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- **FACT Inspector**



- **Commonwealth Scholar 2017/18**, trained at NHS Blood & Transplant (IBGRL)
- **ISBT's Harold Gunson Fellowship Award Recipient**
- **>15 publications** in peer-reviewed National & International Journals
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FACT-JACIE Accreditation in India: Challenges, Opportunities & Global Alignment



- No disclosures
- No conflict of Interest



Bone Marrow Transplant & Cellular Therapy in India



120,000 Annual
Blood Disorder Cases



114+ Centers
Nationwide



26,843 Transplants (1983-2022)



2,500-3,000
Transplants / Year
10% Annual Growth



Limited access & variable practices lead to Inconsistency and low credibility



CURRENT CHALLENGE

Rapid Growth

- 110+ Transplant Centers
- CAR-T Expansion



Need for Standardization & Global Credibility



*Chandy, M. Stem cell transplantation in India. Bone Marrow Transplant (2008)
<https://www.isbmt.org/organisation>*

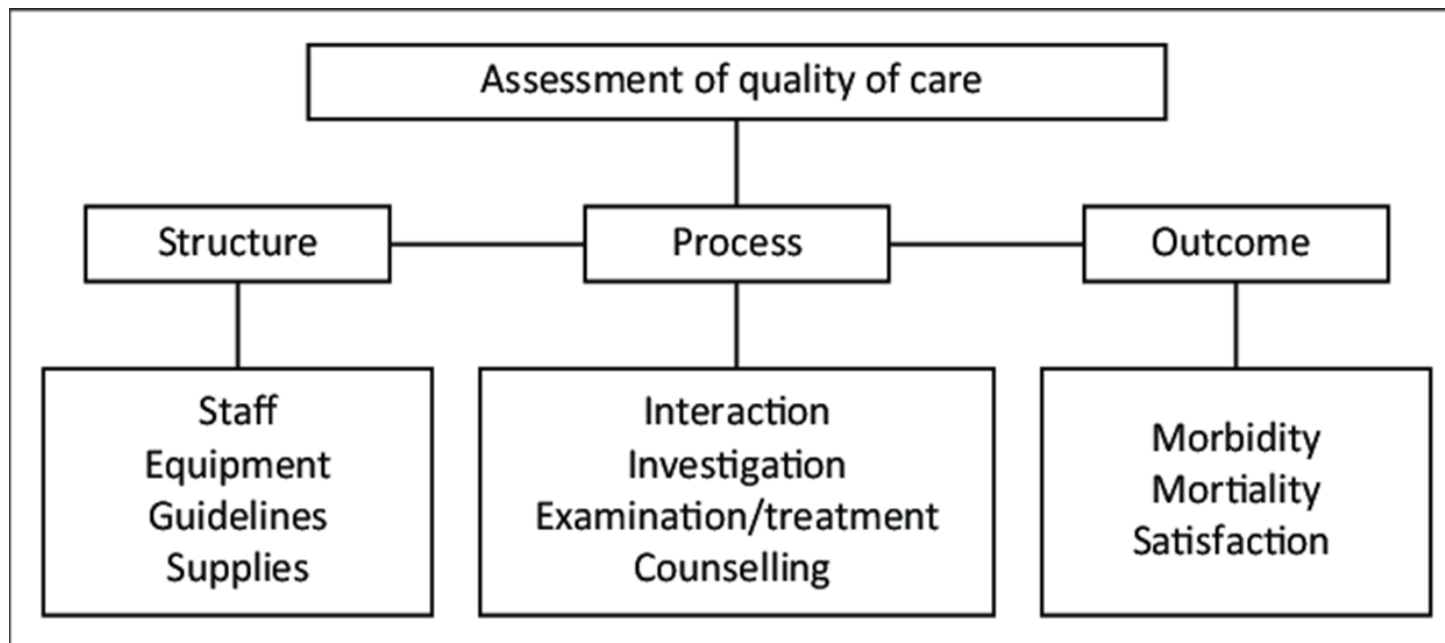
QUALITY IMPROVEMENT- “ PROJECT ”

