Whole blood cannot be used to correct these deficiencies since both platelets and coagulation factors are destroyed at the temperatures at which whole blood is stored i.e., between 2c - 6c. Therefore, these have to separated immediately after blood collection and stored at appropriate temperatures to maintain its viability.*

percent was for fresh frozen plasma and **14.37 percent** was for platelets. Several factors had contributed to this shift: increased availability of fractionated components, a shift in medical discourse across the various specialties about component transfusion and increasing awareness of guidelines had brought about this change in practice.

Inappropriate Use of Fresh Frozen Plasma and Platelets

In the years 1997, 2001 and 2003, single unit transfusion of fresh frozen plasma was 69.7 percent, 50 percent and 26.5 percent and platelets were 50 percent, 62.5 percent and 17 percent respectively, i.e. was high initially though showing a declining trend. The therapeutic dose of fresh frozen plasma and platelets is at least four units per transfusion episode. Inadequate dose amounts to undue exposure without achieving any clinical benefits. The chief reason for single unit transfusion of components given by the prescribing clinicians was non-availability of adequate number of donors, resulting in under transfusion and compromise with safety.

In was found that fresh frozen plasma was transfused in patients with hypo-proteinemia which is found commonly in patients with intestinal perforation and burns. Clinicians opted for fresh frozen plasma or plasma instead of albumin because it was easily available and was a cheaper substitute for Albumin[9] thereby rational in the setting having cost constraints. As one clinician remarked, '*Albumin is costly (Rs. 2840 per unit) and is in limited supply". Also, the blood bank does not insist for replacement donation for fresh frozen plasma as it is surplus'.*

The use of fresh frozen plasma in conditions described above was a deviation from guidelines for which more research, discussions and debate are needed in the context of developing countries. Hence, the reasons for single unit use of fresh frozen plasma and platelets were primarily because clinicians had to manage with fewer donors, for reasons of cost cutting and partly because knowledge of indications was inadequate.

[9] *FOOTNOTE: Fresh frozen plasma is indicated for correction of coagulation factors when INR is more than 1.5, times. The normal, dose is 4 units to 6 units of FFP per patient.*

The Shaping of Prescribing Behaviors: Inappropriateness and Rationality

Prescribing Clinicians' Knowledge of Guidelines

The KAP study with the doctors showed that knowledge of transfusion guidelines was inadequate, as more than half the respondents 56 percent, were not aware of WHO guidelines. Out of the 44 percent who were aware of the guidelines only 18 percent actually used them in practice. In our study it appears that the rest of them i.e., 26 percent could not follow guidelines due to health service system constraints which was revealed by study of the cases and discussions with the prescribers. Similar findings were reported by Salem Sachez (1990), Gupte S.C. (2007), Makroo R (1992), Salem-Sachez et al (1993), found inadequate knowledge of guidelines to be as high as 50 percent among the clinicians in a study based in a teaching hospital, in Massachusetts, U.S. In addition, they attributed reasons for deviations from guidelines to the practice environment, like, peer pressure in group practice, influence of senior colleagues and perceptions of resource availability to be affecting transfusion decisions.

Medical Dilemmas

Constitutional Variations among Patients

Clinicians' were of the opinion that management of a patient involves the evaluation of the patient in totality of which transfusion is just a small part. Therefore, to judge one episode of transfusion in isolation as appropriate or inappropriate would not be correct. Decision to transfuse was based on the evaluation of the individual patient's condition and needs which could differ from one patient to another. Moreover, they felt that the guidelines were a set of broad criteria to aid decision making and patient specific problems needed specific solutions.

This dilemma could be clearly seen in Dengue patients, where there is a rapid fall in platelet counts, leading to fatal internal bleeding. According to guidelines, platelet transfusion is required only when the count falls below 20,000/dl. But some clinicians differed on this as patients could bleed at much higher platelet counts due to co-morbidities and that the clinical picture could vary from one patient to another specially in children and old age patients. There was fear of missing minute hemorrhages also that came as warning signals. In dengue epidemics the situation was

further aggravated by panic created by media reports of platelet shortages and dengue deaths. Anxiety among the general public resulted in demand for platelet transfusions in cases which could otherwise be managed conservatively.

Discussions also revealed that decision making was particularly difficult when the laboratory parameters fell in the grey zone because of incomplete knowledge of critical limits of tissue perfusion and the problem of individual variations in response to treatment. Clinicians preferred to transfuse in such situations and did not want to err on the side of withholding transfusions. When such uncertainties exist, the clinicians rely more on their conventional wisdom and personal experiences as the most immediate concern of the clinician is the wellbeing of the patient.

Transfusion and Wound Healing

Many Surgeons and Gynecologists alike believed that blood transfusion helped in wound healing and fast recovery, while the guidelines suggest that wound healing is affected only when the hemoglobin fell to significantly low levels (Weber et al., 2005). In general, moderate anaemia is unlikely to affect repair in physiologically normal patients (Jonsson et al., 1991). We found that the clinicians maintained a hemoglobin of 10 gm/dl or more, for better wound healing. They also believed that since majority of women in reproductive age group had low iron reserves transfusion resulted in better clinical outcomes.

Technology and Surgical skills

Clinicians pointed out that surgical techniques and modern technology also had an important role in deciding the transfusion requirements in patients. Some technologies like laparoscopic surgery or use of gel foam sponge for hemostasis reduced the need for transfusions considerably. Likewise, the skills and experience of the surgeons in controlling bleeding quickly and effectively could reduce transfusion requirements to a great extent.

Challenges of Sourcing of Blood: Replacement Donors

Sourcing of blood is predominantly dependent on replacement donation resulting in several issues that are vital to blood safety which need to be addressed. Motivation of family members

was difficult and time taking, the onus of which rested on the clinicians. Moreover, there was concern that replacement donors hide facts about their actual health status. 'Paid donors' sometimes 'passed' as relatives of patient because verification of their true identity was difficult.

During discussions, the prescribers unanimously said that motivating relatives for donation was a hard task and many times elective surgeries had to be postponed to build pressure on them to arrange for donors. The blood bank on its part was hard pressed and found it difficult to supply without replacement because of insufficient stock, however they could barely manage to issue for emergency cases. The system of sourcing of blood from replacement donors has its problems, but is the only option available due to low proportion of voluntary donation. Camps are held irregularly, blood collected from camps make up for the shortages but are inadequate. The clinicians said that since all replacement donors did not come at the same time, treatment was started with available units, an important factor that led to many single unit transfusions.

Scarcity of replacement donation resulted in transfusions in inadequate doses as the clinicians had to 'manage' with whatever was available. In the absence of donors sometimes surgeries were postponed and the patients had to be discharged, as beds were limited. Many unnecessary transfusions could be avoided if the blood bank had enough stock and the doctors had the assurance of timely availability of blood and components. The insistence from relatives to transfuse because replacement donation had been made in advance was a pressure that clinicians found difficult to handle leading to few over transfusions also.

Myths and misconceptions about blood donation was one of the chief reasons that lead to unwillingness to donate. There was also a common belief that blood donation resulted in weakness which was reinforced by the fact that they were unable to afford an adequate balanced diet due to economic hardships. In our study we found that 40 percent of donors were rejected for anaemia and 15 percent for being underweight. The system of replacement donors, thereby makes it difficult especially for the low socio-economic sections to replace blood as many relatives were found unfit for blood donation.

Similar findings were reported in studies from Nigeria as well (Emeribe et al., 1993) and Kenya (Lackritz et al., 1993), identified inadequate resources like, shortage of blood bags, tubing, needles and scarcity of "Replacement Donors", as a cause of delay in transfusions

Institutional Factors

Discussions pointed to the fact that the institutional environment shapes the clinicians' perceptions of risk and benefit. The treating physician is directly responsible for the outcome and the user-provider relationship demands accountability to the patient and his family. In such situations therefore the physicians were not willing to take any risk and were liberal with transfusions.

The prescribers pointed out that the patient load especially in the emergency departments was very high and were proportionately understaffed. The doctors were overburdened which resulted in inadequate patient monitoring. Treatment of acute blood loss was particularly difficult without proper monitoring. Acute blood loss is a rapidly changing situation, where close and repeated monitoring of vitals is required for proper assessment of blood loss and overall management. As saving lives was the ultimate goal, many precautionary transfusions were given that could have otherwise been avoided. Similarly, emergency operation theatres could not cater to a high patient load, increasing the waiting time considerably. Actively bleeding patients had to be transfused some of which could be avoided, if timely surgical intervention was available.

Some costly laboratory investigations were done biweekly, hence, in the absence of timely reports the doctors were forced to take decisions based on clinical criteria alone. Proper management of patients entails a careful assessment by both clinical judgments supported by laboratory findings. Many times, the quality of laboratory reports was doubtful. The clinical assessment did not match with the values reported. Here also decision making was difficult and would result in unnecessary transfusions.

Similar working conditions were reported in a study by Emmanuel A.Y. (1991), from Ghana a resource poor country. They found that hasty transfusion decisions were due to large patient load that had to be handled. They also found that delayed and doubtful laboratory reporting resulted in excessive dependence on subjective clinical findings to guide transfusion decisions.

Hence high patient load, inadequate support of laboratory facilities in evening and night shifts, or inferior quality of reports and inadequate institutional support made working conditions difficult. In our opinion transfusions ordered due to apprehension of worsening of patients' condition, could not be labeled inappropriate because there was adequate justification from the clinicians' point of view and were done in patient interest.

In the year 2003, 64 percent of all requests came from all surgical departments put together. In this group transfusions could be minimized with proper patient preparation and correction of anaemia with hematinic. Since surgeries are performed in a controlled environment, it is possible to closely monitor the patients' transfusion requirements it provides ample opportunity for minimizing transfusions. Proper preparation of the patient, better planning of estimation of the allowable blood loss, better preparedness for hemostasis etc., can minimize transfusion needs in this group of patients (Addo-Yobo & Lovel, 1991). In addition to prior planning intra operative blood loss can also be reduced by proper surgical and anesthetic techniques, by maintaining peri operative normothermia, and by the use of pharmacological agents where appropriate.

But due to high patient load and a large number of waiting patients' clinicians preferred blood transfusion over oral hematinic as it took longer time for correction of anemia. With availability of more beds and OTs, transfusions in this group of patients could be minimized and health system constraints leading to over transfusion could be addressed to a certain extent.

Common Perceptions about Transfusion Risks among Prescribers

In our study the findings were contrary to the change in behavior observed in the developed countries. We found that in spite of the fact that 64 percent of the respondents were aware of the window period and disease transmission through transfusion; this issue was not of major concern in decision making. The main focus was on the immediate outcomes and an uneventful postoperative period since this was a major challenge given the conditions under which they worked. Moreover, they felt that tested blood was safe and had "faith in the blood bank".

In the U.S. discovery of AIDS, its perceived health risk by the community and the resulting public pressure altered transfusion practice. Rate of transfusion declined considerably in the 1980s with the largest decrease occurring in 1984 (Atlas et al., 1994; Surgenor et al., 1988). This decline was attributed to more use of autologous transfusion, change in post-operative transfusion practices and stringent thresholds reflecting less 'topping off', with transfusions. This indicated that in the presence of perceived health risks, physicians could alter practice and that they effectively ration scarce resources.

Some single unit transfusions given when blood was released prior to surgery could have been avoided but were justified from the prescriber's point of view as it was done as a precautionary measure to avoid delay due to issue and transport. Though prescribers agreed that after issue the units were invariably transfused and were rarely returned back to the blood bank.

This practice was almost always seen with negative groups which were generally in short supply and had to be arranged in advance. Perceptions of resource availability (Salem-Schatz et al., 1990) and the confidence of the surgeons and anesthetists that blood needs will be met when necessary (Napier et al., 1985), would restrain them from ordering in advance.

Perceptions about Health Services among Community

'Blood' is perceived as a vital force, necessary to preserve life, loss of which could result in death. Blood loss was a cause for panic among relatives, resulting in pressure from them to transfuse. It was found that assurance from the doctors' helped, but sometimes it was difficult to convince the relatives that further observation of the actively bleeding patient was required and that transfusion could be delayed.

Perception of risk, lack of faith in the health system and trust on doctors by patients' relatives led to many transfusions that could have been otherwise avoided. Sometimes proper communication of risk to the patients' relatives was not made by the treating doctors because of work pressure and they too thought that the relatives would not understand the medical issues.

Implications of Contextual Prescribing Behaviors for Adapting Guidelines and Educating Prescribers

Hence, 44 percent of the times i.e., in a little less than half of the times, transfusions otherwise categorized as 'inappropriate' by WHO guidelines, were found to be 'rational' in patient interest. The prescribers were actually adapting to the context, under the given working conditions. Hence there is a need for understanding the local contextual factors and the prescribers' practices in this light as adaptation in patient interest. Guidelines must be adapted to the specific context in consultation with the prescribers and with consideration to their adaptations and concerns.

In 30 percent of the cases there was inadequate knowledge of guidelines where education of guidelines to the prescribers could help improve prescribing practice. There was inadequate knowledge of indications and dose of components, requests for single unit transfusions that could have been avoided in surgical cases and perceptions that blood transfusion helped wound healing and better clinical outcomes, were some areas that could be improved with education.

In approximately 25 percen**t** of cases elements of both inadequate knowledge and adaptation to context were present which could partly be addressed by education and the rest by adapting to the specific situation.

Cost-Effectiveness of Component Separation Technology

The costing exercise of blood and fractionated products showed that in a tertiary hospital where blood intensive procedures are performed, just using whole blood and not having a component separation unit is not a cost effective or viable option. Using whole blood alone in large centers increased the price of one unit considerably by **Rs 416,** in comparison to the cost of a unit when fractions were made i.e., from **Rs 996 to Rs 1412**. Hence these units would be desirable in tertiary centers with super specialty facilities like CTVS. Taking into account the cost of wastage of 20 percent of fresh frozen plasma and 30 percent of the discarded platelets, a further increase of cost by Rs 40 per unit was seen. Therefore, it would be desirable that such facilities functioned as central component separation units, sharing the surplus fractions where feasible with other medical institutions to minimize wastage by which the cost would further come down decreasing proportionately to the scale of operation. Bray T.J. 2001 showed that the principle of 'economy of scale' worked when large centers were involved in collection and processing, making the system more cost efficient. He found that, the direct total cost per unit of whole blood was Rs 1324/-in a center with a monthly collection of 100 units and decreased to Rs 572/- with a monthly collection of 5000 units and Rs.306/- with a monthly collection of 10,000 units. Hence in tertiary centers with component separation units, blood sharing with other hospitals would be a more cost-effective option and would prevent wastage of components.

With functioning at basic level following mandatory regulations to maintain quality and safety of the blood banks, i.e., without high end equipment's and minimal automation the cost was Rs 1162 i.e., the cost saved was Rs 250 per unit (Rs 1412-Rs1162). Therefore, this would be a good

option for situations where only a small number of fractions are required.

Diffusion of technology is generally expected to lower its costs. In this case, observing it over the period 2003-2018, we find that the cost per unit of component has almost doubled in spite of approximately 3 times increase in the number of units produced, mainly because of additional NAT testing and voluntary donation camps. Also cost of some reagents have decreased, while the cost of blood bags have increased considerably, thus adding to the increase in the total cost.

The technology of component separation has added a different kind of irrationality as being witnessed in view of increased availability of components in the study hospital. More availability has meant more prescriptions but its appropriateness as assessed by guidelines is still questionable. Over this period the health service context remains much the same and the socio-economic condition of the patients also has not changed much.

In view of the above findings it was concluded that, for effective translation of guidelines, socioeconomic and health service system issues should also be incorporated into the guideline adaptation process to account for the wide diversity in the practice environment and should not be based on the biomedical criteria alone. The clinicians should be sensitized to the need for knowing the guidelines but also oriented to the rationality of adapting them to their context.