Aims to make a difference to patients

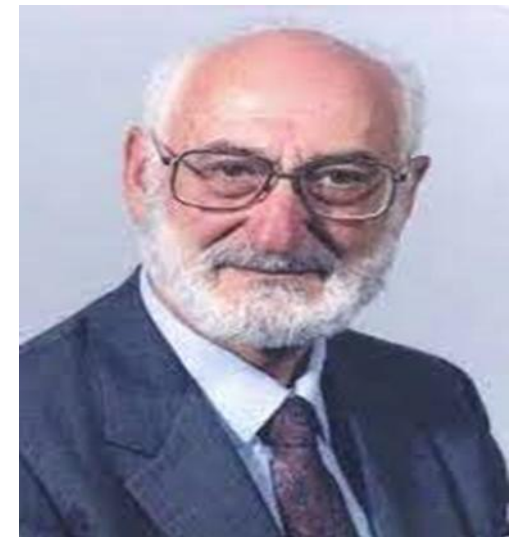
- By increasing safety, effectiveness & experience of care
- Systematic approach to understanding of our complex healthcare environment
- Designing, testing & implementing changes using real time measurements

Jones et al, BMJ 2019

DONABEDIAN MODEL



Hughes, 2008 accessible at <https://www.ncbi.nlm.nih.gov/books/NBK2682/>



Prof Avedis Donabedian

A physician & founder of the study of quality in health care

ACCREDITATION

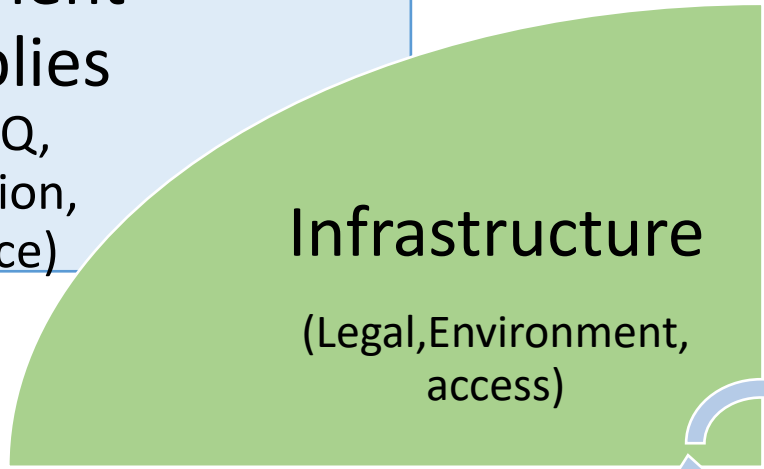


- **Independent, third-party evaluation** of a conformity assessment body **against recognized standards**, conveying formal demonstration of its impartiality and competence to carry out specific conformity assessment tasks
- In simple words : **Peer-review**
- JACIE & FACT actively collaborated on drafting international quality standards
 - Patient care and facilities during the transplant period
 - Donor care during collection of blood and marrow cells
 - Laboratory processing, storage and delivery of the blood and marrow cells



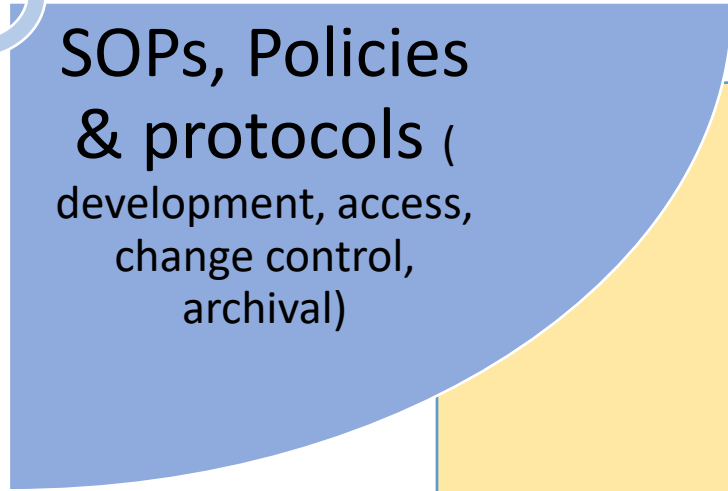
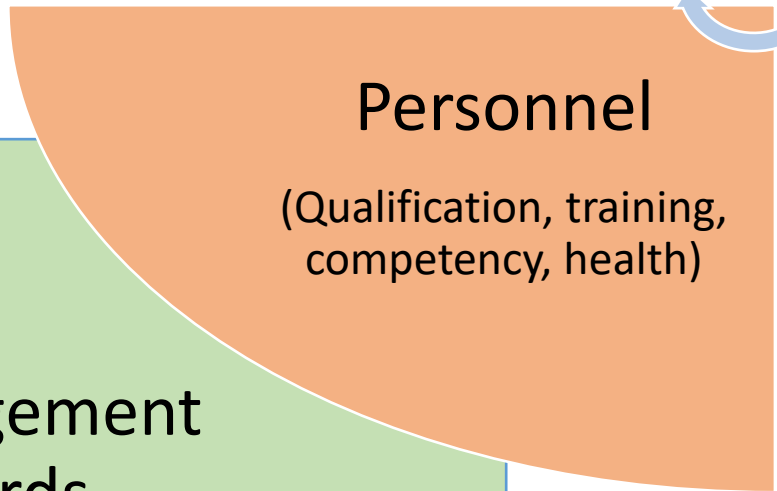
DIFFERENT INGREDIENTS FOR QUALITY