Policy Implications

1. Sourcing of Blood

Sourcing of blood depends predominantly on replacement donation, leading to uncertainty in availability, resulting in a compromise with safety and irrational use. Sourcing of blood from properly counseled voluntary donors would solve this problem to a great extent, thereby ensuring a regular supply of blood and minimizing replacement donation over time. In order to achieve this, a multipronged strategy with aggressive awareness campaigns, clear messages about safety and need for voluntary blood donation and properly spaced voluntary donation camps in terms of time and area is required. Ensuring availability would also increase faith of donors in the system and encourage them to donate.

Voluntary donation is low and a systematic effort to understand the problem is lacking. Most of the research in this area has been done by the developed countries, with limited applicability to low income countries because of socio economic and cultural differences. Therefore, research in this field should be promoted, so that a better understanding of the problems is developed and strategies can be worked out accordingly (Glynn et al., 2002). Also studies on the better performing and the low performing states within India with respect to voluntary donation should be carried out to understand the hindering and facilitating factors. Some areas of research could be on the psychosocial makeup of the voluntary donors, what acts as a barrier and what motivates volunteers and thereby what can be done to attract them in terms of trust generation, convenience of donation, type of IEC messages that would make an impact on donor motivation role of incentives in recruiting voluntary donors and how best they could be channeled in our context, (Sanchez et al., 2001). Further, studies on groups that could be targeted for maximum results, understanding the socio-cultural meaning attached to 'Blood' by the community to dispel myths and misconceptions, fears and taboos, are some of the areas that need to be explored.

2. Relationship with other blood banks and the kind of issues with blood sharing

As has been described earlier, blood banks of Delhi belong to the public sector, private sector and NGO's. The public sector blood banks, in turn belong to different organizations like Central government, state government, autonomous bodies, Municipal Corporation, army and railways with different administrative structures and different sources of funding. In addition, there is multiplicity of regulatory authorities and extremely variable pricing structure. Some of those belonging to the state government, NGO's and railways, charge for blood and components when they supply to private nursing homes and these charges are variable. The private blood banks charge for blood which is considerably higher than that proposed by the government on the pretext of conducting certain additional tests and maintaining quality. The regulatory authorities are concerned with the basic minimum standards required for licensing but price control is beyond their purview. This differential pricing has also created blood and components of two different 'quality' making sharing between blood banks all the more difficult.

The government sector which provides blood units free of cost cannot share with private hospitals because of financial implications. On the other hand, the private hospitals would be at a loss if they shared with government hospitals for free.

Regular sharing of surplus stock between the different blood banks belonging even to the same category of blood banks does not take place routinely. An inclusive policy and a regulatory mechanism to address the issue of sharing between the public and private blood banks would be required. Sharing of information about the stock positions between blood banks would help tackling shortages to a great extent.

Delhi, being the capital city is the best in terms of infrastructure and connectivity by road which is lacking in many other towns and rural areas. Blood storage centers at the first referral units (FRU's) were established for universal access and equitable and timely distribution across the state of Delhi. It also ensured safe blood of uniform standards ensured by centralized collection and testing at regional centers.

3. Implications beyond Delhi

Blood storage centers have been established for proper distribution in the rural areas, where a regional blood centers serve as a mother blood bank to many BSC's in a 'hub and spoke' fashion to supply blood to the periphery. This model though good in principle should be revamped in terms of geographical distribution and universal coverage.

The real challenge faced by the government is provision of transfusion below the level of the district hospitals where the problem of connectivity and infrastructure exists. Given the diverse context of India, and its diverse needs transporting blood or components from the districts to the blood storage centers is not easy in the remote areas of some states. Furthermore, in such area's management of these centers could be difficult because of poor infrastructure and distances from the regional centers which are located at the district hospitals. Moreover, blood donation has to be done at the mother blood bank which makes the process difficult. Distance from the health facility could be one of the factors that, up to 25 percent patients in the rural areas cannot access treatment when they need it as reported by NSSO.

In a study of blood transfusion services in district Dhule in Maharashtra, Tongaonkar (1998) has shown that distribution of blood to the different Talukas, from the District Centre was difficult, because the average time taken to reach the various Talukas varied from six hours to fifteen hours and even more at night. As a solution to this problem, Tongaonkar argued for unbanked directed blood donation (UDBT). In this system, blood is drawn from relatives and transfused to the patients at the time of surgery, in the nursing homes itself. UDBT was discouraged by NACO for concerns of poor quality of testing for TTI's since Rapid tests with lower sensitivity are used. Testing by the ELISA technique requires sophisticated equipment, proper infrastructure and trained staff. The problem of inferior quality testing was acknowledged by the author, but in areas where facilities to support proper storage and testing is lacking UBDT could save many lives. In a presentation in 2001, Dr. Salil Deputy Director Blood Safety NACO pointed out that in spite of UBDT not getting the government's approval, higher number of sales of blood bags than the official figures of total blood collection are a testimony to the fact that UBDT is being practiced in India.

NACO is considering converting blood banks with annual collection of less than 3000 units, into Blood storage centers, which may not be in the best interest of these underserved areas. Tongagaonkar (1998) prepossess establishment of Village blood banks (VBB) with relaxed norms for the difficult and remote areas.

To achieve this, GIS mapping with layering of details of demand and supply and consideration of travel time could be employed to plan better geographical distribution of the blood banks and storage centres. In addition, a proper epidemiological assessment of the requirement of blood and components at the various levels of health care must be made.

4. Role of Component Separation Units in the Indian Blood Banking System

In our study we found that the best option economically was to have component separation units at tertiary centers with super specialty facilities and sharing the surplus fractions with other institutions. This would also prevent wastage of a scarce and precious resource. Further, if such facilities functioned as central units and supplied components to other nearby blood banks and medical institutions, wastage and cost would come down and the cost would decrease proportionately by the principle of economy of scale. Therefore, wherever there is CTVS, or

other super specialties, component separation with sharing would be the best option. Our study also showed that in a tertiary hospital just using whole blood and not having a component separation unit increased the price considerably.

However, rationality of setting up component separation units cannot be assumed to be a universal phenomenon; diverse contexts may require diverse approaches to blood economy and safety based on cost effectiveness and other health systems research findings.

A proper needs assessment of component requirement depending on the epidemiology of diseases at different levels of health care delivery is required. The need for the type of blood component and its quantity would be different for district hospital, community health centers and primary health centers. Our study shows that, diseases requiring component transfusions like aplastic anemia, thrombocytopenia, DIC and blood intensive surgeries like transplants and cardiac surgeries etc. require tertiary level care where components are available. Since some district level hospitals, mostly deal with uncomplicated surgeries and deliveries that can be managed with whole blood, component separation is not desirable both epidemiologically and by cost effectiveness criteria. In the context of India because malnutrition and anemia are prevalent in 60 percent to 80 percent of the population, whole blood could be used to treat anemia unless the patient is in cardiac failure where packed cells are indicated to lower the load on the heart. Anaemia mostly results from nutritional deficiency and not due to selective deficiency of micronutrients, whole blood would be the choice in such areas. Similarly, in elective surgery with acute blood loss, whole blood and other cheaper options of colloids and crystalloids can be used as the first line of treatment. In cases of anemia with cardiac failure proper training to make packed cells by gravitational or centrifugation method should be imparted. Proper infrastructure trained staff and continuous power supply is needed for preparation and storage of components, thus establishing component separation unit at every district level hospital would be difficult. Research should be undertaken to optimize technology requiring less infrastructure, fewer machines and find better ways to do it by developing low cost technology in our context. For the smaller essential requirement of components, other low-cost methods could be employed.

Therefore, instead of viewing component separation unit as an unquestioned universally desirable intervention for blood economy, a proper epidemiological assessment of the indications

for component requirement should be made and the need for components estimated. Thereby the decision to install a component separation unit should be made based on critical needs assessment. Where it is installed the proportion of collection that would be separated into components should also be based on the estimates of need. Moreover, unless sharing mechanism with other users is well established, component separation would not be cost effective because the equipment's for separation, storage and consumables are costly and specially trained manpower is required for the procedure.

5. Measures to Improve Transfusion Prescribing Practices

There was inadequate knowledge of indications and dose of component use as seen in 30 percent of case studies, requests for single unit transfusions that could have been avoided in surgical cases and perceptions that blood transfusion helped wound healing resulting in better clinical outcomes, were some areas that could be improved with education. Education must address the uncertainties as transfusion decision making is a complex procedure and transfusion science is a comparatively recent branch of medicine that is still evolving, as pointed out by prescribers in the focus group discussions.

In 44 percent of the cases it was seen that the prescribers were adapting to the context and hence did not follow the guidelines.

WHO recommends that guidelines should be adapted to the local needs and constraints - "Nevertheless clinical transfusion practice should always be based on national guidelines where available. Users are therefore encouraged to adapt the information and guidance contained in the module and pocket handbook to conform to national guidelines and established procedures in their own countries" (World Health Organization, 2001). The adaptation of guidelines by participatory methods would require joint inputs from transfusion medicine specialists, clinicians, anesthetists and public health experts.

Improved understanding of specific influences in different practice care settings will help develop effective practice change strategies, leading to consequent improvement in the quality of care. 'Any strategy chosen is more likely to be effective if the non-clinical factors and relationships examined above are acknowledged and incorporated into the intervention' (Salem-Schatz et al., 1990). Hence, if the WHO guidelines are to be followed, institutional strengthening

is required with increase in manpower, strengthening of laboratory facilities, and quality assurance measures. Additional manpower is needed for blood bank as it is an emergency department. Awareness must be created at all levels for enrolling voluntary donors and to gradually shift from replacement system of sourcing of blood. Further this is especially needed in view of the fact that most tertiary centers treat referred patients who cannot arrange for the required number of replacement donors.

Our study also showed that in approximately 25 percent of cases that did not clearly fall into these two categories, where there had been elements of both. Education of guidelines along with skill development of the clinicians in adapting to context as an aware conscious process would make it even more rational. Such orientation must be a continuous ongoing process by way of CMEs.

Salient Implications for Future Research and Policy Governance

Our study highlights and demonstrates that participatory research with mixed method designs helps in a better understanding of the context and is critical for Health Systems Research. In this process the participatory engagement of the clinicians along with various other sets of actors like the community, administrators etc. is crucial to the understanding of the context for guideline adaptation and policy formulation.

By employing participatory methods, perspectives of the clinicians would help develop and deepen the understanding of the contextual issues faced by Transfusion Medicine specialists and contribute to the development of this discipline. Transfusion Medicine needs to incorporate the larger systemic, social, economic and health service issues, going beyond the biomedical and behavioral dimensions.

WHO clearly mentions that transfusion practice has to be adapted locally based on the national guidelines, hence must be prepared with sensitivity to contextual factors that clinicians, administrators and patients face. Consideration should be given to their adaptations and ‘deviances’ from the guidelines in order to adopt the salient and contextually rational adaptations that work in the interest of patients health and of supporting appropriate and cost-effective use of technologies. Accordingly, transfusion policy cannot be uniformly applicable and has to be diversified to account for these contextual specificities, which would be different for different

levels of health care delivery and the level to which health services systems have developed in the area.

The benefits of component separation must be acknowledged and ideally it must be universally available, but health system constraints hinder its universal adoption. Until such time that it becomes available in large enough scale, the value of local adaptation of guidelines must be appreciated and retained with the logic of the provider and in the interest of the patient. Locally feasible and cost-effective technologies must be adopted so as to make the benefits accessible as universally as possible.

Also, mere availability of a technology cannot be the sole basis for its universal adoption. Policy makers and administrators must take into account the systemic issues, the epidemiological and the socioeconomic and health systems constraints and thereby assess its appropriateness in the diverse contexts prevailing in the country and across states and districts. This requires a decentralized, flexible approach to decision making and an orientation with capacities to do context specific health systems research and planning.

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Annexure 1

WHO Guidelines for Transfusion

Principles of Transfusion

The appropriate use of blood and blood products means the transfusion of safe blood products only to treat a condition leading to significant morbidity and mortality that cannot be prevented or managed effectively by other means.

Transfusion is only a part of patient's management

Prescribing should be made on national guidelines on the clinical use of blood taking individual patients needs into account. Blood loss should be minimized to reduce the patients need for transfusion.

The patient with acute blood loss should receive effective resuscitation (IV replacement fluids, oxygen etc), while the need for transfusion is being assessed.

The patients' hemoglobin value although important should not be the sole deciding factor in starting transfusion. The decision should be supported by the need to relieve clinical signs and symptoms and prevent significant morbidity and mortality.

The clinicians should be aware of the risks of transfusion transmissible infections in the blood products that are available for the individual patient.

Transfusion should be prescribed only when the benefits to the patients are likely to outweigh the risks.

The clinician should record the reason for transfusion clearly.

A trained person should monitor the transfused patient and respond immediately if any adverse effects occur.

Summary of Components

SN	Component	Storage Temperature	Indications	Content	Effect

1.	WB	2-6 ˚C	Red cell replacement in acute blood loss with hypovolemia. Exchange Tr, or where packed cells are not available.	Up to 510 ml, HB approx. 12gm/dl, HCT-35-45, No functional platelets, No labile coagulation factors (V and VIII) in stored Red Cells	
2.	Packed Red Cells	2-6 ˚C	Restore O2 carrying capacity in symptomatic anemia-acute/ chronic,acute blood loss	RBC-65-80% Plasma-20-35%	1 unit, Increases HB by 1 gm and HCT by 3%
3.	Platelets	20-24 ˚C	Correction of Bleeding due to thrombocytopenia. Dose-1unit of plt /10 kg body weight, 4-6 units in an adult.	$5.5x10^{10}$ Plasma 50-65 ml	Plt count increases by 5000-10000 per unit
4.	FFP	-40 ˚C	Replacement of multiple coagulation factor deficiencies, Warfarin overdose, Large vol transfusions DIC, TTP. Dose-15 ml/Kg body wt.	Mostly factor V and XIII 150-175 ml/bag	

5.	Cryoprecipitate	-80 ˚C	Correction of factor-VIII deficiency and fibrinogen deficiency, source of fibrin glue	Factor VIIIC (80-150IU) Fibrinogen-(150-250 mg) Factor XIII-20-30% of WB level, Vol -25-30 ml	

Adaptation to Anemia:

In cases of anemia, the respiratory and the cardiovascular systems adapt and maintain the oxygen supply to the vital organs as far as possible.

The clinical condition will depend upon, the patient's ability to make these compensatory responses, degree of red cell insufficiency, whether it has occurred rapidly over hours or slowly over months.

The need for transfusion can often be avoided by:

The prevention of early diagnosis and treatment of anemia and conditions that cause anemia

The correction of anemia and the replacement of depleted iron stores before planned surgery

The use of safer alternatives to transfusion like IV fluids which are safer, less expensive and may be equally effective

Good anesthetic and surgical management.

WHO definition of Appropriate Use of Blood Products

"The transfusion of safe blood products to treat a condition leading to significant morbidity and mortality that cannot be prevented or managed effectively by other means."

Transfusion is unnecessary for the following reasons:

1. The need for transfusion can often be avoided or minimized by the prevention or early diagnosis or treatment of anemia and conditions that cause anemia
2. Blood is often unnecessarily given to raise a patient's hemoglobin level before surgery or to allow earlier discharge from hospital. These are rarely valid reasons for transfusion

3. Transfusions of whole blood red cells or plasma are often given when other treatment such as infusion of normal saline or other intravenous replacement fluids would be safer equally effective and less expensive for the treatment of acute blood loss.
4. Patients transfusion requirements can often be minimized by good anesthetic and surgical management
5. If blood is given when it is not needed, the patient receives no benefit and is exposed to unnecessary risk
6. Blood is an expensive, scarce resource. Unnecessary transfusion may cause a shortage of blood products for patients in real need.

The need for transfusion can often be minimized by the following means:

1. The prevention or early diagnosis and treatment of anemia and conditions that cause anemia.

2. The correction of anemia and the replacement of depleted iron stores before surgery

3. The use of intravenous fluid replacement with crystalloids and colloids in case of acute blood loss.

4. Good anesthetic and surgical management, including:

Using the best anesthetic and surgical techniques to minimize blood loss during surgery.

Stopping anticoagulants and anti-platelet drugs before planned surgery, where it is safe to do so.

Minimizing the blood taken for laboratory use particularly in children.

Salvaging and re infusing surgical blood losses.

Using alternative approaches such as Desmopressin, Aprotinin or Erthrythropoitin.

Annexure 2

Supreme Court of India
Common Cause vs Union of India And Others on 4 January, 1996

Bench: S.C. Agrawal, G.B. Pattanaik

CASE NO.:
Writ Petition (civil) 91 of 1992

PETITIONER:
Common Cause

RESPONDENT:
Union of India and Others

DATE OF JUDGMENT: 04/01/1996

BENCH:
S.C. Agrawal & G.B. Pattanaik

JUDGMENT:

JUDGMENT ORDER S.C. Agrawal

1. Blood is an essential component of the body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-beings. At the same time blood, instead of saving life, cannot lead to death of the person to whom the blood is given if the blood is contaminated. As a result of developments in medical science it is possible to pre-serve and store blood after it has been collected so that it can be available in the case of need. There are blood banks which undertake the task of collecting, testing and storage the whole blood and its components and make the same available when needed, In view of the dangers inherent in supply of contaminated blood it must be ensured that the blood that is available with the blood banks for use is healthy and free from infection.

2. In this petition filed by way of Public Interest Litigation under Article 32 of the Constitution the petitioner has high-lighted the serious deficiencies and short-comings in the matter of collection, storage and supply of blood through the various blood centres operating in the country and has prayed that an appropriate writ order or direction be issued directing the Union of India and the States and the Union Territories, who have all been impleaded as respondents in this petition, to ensure that proper positive and concrete steps in a time bound programme are immediately initiated for obviating the malpractices, malfunctioning and inadequacies of the

blood banks all over the country and to place before this Court a specific programme of action aimed at overcoming the deficiencies in the operation of blood banks.

3. For the purpose of regulating its collection, storage and supply, blood is treated as a `drug' under the Drugs and Cosmetics Act, 1940 (hereinafter p referred to as sthe Act'). In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as `the Rules') made under the Act, provisions regarding equipment and supplies required for a blood bank were contained in Part XII-B, which was inserted vide Notification dated June 24, 1967. In the said part, requirements regarding Equipment, Blood collection supplies, Canter equipment and Emergency equipment for the Blood Donor Room were prescribed. Similarly provisions were made for the Laboratory, General suppliers, Technical staff, Accommodation for Blood Bank, Label for whole blood and Colour scheme for Label etc.

4. In 1990, M/s. A.F. Ferguson & Co., a Management Consultancy Firm, was entrusted by the Government of India, Ministry of Health with the study of blood banking system in the country. The scope of the said study was to :

(i) assess the status of Government, Private, Commercial and Voluntary blood banks ;

(ii) recommended policy and procedure changes; and

(iii) prepare a scheme for modernisation :

5. The report submitted by the said consultancy firm to the Government in July, 1990, high-lights the deficiencies which regard to the facilities of testing blood, licensing of blood banks and professional donors and storage of blood. In the said report it was stated :

(i) Out of the total number of 1018 blood banks as many as 616 are reported to be unlicensed. There are only 201 licensed commercial blood banks; the supply of blood by licensed commercial blood banks is only about 1/4th of the blood used in the hospitals of the country.

(ii) No medical check up is done on the blood sellers; their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling their blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many persons who donate blood 5-6 times in a month; poverty makes them to do so first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply.

(iii) It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, viral hepatitis, malaria, veneral diseases etc. It is reported that mandatory tests which are required to be done are rarely conducted. Most of the AIDS surveillance centres are not functioning efficiently and upto 85 per cent of blood collected in the country is not screened for AIDS. Under an action plan to screen blood for AIDS 37 blood testing centres were to be set up in 29 cities, but only 11 testing centres were functioning by July, 1990, and training of technicians for these centres was lagging.

(iv) The blood banks presently thrive on bleeding 4000 to 5000 regular professional donors in 18-20 cities. The professional blood donors, which include many women, are reported to be victims of ill health, low haemoglobin levels and many infections, and are bled at frequent intervals by the commercial blood banks:

(v) Storage facilities in the blood banks are far from satisfactory. The blood banks have necessarily to possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature, for ensuring safety of blood. In the existing blood banks many items of equipment remain unattended for years, electricity failures are frequent, generators are a rarity. This applies not only to commercial blood banks but even to some of the government hospitals. Many items of the basic equipment needed for blood banks are not available and a good part of them do not have even adequate storage facilities.

(vi) Many of the blood banks are located in unhygenic environment and they collect and store blood in very dirty conditions.

(vii) In some places strong middle men operate for the blood banks E by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the level of health etc.

(viii) A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis B and AIDS and are unfit to donate blood.

(ix) Trained personnel are generally not available in the blood banks. Most of the blood banks lack trained post-graduates at the helm; they have no donor organisers to bring voluntary donors; and many of them are manned by technical staff who do not have requisite qualification of a diploma in Medical Laboratory Technology. At present there is not even a course to provide postgraduate specialisation in the field of blood donation and transfusion as in developed countries. The Drug Control departments, which are expected to ensure the appropriate functioning of the blood banks, do not themselves have specified trained personnel.

(x) In the storage of blood the basic and essential requirements of clean environment, shelf life of blood etc. are ignored, Nexus is reported to be existing between the attending doctor of the patient and the commercial blood bank, with the former directing the patients to the latter, and the latter giving a percentage of the sale to the former.

6. According to the report of M/s. A.F. Ferguson & Co. out of the total number of 1018 blood banks in the country, 203 are commercial blood banks and the rest are controlled by the Central Government, State Governments, Private Hospitals and voluntary organisations. The volume of the blood collected by the commercial blood banks is 4.7 lakhs units out of the total of 19.5 lakhs unit by all blood banks and that commercial blood banks are collecting blood mostly from professional donors while the other blood banks under the control of the State Governments, Central Government, Private organisations and voluntary organisations are-collecting blood mostly from the relatives of the patients or from the voluntary donors.

7. In the counter affidavit filed by Dr. Lalgudi Vaidyanathan Kannan, Deputy Drugs Controller, on behalf of the Union of India it is stated that after the receipt of the report of M/s. Ferguson & Co., the Drugs controller, India, by his letter dated August 23, 1990 asked all the State Drug Controllers (who are the licensing and enforcing authorities under the Act) to ensure that inspections are carried out of all commercial blood banks and unlicensed Government blood banks keeping in view the standards prescribed in the Act and rules and a phased programme of inspection covering first the commercial/private blood banks and thereafter the Government blood banks was suggested. It was also suggested that the private/commercial blood banks should not be allowed to operate unless they fulfill all the requirements prescribed in the Rules and each unit of blood is tested for blood transmissible diseases (Hepatitis, HIV, Syphilis etc.) and that unlicensed blood banks are to be licensed only after ascertaining that they conform to

the standards laid down under the Rules. It was also suggested to the State Governments that the licences of blood banks who do not comply with the provisions of the Rules should be cancelled and the State Drug Controllers were asked to send the status reports of blood banks in their respective States. As per the information forwarded by 23 State Governments/Union Territories, about 341 blood banks are unlicensed and most of them are run by Red Cross Societies and Charitable institutions. In the said counter affidavit mention is also made of the steps that have been taken in the matter of testing of blood for AIDS, storage facilities in blood banks, for upgradation and modernisation of Government managed blood banks, and training of drugs inspectors and blood bank technical personnel.

8. During the pendency of this writ petition, action has also been taken to revise the Rules governing the licensing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment) Rules, 1982 published in the Gazette of India vide notification dated January 22, 1993. Part X-B has been inserted in the Rules and Part XII-B has been substituted. In part X-B (Rules 122-F to 122-0 provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products and for grant and for renewal of licence for the operation of a blood bank/processing of human blood for components/manufacture blood products. Under the said provisions licence can only be granted/renewed with the approval of the Central Licence approving Authority viz. the Drugs Controller of India. Part XII-B contains provisions relating to space equipment and supplies required for a Blood Bank.

9. During the course of the hearing of this petition, the petitioner submitted a draft scheme and a scheme was also submitted by the Union of India, In the affidavit filed by Dr. Shiv Lal, Addl. Director, National Aids Control Organisation, along with the scheme, it was stated that the Central Council of Health, in which the State Health ministers are members, is the highest Forum for Policy frame work and that the said Council has given guidelines in respect of Blood Bank and Transfusion Service and its recommendations are as under :

Blood being a vital input in the present day medicare services the acute shortage of which is hampering the effectiveness of our services the joint Conference recommends that urgent steps should be taken by the State/Union Territories Governments and the Central Government. -

1. To build up adequate blood banking services at State/District level including provision of trained/qualified man power. Necessary action should be initiated in right earnest for achieving the objective in view.

2. To educate and motivate people about blood donation on a voluntary basis.

3. To provide adequate encouragement to voluntary donors.

4. To enforce quality control of blood in all its facets of collection, distribution and storage.

In the said affidavit it was also stated that although the World Health Organisation has prescribed that nearly 40 lakhs units of blood is required for the country, the collection is only 19.5 lakhs units at present and, therefore, it is not possible to ban professional donors at this stage unless the donations of blood by way of voluntary donation are increased. In the said affidavit it was further stated that most of the Government Blood Banks are lacking in man power, training and laboratory facilities to test blood for blood transmissible diseases and to augment this, the Central Government has provided funds to various State Government during 1990-91 and 1991-92 to modernise the Government Blood Banks. According to the said affidavit, the main

objective for the modernisation of the Blood Banks have been provided into long term objectives and medium terms objectives as under :

I. Long term objectives :

(a) Make available high quality blood and blood components in adequate quantity to all users.

(b) Ensure wide usage of blood components.

(c) Expand voluntary and replacement donor base, so as to phase out professional blood donors.

II. Medium term objectives :

(a) To provide minimum possible facilities for blood collections, storage and testing in all government Blood Banks.

(b) To make available the trained man-power in all government Blood banks.

(c) To ensure the awareness of clinicians and Blood Banks staff on the advantages of blood components.

(d) To ensure the effective geographical coverage keeping in mind the different volumes of blood requirement in different cities.

(e) To increase public awareness about the risks in using blood from commercial Blood Banks and professional donors and the harmlessness of blood donation.

10. On a perusal of the Draft scheme that was submitted by the petitioner and the draft scheme submitted by the Union of India, it was felt that it would facilitate matters if the question of necessary steps which may be required for further strengthening the existing frame-work about licensing of blood banks and obtaining blood donations is examined by a Committee which would place its suggestions before the Court for consideration. By order dated 11th February, 1994 a Committee of the following persons was constituted to examine the matter and submit its report :

1. Additional Secretary. Ministry of Health holding the charge of Director, National Aids Control Organisation as Chairman.

2. Drugs Controller of India.

3. Mr. H.D. Shourie.

The said Committee felt that since Indian Red Cross Society is presently involved to a considerable extent in blood banking operations and it has branches spread all over the country and it has capacity to further strengthen itself for looking after the various aspects of functioning of blood banks, it may be recognised as a nodal agency in the field of blood banking and blood transfusion technology in the country. The Committee suggested that detailed discussions to finalise assessment in this regard may be held with the Indian Red Cross Society. Having regard to the said suggestions by the Committee constituted by the Court, the Indian Red Cross Society constituted a committee of experts to examine the matter and to prepare a draft blue print. The said committee of experts in this report dated April 15, 1995 has indicated the following fields in which measures are required to be taken:

1. Building a powerful voluntary blood donation movement to augment supplies of safe quality blood and blood components.

2. Exercising economy by processing whole blood for blood components.

3. Introducing screening procedure to minimize the danger of transmissible diseases like AIDS, Hepatitis etc.

4. Standardize technological procedures for rigid enforcement of quality control, and good manufacturing practices.

5. Providing technical services-for raising the standard of Blood centre operations and assistance for administrative, motivational and technical problems encountered.

It has proposed an action plan-in three parts: Immediate Plan, short Term Plan and Long Term Plan, which are as follows :

Immediate Plan

1. To establish an administrative unit at the national headquarters under the charge of a project director.

2. To identify and strengthen a minimum of 2 Red Cross blood centres for each state for augmenting the existing blood programme. Necessary inputs towards staff, equipment and consumables for the development should be made available at once. Basic requirements to procure accreditation from DC(I) should be ensured.

3. Donor recruitment and intensification of donor motivation drive may be taken up on priority basis. Involvement of media may be ensured through Information and Broadcasting Ministry.

4. A crash programme for short term training of medical officers, technicians and medical social workers nurses of concerned centers may be undertaken. This distance learning programme prepared by the WHO may be helpful in updating the knowledge of technologists at the centres being strengthened.

5. In addition to the blood centre strengthening programme, steps may be taken for planning and initiating action for the establishment of Regional blood centres at the following 16 metropolitan cities with 2 million population having many large medical superspeciality institutions.

1. Delhi 9. Bhopal
2. Luckanow 10. Ahinedabad
3. Patna 11. Bombay
4. Calcutta 12. Hyderabad
5. Gauhati 13. Bangalore
6. Cuttack 14. Trivandrum
7. Nagpur 15. Madras
8. Jaipur 16. Chandigarh

Each centre will be expected to collect 150 to 200,000 units annually. These will be screened processed and distributed as blood components to local hospital based centres against service charges. As the regional centres will supplement the blood supplies through the existing systems it would help in weeding out the blood supply from paid blood sellers. Therefore it is of paramount importance that top priority is given for the establishment of these centres.

Short Term Plan :

1. Coordination of the blood programme of large medical colleges having more than 1000 beds and or collecting over 10,000 units.

2. Establishment of post graduate training centres at places where facilities for fulfilling the norms of the Medical Council of India exist. In the initial stages Faculty support can be obtained from departments of pathology. At the following cities post graduate training can be started :

1. Chandigarh 6. Bombay
2. Delhi 7. Hyderabad
3. Lucknow 8. Bangalore
4. Calcutta 9. Trivendrum
5. Jaipur 10. Madras

Training of paramedical workers can also be undertaken at these centres.

3. Coordination of all other voluntary organisations working for the promotion of the blood programme by the Red Cross society would further help in achieving the target of donor recruitment with greater vigour and better evaluation.

4. A national workshop at the Red Cross headquarters may be organised for officers of all centres being strengthened and the representatives of regional centres to provide necessary guidance for uniform and standardized policies and practices.

Long Term Plan :

1. To upgrade all other blood centres.

2. Establishment and upgradation of blood centres in areas where it does not exist.

3. Planning of more regional centres.

4. Establishing fractionation centres.

5. Establishment of therapeutic centres for blood related disorders.

6. Programmes for indegenisation of equipped software and reagents.

7. Establishment of tissue typing facilities for Bone Marrow and organ transplant.

After considering the said report of the Committee of experts set up by the Indian Red Cross Society, the Committee constituted by the Court submitted its final report which was filed along with the affidavit of Shri Ashwani Kumar, Deputy Drugs Controller of India in the Directorate General of Health Services dated October 26, 1995. The Committee has made the following recommendations and has suggested steps for revamping the system of blood banks in the country in the form of plans for implementation on immediate basis and for long term implementation.

FOR IMMEDIATE IMPLEMENTATION

(i) A National Council on Blood Transfusion should be established. It should consist of Director General of health services. Drug Controller of India, representative of Ministry of Finance, high-level representatives of Indian Red Cross Society and selected five major medical and health institutions of the country, and three eminent citizens, presided over by the Additional Secretary of the Ministry of Health who is incharge of operations of the programme of National Aids Control Organisation. The Council should be provided the basic secretariat under charge of a

Director by the Ministry of Health and be located in suitable premises at Delhi for effective functioning.