- **Equipment & supplies**
(IP, OQ, PQ, qualification, acceptance)



- **Consents & labeling**
(Purpose, discard, biohazard, storage period, dates)

- **Data Management & records**
(retention period, archival)



- **Process controls (QC) & sample management**



INFRASTRUCTURE

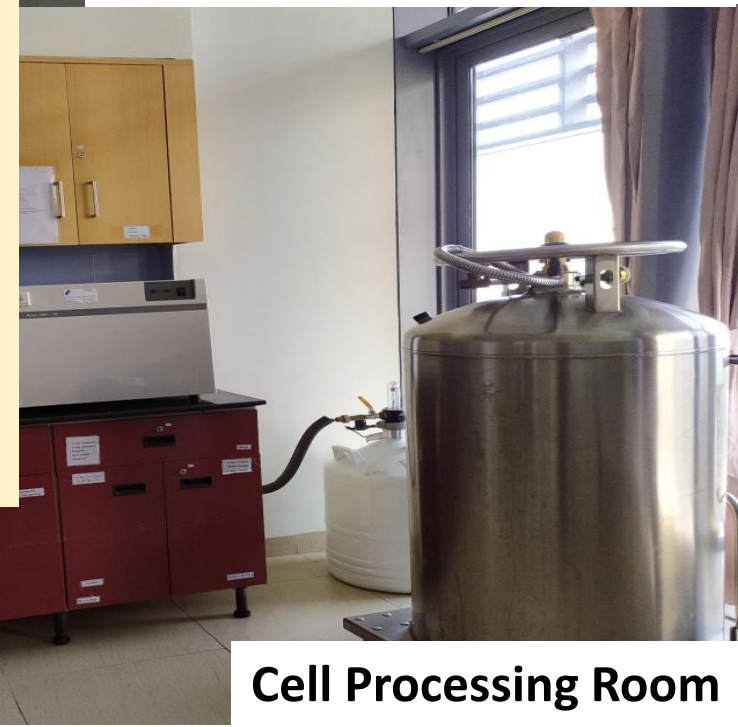
- Unit Design
Process and pathway
- Environment monitoring
cleaning, temp & humidity
- Equipment & Supplies
Maintenance, critical stocks