It would be desirable to register the Council as a Society under the Societies Registration Act for enabling it to have its own identity and funds and also for enabling it to raise funds from various sources including contributions from trade, industry and individuals. The basic requirements of its functioning should be provided by the Ministry of Health. The Council will be policy formulating body in relation to all matters pertaining to operation of blood banks.

(ii) The Ministry of Health, with the assistance of National Council, will ensure the establishment of State Level councils, at suitable centres preferably head-quartered at the premises of some outstanding medical institutions or hospitals. The State Councils should have on them representatives of important medical institutions of the State, selected representatives of blood banks of repute, a representative of Red Cross, and should include the State Director of Health Services as well as State Drug Controller operating under a designated Director and presided over preferably by the State Government Secretary incharge of health. A representative of the State Ministry of finance should also preferably be on the Council. The size of State Council should preferably be restricted to the maximum of about 11 members. The Director of Health Services should provide the Committee the basic essentials of secretariat and funds for its functioning. The State Councils, as in the case of National Council, should be registered as Society under the Societies Registration Act for maintaining their identity and for purposes of collection of funds in the shape of contributions from individual and corporate bodies. The State Councils should endeavour to operate on the basis of policies formulated by the National Council, effectively implementing the policies and programmes formulated by them.

(iii) Programmes and activities of the National Council and State Councils should cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection., storage and utilisation transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of component of blood, and all the basis essentials of the operations of blood banking.

LONG TERM OBJECTIVES:

(i) The programme formulation at the national level and State levels should take into account the requirements of laying down targets for achievement, including the establishment of appropriately designed and equipped blood banks, ensuring that all blood banks are licensed, making satisfactory arrangements for collection and storage of collected blood, fractionalisation of blood into the components, Special emphasis will need to be laid in the programme on the attainment of prescribed targets of organising camps for voluntary collection of blood through motivational campaigns and utilisation of the media. The State Councils shall submit their programmes and targets to the National Council and thereafter continue to submit quarterly reports to the Central Council about the fulfilment of the targets relating to the programmes.

(ii) The National Council and State Councils should launch effective programmes and organise campaigns for collecting funds for implementation of their programmes, supplementing the funds allotted to them respectively by the Government of India and the State Governments. For

the purpose of facilitating the collection of funds for blood banking purposes the Government of India in the Ministry of Finance should, at the earliest, be approached by the Ministry of Health to secure special dispensation Under Section 35 of the Income Tax Act, making it possible to grant exemption of 100 per cent basis to the donations given to registered and authorised National Council and State Councils. The fulfillment of this objective should be specifically reported by the Ministry of Health to the Hon'ble Supreme Court. The National Council and State Councils should also utilise opportunities which may be available for securing financial sanction and other support to their blood banking programmes from International sources and other donor agencies.

(iii) The Ministry of Health should follow up the recommendations made by the Expert committee set up by the Indian Red Cross Society to start M.D. Course in blood transfusion technology, and to also undertake the preparation of comprehensive programme for training of personnel operating in relation to various aspects of functioning of blood banks, storage of blood, fractionalisation of blood, and transfusion of blood.

(iv) The System of licensing of blood banks will be strengthened to ensure that all quality banks operating in the country are equipped with licenses within a period of not more than one year. Whether any blood banks remain ill-equipped for being licensed, and remain unlicensed after the expiry of the period of one year, their operations should be rendered impossible through suitable action under appropriate legislation. It shall be a policy objective of the Ministry of Health as well as the National Council and the State Councils established on the basis of these recommendations that the prevalent system of professional donors is discouraged through utilisation of all appropriate media, through withdrawal of licenses where any such blood bank has been licensed, and by launching prosecutions under the appropriate provisions of law. The objective of total elimination of professional donors should be achieved in at period of not more than two years through utilisation of all requisite measures. For attainment of objectives & programmes of the local organisations, the State Govt. will be approached for providing the requisite Inspectorate for continuing inspection of blood banks.

11. The Committee has taken note of the programme for preventing infection and strengthening of Blood Banking system in the country that is being implemented by the National Aids Control Organisation, which is annexed to the report of the Committee.

12. The Indian Association of Blood Banks has been impleaded as a party in these proceedings and an affidavit of Dr. V. B. Lal, President of the said association, has been filed.

13. We have heard Shri H.D. Shourie, the petitioner in person. Shri A.S. Nambiar, the learned Senior Counsel for the Union of India, Shri P.P Rao, learned Senior Counsel for the Indian Association of Blood Banks Dr. V. Gauri Shankar, learned Senior Counsel for the Indian Red Cross Society and the learned Counsel appearing for the States. Keeping in view the report of the Committee that has been constituted by this Court and the report of the Committee of Experts set up by the Indian Red Cross Society and the programme that is being implemented by the National Aids Control Organisation as well as the submissions of the learned Counsel, we are of the view that suitable action should be taken by the Union Government as well as the Governments of the States and the Union Territories Administration in accordance with the plan for immediate implementation as well as the plan for Long Term implementation suggested by the Committee constituted by this Court.

14. It is no doubt true that after the report of M/s. A.F. Ferguson & Co. the Union Government has taken certain steps towards improving the state of affairs regarding the blood banks in the country and the National Aids Control organisation is also working in this field. But a lot more is required to done as would be evident from the reports to the Committee constituted by this Court and the Committee of Experts appointed by the Indian Red Cross Society. The Committee constituted by this Court has made concrete suggestions in this regard. We are in agreement with the recommendations of the said committee that the entire range of schemes related to operation and requirements of blood banks including the launching of effective motivation campaigns for stimulating voluntary blood donations, launching programmes of blood donations training of personnel in relation to all operations of blood banking should be entrusted to an autonomous representative body at the national level which may be called the National Council on Blood Transfusion, as suggested by the Committee. The National Council would exercise the functions entrusted to it in coordination with similar bodies established at State level which may be called State Councils. In order that they may have their own individuality and funds and are able to raise funds from various sources including of contributions from trade, industry and individuals the National Council and the State Councils should be constituted as societies registered under the Societies Registration Act. The National Council and the State Councils should undertake the measures suggested by the Committee constituted by the Court as well as the Committee of experts appointed by the Indian Red Cross Society and while doing so they should coordinate their activities with those of the National Aids Control Organisation and other agencies in this field. Keeping in view the potentialities of the harm in the prevailing state of affairs and the need for speedy action in this regard, we consider it appropriate to give the following directions ;

1. The Union Government shall take steps to establish forthwith a National Council of Blood Transfusion as a society registered under the Societies Registration Act. It would be a representative body having in it representation from the Directorate General of Health Services of the Government of India, the Drug Controller of India, Ministry of Finance in the Government of India, Indian Red Cross Society, private blood banks including the Indian Association of the Blood Banks, major medical and health institutions of the country and non-Government organisations active in the field of securing voluntary blood donations. In order to ensure coordination with the activities of the National Aids Control Organisation, the Additional Secretary in the Ministry of Health, who is incharge of the operations of the programme of National Aids, Control Organisation for strengthening the blood banking system could be the President of the National Council.

2. The National Council shall have a secretariat at Delhi under the charge of a Director.

3. The basic requirements of the funds for the functioning of the National Council shall be provided by the Government of India but the National Council shall be empowered to raise funds from various other sources including contributions from trade, industry and individuals.

4. In consultation with the National Council, the State Governments/ Union Territory administration shall establish a State Council in each State/ Union Territory which shall be registered as a society under the Societies Registration Act. The State Council should be a representative body having in it representation from Directorate of Health Services in the State, State Drug Controller, Department of Finance of the State Government/Union Territory Administration, important medical institutions in the State/Union p Territory, Indian Red Cross Society, private blood banks, Non- Governmental Organisations active in the field of securing

voluntary blood donations. The Secretary to the Government in charge of the Department of Health could be the President of the State Council.

5. The State Council should have its headquarters at the premises of the premier medical institution or hospital in the State/Union Territory and should function under the charge of a Director.

6. The funds for the State Council shall be provided by the Union of India as well as the State Government/Union Territory Administration. The State Council shall also be empowered to collect funds in shape of contributions from trade, industry and individuals.

7. The programmes and activities of the National Council and the State Councils shall cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation, separation of blood groups, proper labelling, proper storage and transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

8. The National Council shall undertake training programmes for training of technical personnel in various fields connected with the operation of blood banks.

9. The National Council shall establish an institution for conducting research in collection, processing, storage, distribution and transfusion of whole human blood and human blood components, manufacture of blood products and other allied fields.

10. The National Council shall take steps for starting special postgraduate courses in blood collection, processing, storage and transfusion and allied fields in various medical colleges and institutions in the country.

11. In order to facilitate the collection of funds for the National Council and the State Councils, the Government of India (Ministry of Health and Ministry of Finance) should find out ways and means to secure grant of 100% exemption from income tax to the donor in respect of donations made to the National Council and the State Councils.

12. The Union Government and the Governments of the States and Union Territories should ensure that within a period of not more than one year all blood banks operating in the country are duly licensed and if a blood bank is found ill equipped for being licensed, and remains unlicensed after the expiry of the period of one year, its operations should be rendered impossible through suitable legal action.

13. The Union Government and the Governments of the States and Union Territories shall take steps to discourage the prevalent system of professional donors so that the system of professional donors is completely eliminated within a period of not more than two years.

14. The existing machinery for the enforcement of the provisions of the Act and the Rules should be strengthened and suitable action be taken in that regard on the basis of the Scheme submitted by the Drugs Controller (I) to the Union Government for upgradation of the Drugs Control Organisation in the Centre and the States (Affidavit of Shri R. Narayansawami, Assistant Drug Controller, dated September 16, 1994.)

15. Necessary steps be taken to ensure that Drugs Inspectors duly trained in blood banking operations are posted in adequate numbers so as to ensure periodical checking of the operations of the blood banks throughout the country.

16. The Union Government should consider the advisability of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and the operation of the blood banks in the country.

17. The Director General of Health Services in the Government of India, Ministry of Health shall submit a report by July 15, 1996 about the action taken in pursuance of these directions.

18. It will be open to the Director General of Health Services, Government of India as well as the National Council to seek clarification/modification of these directions or further directions in this matter.

15. The writ petition is disposed with these directions. No order as to costs.

Annexure 3

Elements of the National Blood Policy

The blood policy emphasizes that an integrated strategy for blood safety is required which can only be achieved by collection of blood from voluntary, non-remunerated blood donors only, screening for all transfusion transmitted infections and reduction of unnecessary transfusions.

It has eight main objectives.

Objective-1. To reiterate firmly the Government's commitment to provide safe and adequate quantity of blood, blood components and blood products.

Objective-2. To make available adequate resources to develop and reorganize the blood transfusion service in the entire country.

Objective-3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.

Objective-4. To launch extensive awareness programs for blood banking services including donor motivation so as to ensure adequate availability of safe blood.

Objective-5. To encourage appropriate clinical use of blood and blood products.

Objective-6. To strengthen manpower through HRD.

Objective-7. To encourage R & D in the field of Transfusion medicine and related technology

Objetive-8. To take adequate legislative and educational steps to eliminate profiteering in blood banks.

Annexure 4

Interview Schedule:

(The questions in bold were used as probes)

1. What are the five most important conditions that you prescribe blood transfusion for?

2. What criteria do you use for the prescribing of blood and blood components?

Do you sometime have to take the decision even when you would rather wait or try an alternative line of management first? If so, what are they? Is there sometimes a difference of opinion on this between your colleagues?
Do you have to do so due to considerations other than medical, e.g. the patient's social setting?
3. How do you decide the quantity of blood, which is going to be required?

4. What problems do you face once you decide to prescribe blood for transfusion?

(a) At the blood bank level

(b) At the donor level

(c) At the recipient level.

5. After proper testing and with good quality management in blood banks, do you consider blood to be absolutely safe for transfusion?

If No, why?

6. What are the common adverse effects that you encounter?

7. In your opinion is there scope for reduction in utilization of blood in the present circumstances?

8. Do you see a change in blood transfusion practices over the years?

(a) In prescribing practices?

(b) In blood bank practices?

(c) In patient and relatives response?

What do you attribute it to?

9. Are you aware of WHO or national guidelines on the prescription of blood and blood products?

If Yes, Do you use it?

Do you find it relevant? (Yes/ No) Why?

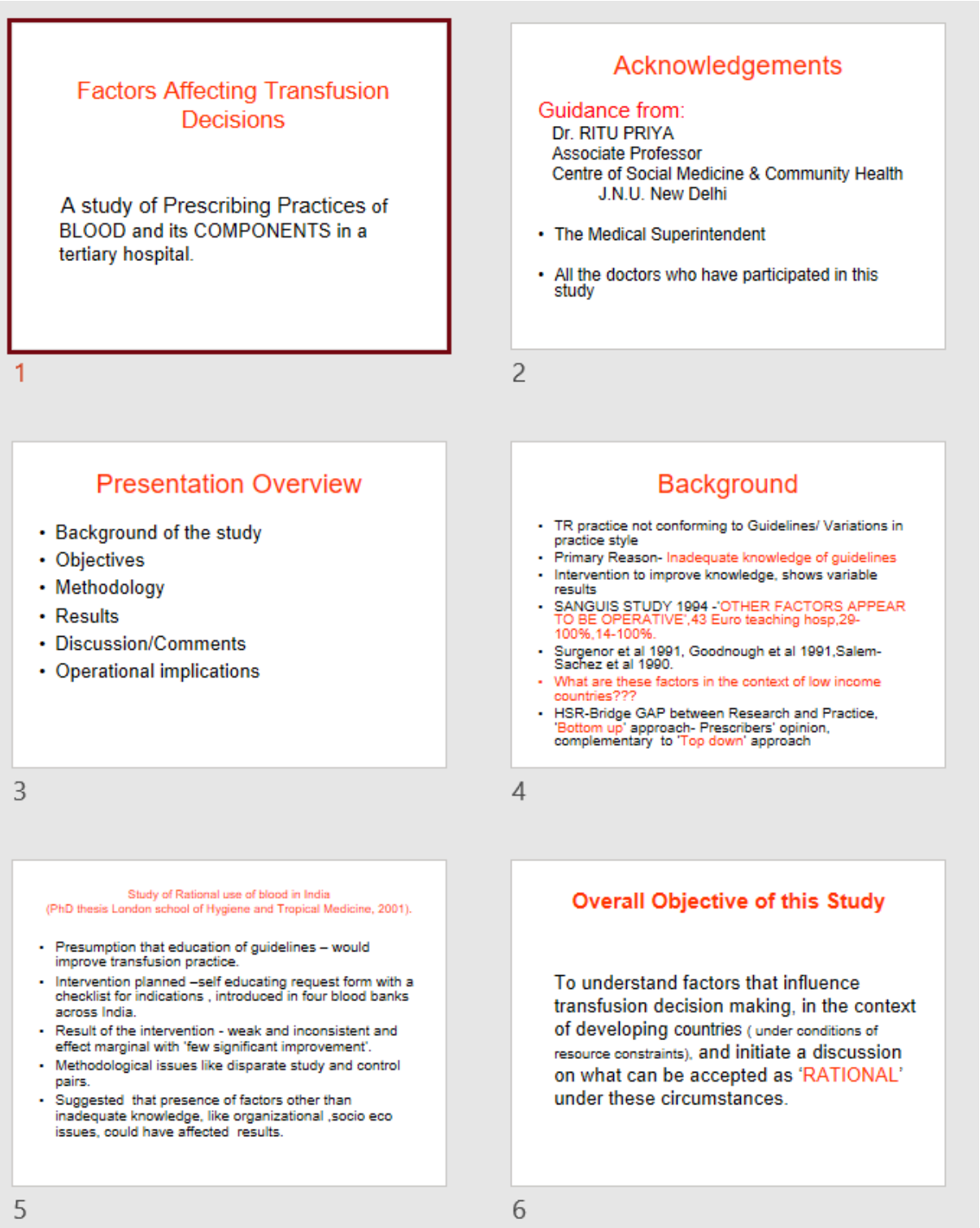
Do you think the guidelines need some modifications according to local needs? What modifications would you suggest?