Out Patients' waiting Room



Out patients' Room



Cell Processing Room

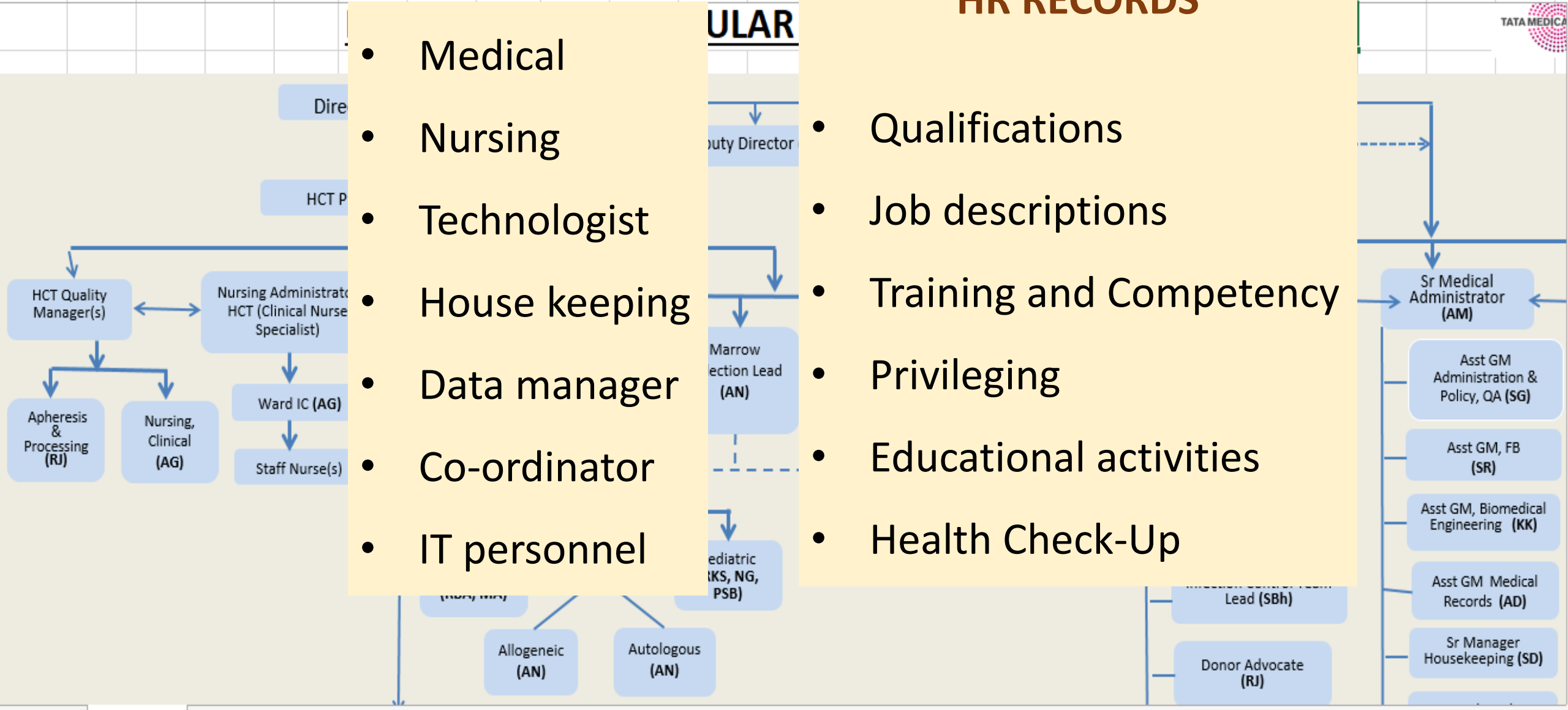


PERSONNEL

HR RECORDS

- Medical
- Nursing
- Technologist
- House keeping
- Data manager
- Co-ordinator
- IT personnel

- Qualifications
- Job descriptions
- Training and Competency
- Privileging
- Educational activities
- Health Check-Up



PROCESS AND PRODUCTION CONTROL

- Customer Requirements
- Supplier Quality
- Identification / Traceability

CHANGE MANAGEMENT

- Design Change Management
- QMS Change Management
- Risk Review

DESIGN CONTROL

- Risk Management
- Inputs / Outputs
- Verification / Validation

PRODUCT SURVEILLANCE

- Complaint Handling
- Risk Monitoring
- Vigilance

RESOURCES

- Personnel Competency
- Infrastructure
- Work Environment

QUALITY MANAGEMENT SYSTEM

QMS IMPLEMENTATION






- QMS Manual
- Policies = 42
- SOPs = 23
- Worksheets, Registers & Consents = 110
- Information booklets = 4
- Labels for products

COMMON CODING & LABELING SYSTEM

- Global standard for identification & labeling of medical products of human origin
- Improves traceability, transparency, vigilance, surveillance & interoperability
- WHO recognized body ICCBBA that manages, develops, and licenses ISBT 128
- Validated, temp-controlled transport mechanisms



Figure 19 Cellular Therapy Example Labels

 A9996 17 987654  P Collection Center 2nd Line of Name City, Country, Postal Code	 4700 O RhD Positive
Collection Date/Time 22 JAN 2017 13:59	For Use by Intended Recipient Only Related Donor, 1st or 2nd Degree CARLSON, ERIC L Donor # W0001 123654451 Date of Birth: 12 MAY 1995
Do Not Irradiate Do Not Use Leukoreduction Filters	
 S1125400	 0170241359 Expiration Date/Time: 24 JAN 2017 13:59
HPC, MARROW 3rd Party Blood Component Present See Attached Documentation	Intended Recipient: PATRICK, ANNE Recipient ID: 123456721 Date of Birth 07 JAN 1994
Total Volume _____ mL containing approx ____ mL of ____ Heparin (____ U/mL)	Processing Facility 2nd Line of Name City, Country, Postal Code
Store at 1 to 10 C	

The Umbrella of Quality



Quality Management System

All organizational processes that ensure quality

Quality Assurance

All the planned activities that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality

Quality Control

The inspection of implemented techniques and activities to ensure they are fulfilling requirements for quality

- Validation of all procedures & process
- Calibration of Equipment
- QC for tests
- Deviations
- Change Control
- Audit schedules
- Risk assessment
- Disaster Plan

EVALUATION OF QMS EFFECTIVENESS

Writing Your Program's Story: The Annual Quality Report

Scenario

You have developed a Quality Management Plan. A year has passed since you implemented the plan or last reviewed it and it's time to assess its effectiveness. [D4.18, D4.18.1]*

- What is the scope of the report?
- Who is the audience?
- Who works on the report?
- What resources and data would you use when developing the report?
- What challenges are encountered when developing the report?
- What has been achieved and accomplished?
- Are the current benchmarks appropriate?
- Goals for next year?
- Refer to the following two grids:
 - Grid 1: Overall Assessment Categories
 - Grid 2: Quality Elements



*FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Eighth Edition



CIBMTR AUDIT REPORT

Audit Report_CIBMTR
Version. No. 1.0
Page 1 of 5



CIBMTR
CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

COMPARISON OF DATA ACCURACY IN 2021 AND 2022 AUDITS

2021			2022		
FIELDS AUDITED	NO. OF COMPLIANCES	NO. OF NON-COMPLIANCES	FIELDS AUDITED	NO. OF COMPLIANCES	NO. OF NON-COMPLIANCES
145	75.17%	24.83%	190	91%	8%

Audit Observations & Improvement Recommendations:

Overall percentage of non-compliance was 8%. However, it shows a decline (17%) from last year audit.

Overall Findings

Root Cause Analysis (5 Whys)

Recommendations/Corrective action:

Error in documentation & Transcription

Why- Gaps in understanding during data entry
 Why- lack of stable manpower
 Why- lack of ongoing training
 Why- lack of continuous supervision

- The importance of aligning the data entered with the appropriate source note was stressed
- Training and education of new data managers to familiar with terms & source documents used in
 - transplant
 - Periodical supervision of data entry by doctors

Date of Audit: 30 January, 2023

Department /unit audited: BMT/CT program

Audit title: CIBMTR Internal Audit 2022 (for transplants done in 2021)

Auditors: Dr. Arijit Nag and Dr. S Bhave

Report analysis & preparation: Quality Assurance team, Dr Rizwan, Ms. Srija and Mr. Arnab (Data Managers)

Audit Plan: Manual audit of electronically submitted TED forms for autologous transplants occurred in 2021. Audit of 6 patients (sample size > 10%) was planned. Audit was intended to:

1. assess accuracy of transcribed information
2. ensure compliance to departmental SOPs and policies for transplants
3. ensure patient consents were signed
4. source documentation was checked and verified

Type and Audit period: Annual audit of electronically submitted TED forms in 2021

Audit Goal: To review and streamline the data entry process in BMT after the managers and identify trend of errors for further analysis and corrective action

Audit Purpose and scope:

- In alignment with FACT standards B4.8.3.3, accuracy of data in Transplant CIBMTR or the Minimum Essential Data -A Forms of the EBMT is assured
- The purpose of this internal audit was to evaluate the accuracy of the data of 6 patients (>10% of patients transplanted in the given period) who underwent allogeneic transplants in the calendar year 2021.
- The scope of this audit was comprehensive and included review of

Quality Indicators: Objective assessment & monitoring

Year		2024	2023
Mobilization Failure Rate	$\frac{\text{No. of patients who did not mobilize (pCD34 < 10 on day 5 of G-CSF)}}{\text{Total no. of patients receiving mobilization (G-CSF + prelixafor)}}$	6.6 %	9.5%
Mobilization-related Adverse reaction rate	$\frac{\text{No. of patients having adverse reactions (Grade III and IV)}}{\text{Total no. of patients who received mobilization}}$	41.2%	35%
Procedure-related Adverse reaction rate	$\frac{\text{No. of patients having adverse reactions (Grade III and IV)}}{\text{Total no. of patients undergoing apheresis}}$	0	0
Target CD34 + cells yield achieved	$\frac{\text{No. of HPC products (CD34+ > 4 million/kg in autologous \& >3.5 million/kg in allogeneic collections)}}{\text{Total no. of patients underwent PBSC collection}}$	81.8 %	89.7%
Microbiological Culture positive rate	$\frac{\text{No. of Microbiological Culture positive HPC products}}{\text{Total no. of HPC products prepared}}$	3.5 %	0
Mean Collection Efficiency of Equipment	$\frac{\text{Total CD34+ cells obtained from apheresis}}{\text{peripheral CD34+ cells/}\mu\text{L} \times \text{apheresis volume processed (}\mu\text{L)}}$	49.3 %	53%

OUTCOME ANALYSIS - Setting Indian Benchmarks !