10. Are you aware of the availability of blood components in our hospital?

Do you feel the need to consult the blood bank staff for advice on the use of the most appropriate component? Have you ever done so? If yes- how frequently?

Annexure 5

Focus Group Discussion (PPT)



AS

- Improved understanding of specific influences in different practice care settings will help develop effective practice change strategies
- Leading to consequent improvement in the Quality of care.

7

Sub Objectives

- To study the change in blood banking system in the wake of Aids control efforts
- Gaps in ensuring safe blood banking practices
- Problems in 'Rational' prescription
- Factors other than clinical, affecting transfusion practice and their implications

8

The Study Setting

- 1000 bedded, super specialty, not-for-profit, public sector hospital, New Delhi
- Well equipped blood bank with Comp separation facility -2001
- Whole blood, Packed cells, FFP, Platelets,& Cryoppt.
- Blood/Components supplied free of cost against Replacement donation

9

METHODOLOGY

3 YRS REQUEST FORMS ANALYSED

SCHEDULE BASED INTERVIEW WITH 104 CLINICIANS

INDEPTH STUDY OF 80 CASES WHERE USE WAS VIOLATIVE OF WHO GUIDELINES

Focus Group Discussion

10

Trends in Prescription

- To study transfusion prescription practices and identify gaps
- To document changes in practice before and after component separation unit established.
- To analyze trends in component prescription over this period.

11

Rationale

NACP-1987

WB FUND-1992

Major Policy & Regulatory decisions

Landmark Supreme Court Judgment

Mod. of BB ZBTC Comp Sep Tr.Rat.BL Use units

Analyze impact on transfusion practice

12

Methodology

50% sample of blood request forms

1997	2000	2003
n=3261	n=3954	n=4918
Baseline Supreme Court Landmark Judgment	Before Component Separation 2001	2 yr After Component Separation

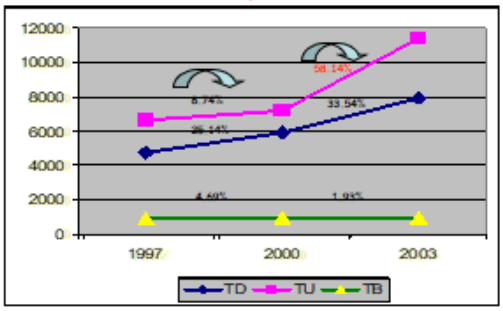
13

Overview of IMP Indicators: Trend (Increase)

% INCREASE	% 1997 to 2000	% 2000 to 2003
T Donors	25.14%	33.54%
T Units Issued	8.74%	58.14%
T Beds	4.69%	1.93%
T Admission	10.54%	5.71%
Request Forms	21.25%	24.38%

14

Trends Imp Indicators



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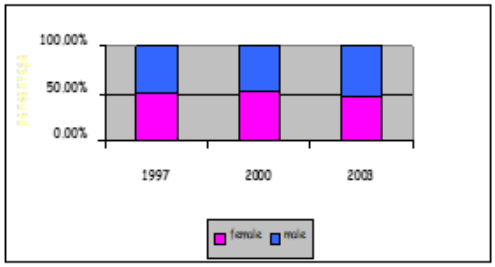
SEX DISTRIBUTION



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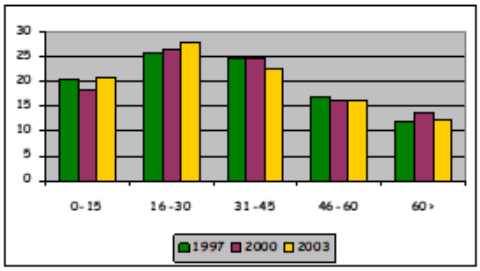
Age Distribution



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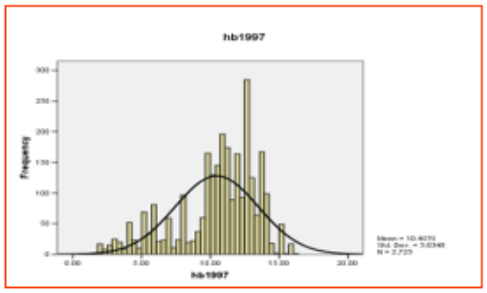
HB:1997



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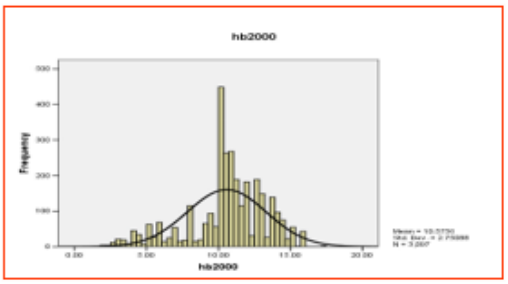
HB:2000



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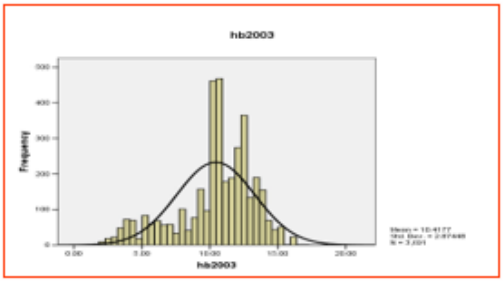
HB:2003



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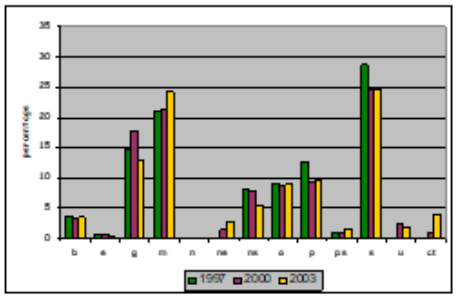
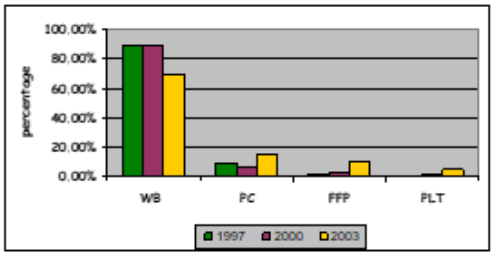
Distribution of Demands Department-wise



21

Trends: Component Demand



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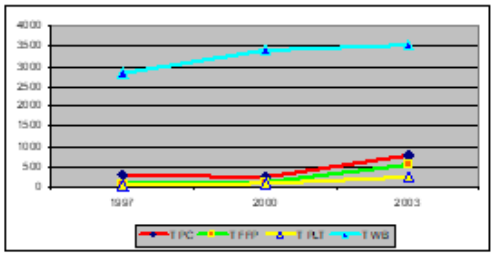
Trend: Component Demand



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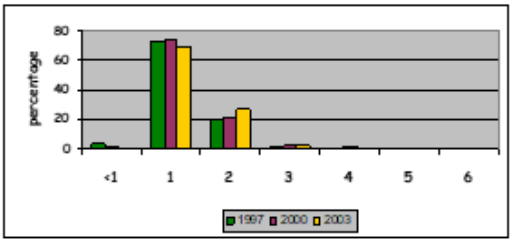
Trend: Total WB



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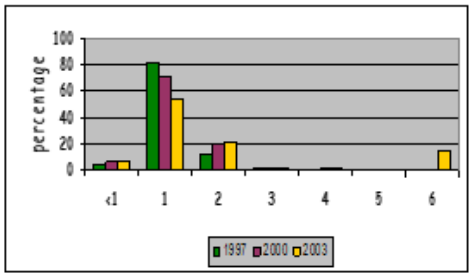
Trend: Total PC



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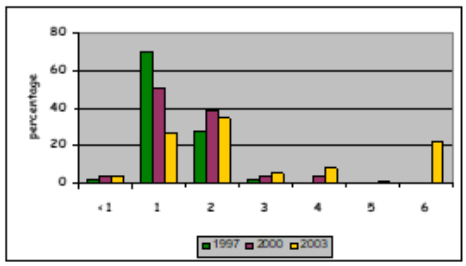
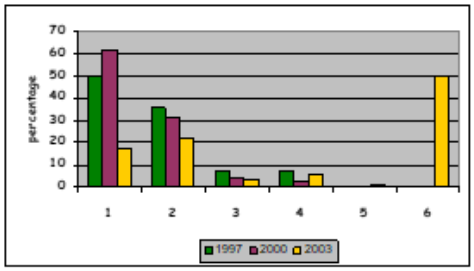
Trend :Total FFP



26

Trend: Total PLT



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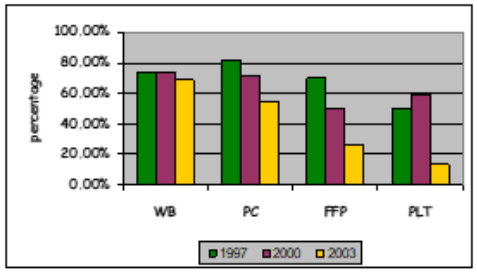
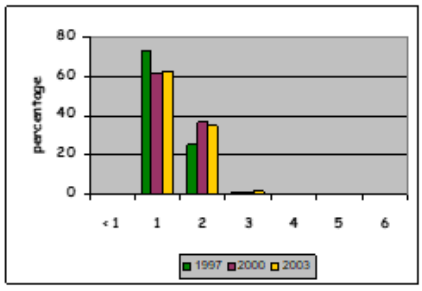
Trends: Single unit Component use



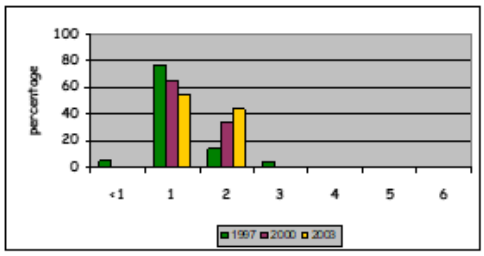
28

WB use : Medicine



29

PC use: Medicine



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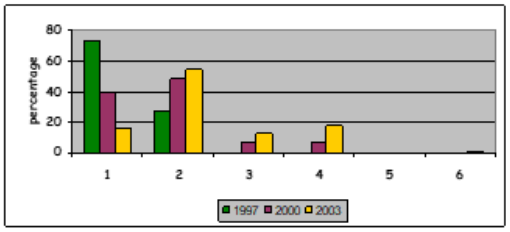
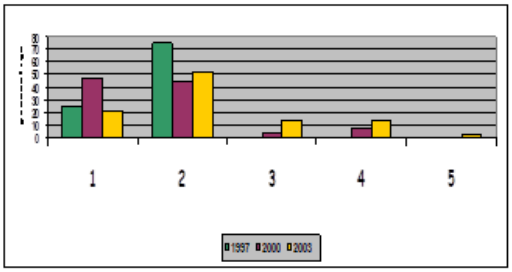
FFP use: Medicine



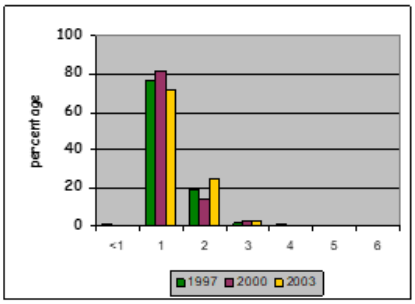
31

PLT use: Medicine



32

WB use: Surgery



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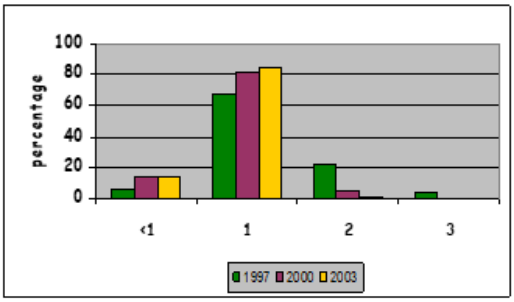
PC use: Paeds



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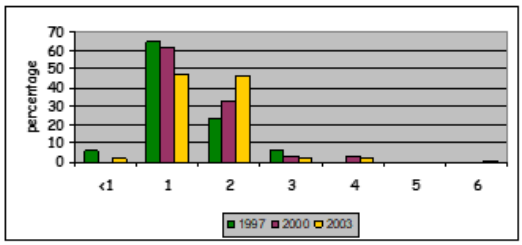
FFP use: Surgery



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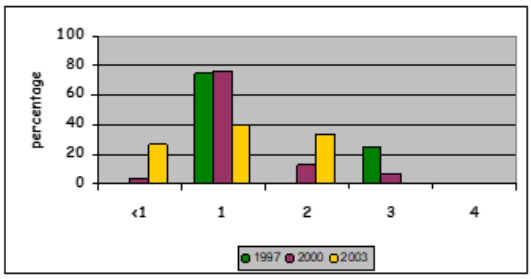
PLT use: Paeds



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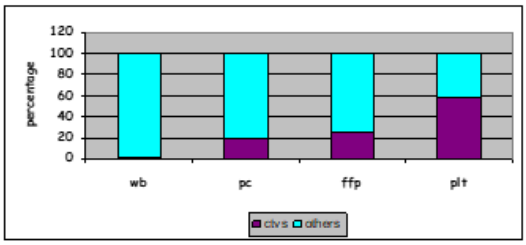
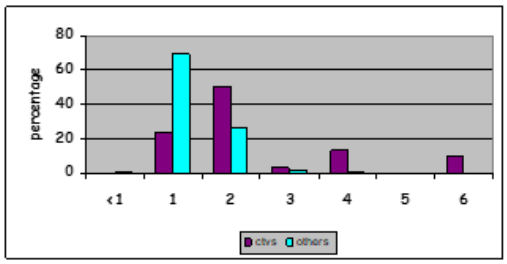
CTVS Vs OTHERS



37

WB: CTVS Vs Others



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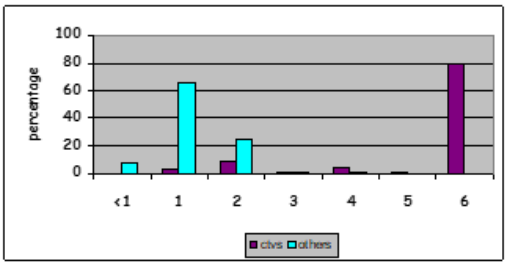
PC: CTVS Vs Others



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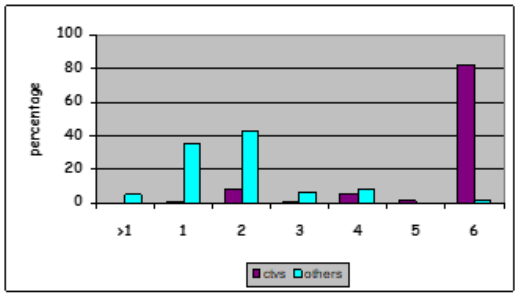
FFP:CTVS Vs Others



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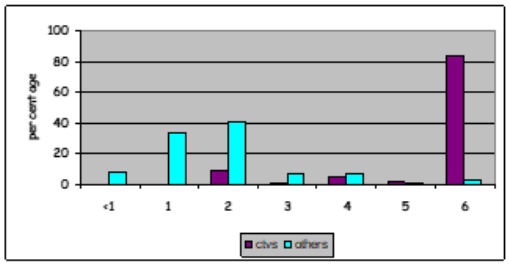
PLT: CTVS Vs Others



41

Summary

- AGE: Most frequently transfused cat.- 16-30 yrs, next- 31-45 yrs, together accounting for 50% of all the demands. similar pattern across the three yrs. Least transfused group>60yrs
- Sex: Proportion of demands for male / female patients equal-all 3 yrs
- SPECIALTY: Max demands from G. SUR;ENT-least, uniform trend seen all three yrs.

42

Summary

- COMPO use :There has been a definite inc in component use, BUT For all three years/all Depts, predominant demand was for WB.
- Surgery used maximum number of WB units, difference was statistically significant ($p<0.05$).Most given in the form of single unit,same finding for all three yrs.
- PC- Pediatrics used the maximum number of PC units, difference was statistically significant ($p<0.05$).
- Rising trend of PC,FFP,PLT use seen in 2003.Change in trend in the no. of demands/request. Increase in demands for 2,3,4,6 units seen. This could be partly explained by the demands from the dept. of CTVS.

43

Summary

- Single unit WB was the predominant form of transfusion across all specialties /across all three years.
- Reasons for Single unit demands: Inappropriate use, Restrictive practice or Under transfusion.
- Questionable if used for planned uncomplicated surgery/could be avoided. Aprox. 45-50 % of Single unit WB demands would fall into this category.
- Some Single unit demands from medical specialties -could be justified as cautious practice due to risk of T.T.I.'s.

44

Summary

- Inadequate Dose- Single unit demands for FFP and PLT is inappropriate use, but showed a declining trend over this period.(Ffp-69.7%,50%,& 26.5%;Plt-50%,62.5% & 17%)
- Trend could be attributed to appropriate blood use, due to improved knowledge of guidelines.

45

KAP Study-OBJ

Knowledge of Guidelines, Attitude towards Blood Safety and Transfusion Practice

a) Documenting the level of knowledge of clinicians about blood /component use and Safety,

b) Problems faced in adhering to guidelines,

c) Change in practice style in the wake of discovery of the AIDS virus,

d) Effect of non clinical factors in decision making,

e) Scope of optimizing blood use in the given circumstances

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Results-KAP

Conditions for which transfusions required:
Anemia –to enhance the O2 carrying capacity of Blood
Acute/Chronic Blood loss
Anemia of different etiology
Elective surgery/Pre op, Post op for Anemia
Emergency Surgery
DIC, Shock, Septicemia
Coagulation Fact Def.
Platelet Def.
Regulation of Plasma Volume

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Results-KAP

Criteria for transfusion: (Have to save patient at any cost)

WHEN :

lab criteria+ clinical judgment

Guided by a transfusion trigger for Hb. level

(Range <2.5%-10.0%, median 6gm%)

HOW MUCH :

Per Op. loss -estimation easier

Ac. blood loss- transfused aggressively

EXP WITH TRANSFUSION AS A T/T OPTION: POSITIVE

Few mild reactions, only 1 respondent had seen a fatal haemolytic reaction

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Results-KAP

- **Notion about safety of tested blood**:
  Tested blood absolutely safe-38%
- **Difference of opinion among colleagues**:
  Diff. of opinion within the same unit-56%
- **OVER PRESCRIPTION**:
- No of transfusions gone down considerably in the last 10 years *(Attributed to: Increased awareness of TTI's, Advancement in techniques/technology)*
- **Scope for reduction in transfusions: PRESENT**
  Acknowledged over prescription-62%

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Results-KAP

- **Awareness of WHO or National Guidelines for Transfusion Practice:**

Not aware of any guidelines-56%,*Aware of guidelines-44%, but only 18% actually used them)*

- **Influence of factors other than clinical**:

Working conditions, Socio economic conditions of the patients, do not affect 'scientific' practice-92.6%

- **EXP WITH BLOOD BANK**: POSITIVE

Problem EVE shift, resolved after personal commu

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Case Study-Obj

- To identify reasons for the prescribing practices considered Irrational by WHO Guidelines –through concrete case studies.
- To study problems faced by clinicians in translating guidelines into actual practice.

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Case Study

- Retrospective Study-Inappropriate Transfusions-WHO guidelines
- Purposive Sample-80 cases at variance with WHO guidelines selected from Request forms, Case sheets studied in depth
- Categories 20 each- Elective Gen Surgery, Elective Gynaec Surgery, Anemia, Acute blood loss (Patho-Physiologic / Hemodynamic differences in Anemia)

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Case Studies

- A Retrospective study of 80 cases, 20 each, from 4 categories of elective Gynecological surgery, elective General surgery, Anemia, and Acute blood loss, that had received inappropriate transfusions, was undertaken.
- The diagnosis clinical/lab criteria for transfusion, pre op/post op Hb, type and quantity of components used, timing of the transfusions in relation to admission/ investigations/surgery.
- Questions based on these observations were posed to the treating physicians to understand their rationale for the transfusions.

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Overview of Categories-Ane

Age	16-60 yrs
HB	7-8.8 Gm %
Components	Whole Blood, Packed Cells, Fresh Frozen Plasma, Platelets
Unit/Episode	1-3
Summary of Cases	12-Iron Def/ Megaloblastic Anemia,5-Pancytopenia,1-Burn,1-Malaria,1-Cellulitis

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Results-Anemia

- Rationale:
- Clinically HB could be lower, questionable lab reports, fear of impending failure
- Once reported to the emergency cannot keep patient waiting on oral Iron & B complex, pressure for active intervention from relatives
- Routine INV could be sent next day
- Patient not in failure so WB transfused
- 2 units PC required, but transfused 1 U as only one donor available
- Low socio eco gr, nutritional anemia generally dimorphic, WB would provide protein, Albumin costly

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CASE STUDY-Anemia

45yr M, C/O weakness,giddiness-1mth, HB 7.5gm%,no signs of failure, No H/O bleeding, reported to emergency

Diag: Anemia

- TR:2 units WB, on day of admission
- Q: Why not PC, why did not wait for reports when not in failure?
- R: Plasma would make up for proteins as could be nutritional anemia, also not in failure, looked clinically pale, HB could have been much less, questionable lab reports, complete INV would take at least two days.

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Results-Anemia

Tr started before Inv, HB 7 gm,1U WB	Clinically pale, could go into failure, reported to emerg, Inv would start next morning
Hb 7.5 gms, not in failure,2WB	Low socioeco gr, nutritional anemia generally dimorphic, WB would provide protein, not in failure, Albumin costly
Cellulitis Thigh with anemia, HB 9.1,1U WB	GC poor, blood stained pus drained ,better wound healing
Iron def anemia, 7gm,not in failure,1WB	Once reported to emerg, weakness, cant keep on oral Iron/B com, active interven. needed
Pancytopenia, PLT-60,000,2U	Downward trend, cant wait for bleeding to start, may miss small Hemgaes, only 2 donors available at present
Anemia with Malaria, HB 8.5gm	Pt toxic, clinically pale, complicated case, so transfused, help recovery

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Overview of Categories-Acute Blood Loss

Age	27-60 Yrs
HB	7-12.4 Gm%
Components	Whole Blood &FFP
Units/Episode	2-7
Summary of Cases	7-Hemetemesis,5-Peroperative bleeding,2-RTA,2-Bleeding Piles,2-Ruptured Ectopic,2-Hemoptysis.

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Results-Acute Blood Loss

- Rationale:
- Sight of blood associated with panic, pressure from relatives
- Fast changing situation, assessment of blood loss difficult
- Problems in clinical monitoring for amount of loss, as high patient load in emergency, understaffed
- Hemostasis could take time, possibility of delay in arranging emergency OT
- Would not be able to handle if condition deteriorates

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Case study # - ABL

32 yr M, brought to emergency with H/O RTA # Rt Tibia & Abd injury, HB:10.5gm%

Diag: # Rt Tibia, suspected Hemoperitoneum

- TR: 2 WB, 2 FFP
- Q: Was clinical monitoring/estimation of blood loss made?
- Rationale: borderline HB, Rapidly changing situation, panic among relatives, may take time to arrange emergency OT, monitoring serious patients difficult, high patient load

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Results-Ac. Bl. Loss

Hematuria,4WB HB 10gm	Panic at the sight of blood, pressure from relatives, take no chance, passing blood 3 days
Per Op Bleeding TURP 4U	Unexpected blood loss, Anaesthetist advice, Tr as precaution, avoid shock, Pt 60yrs old
RTA/Trauma, Tr/ I V fluid, no clinical assess of bl loss	Problem in closely monitoring, high patient load,ill equipped to handle if condition deteriorates, understaffed
Trauma, Tr/IV fluid Hb 12, for Surg	Rapidly changing situation, Delay in OT in emergency hours, Tr given till hemostasis achieved
Active Hemet, Hb10.5, 4 FFP	Liver Dis, invariably deranged Coagulation, cannot wait for reports, Tr. as precaution
Active Bl Piles-15days, Hb 8 gm, 4 U	Assessment of amt of blood loss difficult to make, Imm Surg with Tr support, to stop bleeding early

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Overview of Categories-Elective Gynecological Surgery

Age	30-55yrs
HB	8.5-14.2 gm %
Component	Whole Blood
Units/Episode	1-3
Summary of Cases	10-Total Abd. Hysterectomy, 8-Vaginal Hysterectomy, 1-Mod.Shirodhkars,1-Ovarian Cyst

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Results- Elective Gynaec Surgery

Rationale:

- Anesthetists advice
- For Wound healing, Imm. concern is uneventful post op period
- Fear of loss to follow up, Some women do not come back for regular check up
- Clinically pale postoperatively, questionable lab reports
- Pt. was a VIP did not want to take chance
- Menorrhagia- 3 yrs, reserves low
- To raise HB to 10 gm for PAC fitness

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Case study # 1(GYN)

47 yr old F,C/o Bleeding P/V-1 yr, HB 11.7gm%,

- Diagnosis: Fibroid Uterus
- Surgery: TAH
- TR:1 UNIT whole blood
- Q: Why WB? could be avoided, loss 500-700 ml
- Rationale: WB to make up for vol. loss,1 unit released to OT, Reserves low-bleeding 1 Yr, Tr as precaution for better wound healing

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Results –El. Obs/ Gynae

WB for PC	For Vol replacement
HB 9 gm Preop Tr	To raise HB to 10gm for PAC fitness
Post OP Tr	Clinically pale, lab results cannot be relied upon, Imm concern-healthy wound, relief of symptoms, post op uneventful
Post OP Hb 7 gm-why 1 U	Only one donor so 1U given
Pre Op HB11.5;Loss in AH 500-700ml;1U	Tr given as reserves low Menorrhagia -1yr,for better Wound healing
VH why 2 U, Pre Op HB 12.5 gm	generally given 2 units, bleeding on tissue dissection

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Overview of Categories-Elective General Surgery

Age	16-60 Yrs
HB	8-14.5 Gm%
Component	Whole Blood & FFP
Units/Episode	1-4
Summary of Cases	8-Perforation Peritonitis/Inst.Obstruction,2-Cholecystitis,2- Ca Breast,2-# shaft femur&# shaft tibia,2-Subdural Hematoma, 2- Renal Calculi,1-Goitre1-TURP

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Results-Elective General Surgery

Rationale:

- Would help in wound healing
- WB to make up for volume loss
- Anesthetists' want blood in readiness in OT, once released generally transfused
- PAC fitness only if HB 10gm%-to build up HB
- Required 2 units- one donor available so TR 1 WB along with 2 FFP
- Case of Carcinoma could require Chemotherapy later- to build up GC
- Tubercular Int Obstruction, Pt low socioeconomic Gr would improve GC
- Imm concern-healthy wound, relief of symptoms, no post op complications

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CASE STUDY# G. Sur

- 27yr male, c/o acute pain abdomen vomiting, reported to emergency, HB:10.5gm%
- Diag: Inst Obst /suspected Perf Peri
- Surg: Exploratory Laprotomy
- TR:1 WB,1 FFP
- Q: Could 1 U WB be avoided, why FFP?
- Rationale:
- Anaesthetist wants blood in readiness in OT, HB borderline to help wound healing, FFP for Vol loss, operated in emergency did not want to take chance

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Results - El. Surgery

Why not PC for Wb	Wb for VOL Replac in blood loss
Uneventful sur why Trans	Anaes want bl ready,1U arranged, so trans, Neg Gr blood available now
Post OP Trans,1U,case----	Assess of loss in OT not accurate, PT clinically pale, lab results cannot always be relied upon,1 U arranged
Pre Op HB 9 gm %,1Ucase of---	To raise HB to 10gm% for PAC fitness, Better wound healing
Post Op FFP,2U,case of --	Bl stained discharge from drain, assessment of loss difficult, no donor so FFP given
1U in Place of 2U/undertransfused------	Only one donor available
Why for CA breast at 12.5%	Would require chemo later, to improve GC
Perf Peritonitis/Inst Obs	Pt low socioeco Gr, Tuberculous, no chance taken

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Summary

- Transfusion decision making is a complex interaction of multiple factors
- Clinical + Non clinical factors (Structural, organizational, socioeconomic) influence decision making
- Primary reason for inappropriate practice- Inadequate knowledge of transfusion guidelines
- GAPS in knowledge like critical limits of tissue perfusion, FFP/ PLATELET use not well defined
- Decision making particularly difficult in cases that fall in the GREY zone.
- Complexities of actual practice become more pronounced in conditions of resource constraint- pt load, lack of proper institutional support
- Saving the life of the patient- Immediate concern

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Suggestions

- Evidence Base-Multidisciplinary, establishing linkages between the various factors that define the context (practice environment) in which the clinicians operate
- As, "Rational Transfusion Practice" depends not only upon the Technical/ Medical criteria, but also upon
  Prevailing conditions of health, the Degree of health service development, the Available Resources, Epidemiology of blood borne diseases &Socioeconomic condition of the patient
- Reinforces the fact - Guidelines must be contextually adapted,/inclusive incorporating the biological/clinical as well as the non clinical factors and education must be on these lines

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SUGGESTIONS

Clinical factors:

- Education of guidelines
- Development of clinical skills- Proper assessment of blood loss
- Proper documentation of indications for transfusions

Non clinical factors:

- Commu between providers and relatives, building trust to allay fears and prevent panic.
- Commu between the prescribers and the blood bank, to sort out problem/ build trust
- Consensus development, may need contextual studies, IMP role of HTC for formulating locally relevant guidelines

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Group Discussion

Focus group discussions with clinicians based on these case studies

*TO get FEEDBACK/Comments from THE CLINICIANS, on these findings.

*Identify areas that require change or intervention to encourage good transfusion practice.

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SOME ISSUES

- **WB used across all categories**
- **No doc of Amt of Bl loss- Surg /Active Bl or indication for transfusion.**
- **Tr. in anticipation of blood loss**
- **Ac Bl loss trans aggressively/visual assessment/not based on clinical signs.**
- **PAC fitness only at 10 gm%, invariably transfused if HB<10; Anesthetists want Blood ready in OT**
- **Assessment solely based at HB values not HCT**
- **FFP- transfused for liver disease as a precaution**
- **FFP/PL not ALB used in burn cases to build up Se protein, high cost**
- **FFP perceived as a by product, so no Repl sent,**
- **Assurance From Blood bank?**
- **Platelet-decision not made on counts/Tr given if downward trend seen**

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Some Issues

- What is the harm in giving WB in a bleeding patient-VOL Replacement/ Protein Replacement
- Pressure from relatives to transfuse as donation after much coercion
- More clarity needed for per op assessment of blood loss,/bed side assessment.
- Anxiety among patients relatives/among doctors
- Monitoring of blood loss difficult-in Acute loss
- There is no general agreement at which point Tr should be given and the optimum target concentration to be achieved.

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Operational Implications

Clinical factors:

- Education of guidelines
- Development of clinical skills-Proper assessment of blood loss
- Proper documentation of indications for transfusions

Non clinical factors:

- Commu between providers and relatives, building trust to allay fears and prevent panic.
- Commu between the prescribers and the blood bank, to sort out problem/ build trust
- Consensus development, may need contextual studies, IMP role of HTC for formulating locally relevant guidelines

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WHO Guidelines Dose & Indications

COMP	DOSE	INDICATIONS
WB	Unit by unit	RARELY
PC	Unit by unit, till symptoms relieved	To enhance Oxygen carrying capacity in Anemia.
FFP	PT,PTTK>1.5 Times normal	Coagulation Disorders (X-Vol Repl, Pro Def.)
PLT	<20,0000-without Bl <50,000-with Bleeding	Thrombocytopenia

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WHO Guidelines

Anemia	**INV for Type of Anemia** **Compensated-Trial of Hematinics, Decompensated-Packed cells**
Acute Blood Loss	**Supportive T/t, IV Cryst /Colloids, Assessment of blood loss, Periodic Monitoring of vitals,** **Amt of loss>1000ml-Transfusion**
Ele. Surgery	**Preanaesthetic workup, Hematinics to build up HB** **IV Cryst/Colloids, PC if loss>1000 ml**
Ele. Gyn Sur	**Preanaesthetic workup** **Hematinics if Surgery can wait, IV Cryst/Colloids** **PC if loss >1000 ml**

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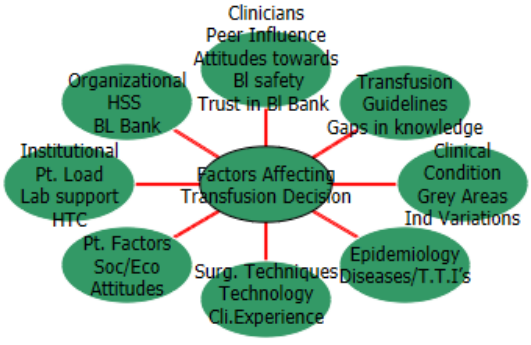
Discussion



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THANK YOU

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Annexure-6

List of Conference Presentations and Published Abstracts

1. 16-19 Nov.2019-***Activity Wise Unit Cost of Blood Components in a Tertiary Care Hospital Blood Bank for the Year 2018,*** Anupa Pokhrel, Kiran Chaudhary, Prerna Sachdeva, Anubhav Gupta, Shilpi Varshney & Harkiran Arora, Oral Presentation at the 30th Regional Congress of the ISBT Asia, Bangkok.
2. Nov 2009- ***'Laboratory costs of providing Blood and Components in a Public Hospital based Blood Bank in Delhi',*** *poster presentation, Nagoya, Japan.*
3. 18/9/08: ***'Blood Transfusion Services in India: An Overview',*** Oral Presentation at the Hemominas Foundation, Belo Horizonte, Brazil.

8/6/08-12/6/08: ***'Understanding the Clinicians' Perspective-A Retrospective Study of Transfused Cases at a Public Sector Hospital in India',*** Oral Presentation at the XXXth International Congress of the ISBT at Macau, SAR, CHINA.

4. 10/11/2007-13/11/2007: ***'Trends in Transfusion Practice: A Seven Year Retrospective Study of Prescription Practices of Blood and Components at a Tertiary Hospital in India',*** Oral Presentation at the XVIII th Regional Congress of the ISBT, Hanoi, Vietnam.
5. 15/10/2007-16/10/2007***: 'Universal Access and the Cost of Safety: Role of State in Technology Assessment and Regulation of Blood Transfusion Services.'*** Oral Presentation at the joint regional conference on comparative health policies within welfare states in developing societies, organized by IPSA,RC-25and RC-39,Univ. of Delhi, South Campus.
6. 2/9/2006-7/9/2006: (A) ***'Organizational and Social factors affecting transfusion: need for contextual adaptation of international guidelines.'*** Poster Presentation at the XXIX th International Congress of the International Society of Blood Transfusion, Cape Town, South Africa.

(B) ***'Knowledge of guidelines, Attitude towards Blood Safety and Transfusion Practice: An Indian Experience'.*** 'Poster presentation at the XXIX th International congress of the ISBT, Cape Town, South Africa.

1. 21/4/06-23/4/06: (A) ***'Effect of Clinical and Non-clinical Factors, Knowledge of Guidelines and Attitudes towards Blood Safety on Transfusion Practice: A Study of Rational Use of Blood.'*** Oral Presentation, National Research Conference on HIV& AIDS, NACO, New Delhi, India.

(B) ***'Conceptualizing and Designing Research in HIV/ Aids.'*** Oral Presentation at the 'skill building workshop' at the National Research Conference on HIV and AIDS, New Delhi, India.

2. 12/11/05-15/11/05:(A) ***'Optimizing Blood Use: A Study Exploring Possibilities of Rational Blood Use in a Tertiary Hospital of a Low-Income Country'*** Oral Presentation at the 26th Regional Congress of the International Society of Blood Transfusion -Asia, Bangkok, Thailand.

(B) ***'Pattern of blood Utilization at a Tertiary Care Hospital in India'*** Poster Presentation at the 26th Regional Congress of the ISBT, Asia, Bangkok, Thailand.

Annexure-7

Indian J Hematol Blood Transfus (Apr-June 2020) 36(2):368–373
https://doi.org/10.1007/s12288-019-01212-8

ORIGINAL ARTICLE

Activity Wise Unit Cost of Blood Components in a Tertiary Care Hospital Blood Bank for the Year 2018

Anupa Pokhrel[1] · Kiran Chaudhary[1] · Prerna Sachdeva[1] · Anubhav Gupta[1] · Shilpi Varshney[1] · Harkiran Arora[1]

Received: 11 July 2019 / Accepted: 5 October 2019 / Published online: 22 October 2019

Abstract The present study on cost of a unit of blood was conducted in blood bank of a tertiary care public hospital with an annual collection of 20,748. A retrospective chart review was done to calculate the activity wise annual unit cost of blood, based on WHO guidelines (Blood Safety Unit. safe blood and blood products: costing blood transfusion services, World Health Organization, Geneva, 1998). Cost of blood collection, processing and storage were included. Annualized economic cost of equipments, maintenance, personnel salaries, and consumables were enlisted. It was assumed that all component units prepared carried equal cost. The cost of building, maintenance and office stationary were excluded. Data extracted from records was compiled and analysed using MS Excel. The annual unit cost of blood with component preparation and NAT testing was Rs 1829. Unit cost of blood without NAT testing was Rs 1255. Unit cost of blood if total collection was in-house, that is, excluding expenditure on camps was Rs 1738. The cost of whole blood (that is, if no components were prepared) with ELISA testing, done to ascertain cost at basic functioning was Rs 2521. With NAT testing the unit cost increased by Rs 575, the additional expenditure being equally divided among all components. Expenditure on NAT was high which was 1/3rd of the total expenditure on consumables. The additional cost incurred on each unit due to expenditure on camps was small i.e. only Rs 91 with 30% collection from camps. Voluntary camps ensures safe blood at minimal cost increment and component separation reduces cost and permits judicious use. Hence these activities should be promoted.

Keywords Blood transfusion · Cost · Unit

Introduction

Blood transfusion is a vital part of patient care. The rising cost of Blood reflects the rising cost of healthcare globally. Though Blood is sourced from voluntary or replacement donors, its collection, processing, component preparation, testing, storage and distribution involves expenditure. To meet this expense, blood banks charge for the ready to issue blood unit but the cost may vary from country to country and region to region even within the same country. Blood Transfusion Services of a country may be centralized, regionalized, standalone, hospital based or some combination of them [1]. The cost of blood unit may even vary between government, private and Non-Governmental Organisation (NGO's) managed blood banks [2], depending on their source of funding. Most government blood banks supply for free whereas the NGO and private blood banks charge the patients. The rates are not uniform and vary greatly from one blood bank to another.

There are different ways of calculating cost of a unit of blood. According to World Health Organisation (WHO) costing guidelines, economic cost is used for calculation that takes annualized value of capital goods. The societal perspective of cost calculation includes hidden costs like, cost incurred by the donor like loss of wages, loss in production, cost of travel to and from the blood centre etc. [3]. Costing of blood transfusion services is necessary for policy makers and transfusion service managers for

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Annexure-8

Abstract Title: PATTERN OF BLOOD AND PRODUCT UTILISATION IN A TERTIARY CARE HOSPITAL IN INDIA

Poster presentation at the XVIth Regional Congress of the ISBT, Asia, Bangkok- November 12 - 15, 2005 (5P-149)

Topic-6.5 Other

Abstract text

Background:

Establishment of superspecialist departments like, cardio thoracic vascular surgery, nephrology, gastroenterology etc. has increased demand for blood and component use. Evaluation and studies have shown inadequacies in appropriate clinical use of blood and blood products. Irrational blood use has increased tremendous pressure on the blood banks to maintain a continuous supply, especially in a country where motivating donors is a big problem. Therefore, a study was undertaken to analyze the pattern of blood utilization, in a hospital that has a well-equipped component separation facility.

Aim of the study:

Specialty wise categorization of demands for blood and products,

Specific conditions for which blood and products utilized,

Identify gaps in prescribing practices and

Explore possibilities for rational practice.

Methods:

This study was undertaken in a 1000 bedded tertiary hospital in New Delhi, India.

A retrospective analysis of 1764 requisition forms, for three alternate months in the year 2004, was done to study the utilization patterns.

Results:

Maximum numbers of requests were from the department of surgery (31.84%), and the least was from Burn and plastic surgery (3.51%). 80.35% of the demands were for whole blood. Most of the demand for blood fractions was from the department of CTVS. Blood processed into fractions was 20% of the total collection and mostly depended on the demand from CTVS department. Demand from cases posted for planned uncomplicated surgery was almost 30.0%,

and demand from acute emergency cases was approximately 20%. Demand for the much debatable single unit transfusions was 64.25%.

Conclusions:

By proper pre-operative work up of the uncomplicated cases posted for surgery, there is a possibility of reducing transfusions in this group of requests. Most of the Fresh Frozen plasma was used for volume expansion; here colloids and crystalloids could have been a better option. Most prescribers are not well informed about the indications for component use, therefore hesitate to order them and have more faith in the old practice of using whole blood. Therefore, proper training of the clinicians in appropriate use of blood and components is required. There is also a need for constitution of a “hospital transfusion committee” to formulate a policy for rational blood use.

Annexure-9

Abstract Title: OPTIMISING BLOOD USE: A STUDY EXPLORING POSSIBILITIES OF RATIONAL BLOOD USE IN A TERTIARY HOSPITAL OF A LOW-INCOME COUNTRY

ORAL presentation at the XVI th Regional Congress of the ISBT, Asia, Bangkok, November 12 - 15, 2005 (3PS-08-05).
Topic: 6.5 Other

Abstract Text

Background:

Variations in practice style for clinical use of blood are common among clinicians from the same discipline and even for comparable group of diseases. Many clinical demands do not meet internationally accepted guidelines for transfusion resulting in over prescription and increased pressure on the blood banks. These problems become more aggravated in low-income countries, where lack of proper infrastructure and resource crunch are the major issues, forcing clinicians to adapt their practices to the settings they work in. What is "rational" then depends upon the context of the prevailing conditions of the health services, the degree of health service development, the available resources and the epidemiology of blood borne diseases.

This paper attempts to,

a) Study prevailing prescription practices and identify gaps therein,

b) Identify factors that influence transfusion decision-making in the context of low-income countries.

c) Explore possibilities for promoting evidence based, rational blood use.

Methods:

The study was undertaken in a tertiary care hospital in India.

Retrospective analysis of 1764 requisition forms (three months) were undertaken to study the utilization patterns and identify gaps; prospective study of 40 cases of inappropriate blood use provided a background for discussion with physicians for their rationale; schedule-based interview with 104 clinicians for eliciting responses about:

1) Problems faced in adhering to the WHO guidelines,

2) Change in practice style in the wake of discovery of the AIDS virus.

3) Effect of socioeconomic status of the patient in transfusion decision-making

4) Scope for optimizing blood and product use in the given circumstances.

Results:

Analysis of requisition forms showed that 80.35%of the demands were for whole blood, demand for the much-debated single unit was 64.25%, and department of Cardio thoracic surgery demanded most of the components.

Case studies showed that transfusion was given mostly in anticipation of blood loss rather than actual blood loss, fear of impending heart failure, pressure from anesthetists, lack of proper knowledge, and sometimes had to adapt to the context in which they practice.

Interviews with prescribers revealed that 56% of the respondents had a difference of opinion with their colleagues, 38%thought that properly tested blood was absolutely safe for transfusion, 62% thought that there was over prescription and there was scope for reduction of blood and component use, 56% were not aware of any guidelines.

Summary and conclusions:

There is a scope for reduction of unnecessary transfusions.

Most of the prescribers depend upon a “risk approach” for their transfusion decisions. Regular updates are required to keep the clinicians abreast with the progress made in transfusion medicine.

A hospital transfusion committee for monitoring (periodic review and revision) and formulation of an evidence-based policy could be a useful mechanism.

Annexure-10

Abstract Title: ORGANISATIONAL AND SOCIAL FACTORS AFFECTING TRANSFUSION PRACTICE: NEED FOR CONTEXTUAL ADAPTATION OF INTERNATIONAL GUIDELINES

POSTER presentation at the XX1Xth International Congress, ISBT Cape Town, September 2 - 7, 2006(P-696)

Topic-14 Transfusion in Resource Limited Countries

Abstract Text

Background:

Prescription practices not conforming to international guidelines are common across diverse practice settings. Evidence shows that inadequate knowledge about transfusion among clinicians is the predominant factor that leads to irrational blood and product use. In an attempt to raise knowledge levels various methods to educate clinicians like, face-to-face sessions, reminders, printed information, conferences etc. have been tried with variable results. A study of 'Rational use of blood' in India used an intervention based on the assumption that inadequate knowledge leads to inappropriate use. A new request form with a checklist for indications of blood and component use was introduced at hospitals in four districts in India. The result of the intervention appeared to be weak and inconsistent and the effect marginal with 'few significant improvement'. Though there were several methodological issues like disparate study and control pairs affecting the result, the researcher acknowledged the presence of factors other than inadequate knowledge, like the state of health services and socio-economic issues, to be also affecting the results (PhD thesis, London school of Hygiene and Tropical Medicine, 2001).

Objective:

To understand the influence of non-clinical factors like organizational problems, social and economic factors in resource limited countries on transfusion decision-making. This paper, which is part of a larger study, attempts to provide insights into the realities of working in such practice settings and their implications for rational prescribing practice. Methods: The study was undertaken in a 1000-bedded, not- for- profit super specialty hospital at New Delhi, India. 1) An analysis of 1764 blood request forms, 2) A KAP type study, by way of schedule based interview

with 104 clinicians, 3) Retrospective study of 40 cases of inappropriate blood use according to WHO Guidelines to understand the factors that affect decisions and their rationale in specific situations.4) Focused group discussions with clinicians based on these case studies to elicit their reflections and opinions and to generate a debate on what can be accepted as rational in the given circumstances.

Results:

Results of the first exercise are not being presented here. Interview with clinicians corroborated the findings of other studies showing inadequate knowledge about transfusion guidelines. But the third part of the study highlights the influence of several additional factors- social problems, as well as those arising due to overburdened health services in a resource limited setting.

Conclusion:

In addition to inadequate knowledge, there are several non-clinical factors that influence transfusion practice and adapting WHO guidelines to specific local health service context appears to be essential. Rational practice needs to be redefined within this framework.

Annexure-11

Abstract Title: KNOWLEDGE OF GUIDELINES, ATTITUDE TOWARDS BLOOD SAFETY AND TRANSFUSION PRACTICE: AN INDIAN EXPERIENCE

POSTER presentation at the XX1Xth International Congress, ISBT, Cape Town, September 2 - 7, 2006 (P-695)

Topic-14. Transfusion in Resource Limited Countries

Abstract Text

Background:

Evaluation and studies have shown that blood and blood components, like other health resources are often used inappropriately. The reasons could be many but inadequate levels of knowledge about guidelines among clinicians, seems to be the most important cause. Transfusion medicine is considered to be less important specialty among medical practitioners and has a low priority status. Therefore, not much attention is paid to the advances made in this field resulting in low knowledge levels and non-adherence to the established guidelines. Inappropriate use leads to pressure on the blood banks, a compromise on blood safety and adds to the already rising costs.

Objective:

To assess levels of knowledge of guidelines, perceptions of blood safety and other factors affecting practice among prescribers of blood and blood components.

Methods:

This study was conducted in a 1000 bedded, super specialty hospital at New Delhi. A schedule-based interview with 104 clinicians was undertaken for eliciting responses to questions about: indications for blood and blood product use, attitudes towards blood safety and economy, reasons for differing from the WHO criteria, and influence of institutional and other factors on practice.

Results:

Knowledge about transfusion guidelines was very low among prescribers resulting in over prescription. 56% of the respondents were not aware of any guidelines, 38% thought that tested blood was absolutely safe for transfusions. Transfusions were given in apprehension of blood

loss; plasma was preferred to albumin because of high cost. Acute blood loss was treated aggressively as close monitoring was not possible due to patient load. Conclusions: Proper training of clinicians can minimize inappropriate transfusions to a large extent. Blood banks should play a proactive role in disseminating information about the recent advances made in transfusion medicine.

Annexure-12

Abstract Title

EFFECT OF CLINICAL AND NONCLINICAL FACTORS, KNOWLEDGE OF GUIDELINES, AND ATTITUDES TOWARDS BLOOD SAFETY ON TRANSFUSION PRACTICE: A STUDY OF CLINICAL USE OF BLOOD

Oral Presentation at the National Conference on Research in HIV/AIDS in
New Delhi from January 10-13, 2006

TRACK -C /SUBTRACK- 4: BLOOD SAFETY

KEY WORD: BLOOD SAFETY

BACKGROUND:

With advancement of knowledge and stringent donor selection criteria, increased donor deferrals, has resulted in a shrinking donor base. Regular voluntary donors have increased only marginally. Introduction of newer tests has increased discard rates and made blood and blood components a significantly expensive product.

'Irrational' prescribing by the clinicians adds to the shortage of this already scarce resource. Evaluation and studies have shown that many a times the demands do not conform to internationally accepted guidelines. The reasons could be many ranging from, lack of proper knowledge of guidelines, problems of working in situations of resource constraints, lack of proper infrastructure, especially in low-income countries, forcing the clinicians to adapt to the settings they work in. What is 'Rational' then depends on the context of the prevailing conditions of health services, the available resources and the epidemiology of blood borne diseases. This paper attempts to understand factors which influence transfusion decision making under conditions of resource constraints, and initiate a discussion of what can be accepted as 'Rational'.

OBJECTIVE:

To study the prevailing transfusion practices and identify gaps therein,

To identify factors that influence transfusion decision making in the context of low-income countries

METHODS:

1)A retrospective analysis of 1764 request forms were undertaken to study the utilization patterns

2) In depth study of 40 cases where blood and component use was violative of WHO guidelines

3) A schedule-based interview with 104 clinicians, for eliciting responses regarding levels of knowledge, problems faced in adhering to guidelines, effect of nonclinical factors in transfusion decision making, and scope for reduction of transfusions.

RESULTS:

Analysis of requisition forms showed that 80.35% of the demands were for whole blood. Single unit transfusions were 64.25%. Most of the components were demanded by the Dept of CTVS.56% of the respondents were not aware of any guidelines.

Case studies showed that transfusion was given in anticipation of blood loss,

pressure from the anaesthetists and lack of proper knowledge, sometimes had to adapt to the working conditions.

CONCLUSION:

There is definitely a scope for reduction in transfusions. Lack of knowledge among clinicians reflects low priority given to transfusion medicine. More studies should be planned to produce evidence base, in context of low-income countries.

Annexure-13

Abstract Title -TRENDS IN TRANSFUSION PRACTICE: A SEVEN YEAR RETROSPECTIVE STUDY OF PRESCRIPTION PRACTICES OF BLOOD AND COMPONENTS AT A TERTIARY HOSPITAL IN INDIA

Oral presentation at the XVIIIth Regional Congress of the ISBT, Hanoi November 10 - 13, 2007

Topic- Session 5: Transfusion Systems in Resource Limited Countries

Abstract text

Background:

The National Aids Control Programme of India was launched in the year 1992, with 'blood safety' as the major thrust area. As a result, several developments took place at the policy and regulatory levels, like modernization of blood banks, setting up of zonal blood testing centers, component separation units, and training of doctors in rational blood and component use.In order to analyze the impact of the policy decisions on actual transfusion practice, trends in blood and component use were studied retrospectively for over a period of seven years, at a 1000 bedded, tertiary hospital in New Delhi.

Objective:

To analyze the trends in blood and component use, in the context of the developments mentioned above and identify gaps,

To document changes if any, in transfusion practice over this period,

Methods:

A 50% sample of request forms for the years 1997, 2000, 2003, was analyzed. The year 1997 was taken as the baseline. Component separation was started in 2001; therefore, requests of years 2000 and 2003(before and after) were included. The demands were analyzed for age/sex distribution, hemoglobin, specialty wise categorization, disease profile, component use and general trends.

Results:

A total of 3261, 3943, 4914, request forms for the years 1997, 2000 and 2003, were analyzed. 8.2

units per bed, 7.6 units per bed, and 11.3 units per bed were transfused for the above years. Per major surgery, 0.8, 0.8 and 1.1, units were transfused respectively.

For all three years, Surgery used maximum number of WB units, statistically significant ($p<0.05$).However for packed cells it was Pediatrics which used the maximum number of units ($p<0.05$).

Most heavily transfused age category was, 16-30 years, followed by 35-40 years, these together accounting for 50% of transfusions, trend being uniform for all three years.

For all components prescribed in all study years, single unit demand was the norm. Demand for single unit WB, &PC showed a drop (76.5%, 75%, and69.5%), but an increasing trend of demand for 2units PC was seen (20.2%, 21.7%and27.3%).Component demands increased considerably, CTVS compared with all other depts. taken together, showed that a large %of components was being utilized by CTVS (WB- 0.89%vs 99.10%, PC-19%vs 80.99%, FFP-24.79% vs. 75.20%, PLT-58.82% vs. 41.17%).Outside CTVS most PC was used by Medicine mostly for Anemia and Paeds for Thalassemia, FFP was used by Medicine for liver disease,PLT was used by Medicine for Aplastic anemia.

Conclusion:

This study shows that component use has increased over this period, but their appropriateness is questionable. The increase in component use is partly due to the availability and increased demands by CTVS. Most demands for components were single units, those for FFP and PLT being grossly inappropriate in single unit doses. Corroboration with the diagnoses showed that many of these were wrongly indicated,transfused in inadequate doses or avoidable. Results of this study highlight the fact that mere availability of components would not ensure appropriate practice. Knowledge of guidelines and addressing certain non clinical issues that influence transfusion decisions in low income countries could help improve practice.

Annexure-14

Abstract Title: UNDERSTANDING THE CLINICIANS' PERSPECTIVE: A RETROSPECTIVE STUDY OF TRANSFUSED CASES AT A PUBLIC SECTOR HOSPITAL IN INDIA

ORAL presentation at the XXXth International Congress of the ISBT, Macao SAR China, June 7 − 12, 2008. (5A-S38-04)

Topic-(16.0) Transfusion in resource limited countries - in general

Abstract text

Background:

Evaluations of transfusion practice have shown inappropriate blood and component use. Inadequate knowledge of transfusion guidelines is thought to be the predominant factor leading to inappropriate use.Several methods to educate clinicians have been tried with variable results. In order to understand the perspective of the treating clinicians, on the factors that influence transfusion decision making, this study was carried out at a 1000 bedded, public sector hospital in India.

Aim:

To understand the rationale for transfusions

To identify the circumstances, under which the transfusions were ordered

Methodology:

A retrospective study of 80 cases, 20 each, from 4 categories of elective Gynecological surgery, elective General surgery, Anemia, and Acute blood loss, that had received inappropriate transfusions in the years 2005-2006, was undertaken. The case sheets were studied for, the clinical/lab criteria for transfusion, pre op/post op Hb, type and quantity of components used, timing of the transfusions in relation to admission /investigations/ surgery. Questions based on

these observations were posed to the treating physicians to understand their rationale for the transfusions.

Results:

The responses could be divided into two broad categories. One, decisions made as a result of inadequate knowledge of guidelines and other, the best that could have been done in the given circumstances. Most transfusions for elective surgery were given to help wound healing specially in patients coming from low socioeconomic strata. Blood loss was replaced by Whole blood transfusions to avoid multiple donor exposures. Cases of Menorrhagia for elective hysterectomy were believed to have low reserves, so transfusion would help post-op recovery. Acute blood loss was always a panic situation and saving the patient was top priority. Sometimes accurate estimation of actual loss was not possible in these cases, monitoring was difficult especially in emergency hours, residents overburdened, and ill equipped to handle situation if condition deteriorated. Few cases were even under transfused due to unavailability of replacement donors. Packed cells were used for anemia in failure. Clinical judgment formed the basis of transfusion in cases of anemia that fell into grey zones (Hb 7-10 gm %), as lab results could not always be relied upon. In alcoholic liver disease with Hematemesis, FFP was given as a precaution. In dengue, experience showed that patient could bleed even with adequate platelets, fear of missing minute hemorrhages, patient anxiety and panic created by media, were possible reasons for transfusion. Risk of withholding transfusions in VIP patients was rarely taken. FFP/Plasma was preferred to albumin because of cost constraints.

Conclusion:

Transfusion decisions are the result of interaction of multiple factors. Most immediate concern of the clinician is the wellbeing of the patient. In the absence of enough evidence-based studies and poorly defined critical limits of tissue oxygenation, personal experience and conventional wisdom guide decisions. In addition to inadequate knowledge of guidelines, structural, organizational, socioeconomic factors also influence decision making the effects of which are likely to become more pronounced in conditions of resource constraint.

Annexure-15

Abstract Title: LABORATORY COSTS OF PROVIDING BLOOD AND COMPONENTS IN A PUBLIC HOSPITAL BASED BLOOD BANK IN DELHI

Poster presentation at the XXth Regional Congress of the ISBT, Nagoya, Japan November 14 − 18, 2009 (P-017)

TOPIC-1.3 Cost/Effectiveness in BTS

Abstract Text

Background:

The blood safety programme in India funded largely by donor agencies runs as vertically organized programme. The public and private hospital-based replacement donor system is widespread, supplemented by few NGO run blood banks. Different types of blood banks coexist, belonging to different organizations, with different sources of funding leading to wide disparity in cost. The private blood banks charge for cost recovery, the NGO blood banks take processing charges and the public hospital-based blood banks provide blood and components free of cost. Evidence suggests that integration of the programme into the existing public health institutions would lower running costs. For an economically sustainable programme especially in the context of low-income countries, both options, i.e. of centralized services, or integration into the existing public health care system, need careful consideration. Therefore it is essential to estimate the cost incurred by these public institutions in providing safe blood and components.

Aims:

This study was undertaken to evaluate the cost of laboratory resources needed to provide a unit of whole blood and component in a public hospital-based blood bank in Delhi.

Methods:

Cost of providing a unit of whole blood and component was evaluated in a retrospective observational study for the year 2008, in a 1000 bedded public hospital-based blood bank. The total collection was 9586 units, with 49,5% of the collection being separated into components.

As the supply depended on replacement donors, and blood was utilized within the hospital, costs incurred by the activities of recruitment and distribution was not included. The methodology used had some similarities to the costing guidelines provided by WHO. The unit of output was the cost of a single unit of blood or component and it was assumed that all components had equivalent costs. The capital and the recurring costs were enumerated separately. The cost of building and maintenance were not included in the capital cost as the blood bank was part of a tertiary care public hospital. The recurring expenditure included staff salaries, consumables and miscellaneous items.

Results:

Out of 11,894 donors screened, 9586 were found to be fit for donation. A total of 16,790 units were issued which consisted of whole blood, packed cells, fresh frozen plasma and platelets. The cost of each unit of component was INR 935, equivalent to USD 19.5. Out of the total recurring expenditure, 60% was spent on staff salary and 30% was spent on consumables.

Conclusions:

The hospital-based system has an advantage over the centralized system as only the costs incurred by the activities of collection and processing are only involved. Cost related to donor recruitment and distribution is not included. In the absence of data on activity wise costs of blood transfusion services from India, it is difficult to ascertain the economic advantage between a centralized system and the hospital-based system. But it appears that despite policies advocating centralized transfusion services, the hospital-based replacement donor system is a cost-efficient option in the context of low-income countries like India.

Annexure-16

Abstract Title-PARTICIPATION OF CLINICIANS IN CONTEXTUAL ADAPTATION OF TRANSFUSION GUIDELINES: BRIDGING THE GAP BETWEEN POLICY AND PRACTICE

POSTER presentation at the XXXI st International Congress of the ISBT, Berlin, Germany June 26th to July 1st, 2010 (P-0917)

Topic-Clinical Transfusion - 6.3 Evidence Based Transfusion Medicine Practice

Abstract Text

BACKGROUND:

Several studies have found that transfusion practice does not conform to guidelines, and variations exist between different clinical settings. This study was conceptualized with the understanding that transfusion decision making is complex and multi factorial and is also influenced by the organizational, socio-economic, and cultural factors related to the practice environment. The differences in these factors between and within countries can lead to legitimate variations in recommendations, even when the evidence base is same and requires adaptation of guidelines for 'Rational' practice. To achieve this, participation of end users is essential as they are aware of the specific contextual issues.

AIM:

This study attempts to examine the nature of socio-economic and operational factors affecting transfusion practice from the clinicians' perspective, and explore specific issues of concern, for adaption of guidelines to the context.

METHODS:

This study was conducted between 2003 and 2008 in a 1000 bedded tertiary hospital in India. Identifying such factors which are complex in nature requires in depth qualitative and quantitative investigation for their appreciation for which participation of clinicians is essential. Therefore, first a schedule-based interview was conducted with 104 clinicians to elicit responses

related to prevailing transfusion practices, their attitudes towards blood safety, reasons for differing from the W.H.O. criteria, and influence of any organizational and socioeconomic factors on decisions. This was followed by a retrospective study of 80 cases that were at variance with guidelines, to understand the rationale for transfusion, and problems faced by clinicians in translating guidelines into actual practice. Finally a focus group discussion with prescribers was conducted to help identify issues which could be addressed by guideline modification.

RESULTS:

The findings highlight the influence of several social factors, as well as those arising due to overburdened health services in a resource limited setting. Problems like high patient load, lack of proper facilities (inadequate lab support, shortage of beds/operation theatres), unavailability of donors and high cost of commercial substitutes, are some important issues that influence decision-making. Acute blood loss cases are difficult to monitor as emergency wards are understaffed. Blood bank delay adds to the problem. Facility for coagulation profile testing is available biweekly, so FFP is transfused in liver disease as a precaution. In Dengue, patient anxiety and media pressure lead to over prescription. Plasma is preferred to Albumin because of cost constraints.

CONCLUSION:

The process of adaptation of guidelines requires evaluation of contextual factors, building on established evidence and experience from other countries. Health service system issues would require policy recommendations which would be different for different levels of health care, even within the same country. Therefore, mechanisms have to be developed for consensus development and rational practice needs to be redefined within this framework. Some operational barriers like delays on part of blood bank or laboratory could be addressed locally by discussion/ protocol formulation for better adherence of guidelines. Issues involving cost effectiveness would require contextual studies. Skill development of clinicians in proper assessment of transfusion indications would ensure practice of already available evidence.