Quality Parameter	2024	2023	2022 (%)	2021 (%)	Benchmark (%)	References
Engraftment Failure						
Autologous	0	0	0	0	5	Valcarcel D, Sureda A. Chapter 41: graft failure. In: Carreras E, Dufour C, Mohty M, Kröger N, editors. EHCT handbook. Switzerland: Springer Open; 2019. Fondation José Carreras, contre la leucémie.
Allogeneic	1.7	0	0	0	10	
Graft Versus Host Disease (GVHD)						
Acute Grade 2-4	28.1	15.9	14.3	48.57	45-55	B. George et al. / Transplantation and Cellular Therapy 28 (2022) 45.e1-45.e8 Wellington F. Silva et al. / Transplantation and Cellular Therapy 28 (2022) 763.e1-763.e7
Acute Grade 3-4	10.4	6.8	11.4	22.85	23.9	
Chronic GVHD	39.5	31.6	22.8	10.05	26-42	

Accreditation Overview

- *Voluntary Accreditation Process*

Accreditation is based on documented compliance with current Standards

- Submitted documents
- On-site inspection
- Accreditation Committee review

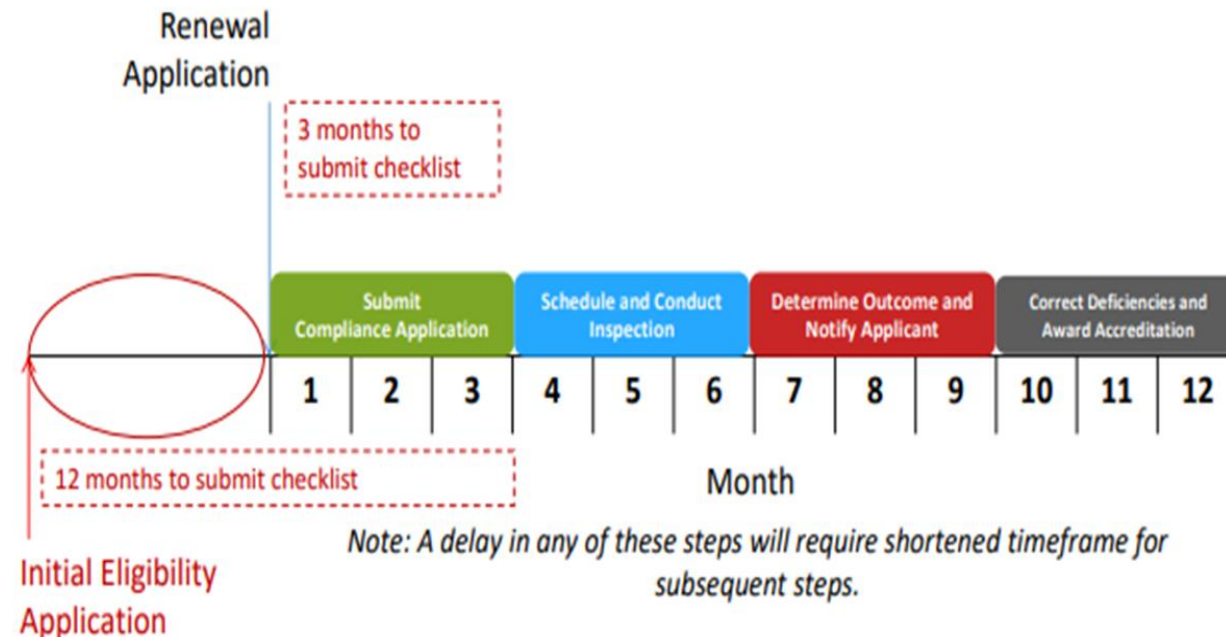
Eligibility (initial) and Renewal Applications *(10 Allo or 5 Auto transplants annually)*

- Demographics; services
- Length of time in operation; presence of required personnel; number of procedures

Compliance Application – “checklist”

- Includes each Standard
- Customized to each specific program or bank
- Requires uploaded documents

Discounted Annual Fees: USD 6000



MATCHED UNRELATED HPC COLLECTIONS



New Jersey, USA
Boston, USA

Sheffield, UK

Ankara, Turkey

Delhi

Vellore
Kochi

BENEFITS OF ACCREDITATION

- **INTERNATIONAL CONSENSUS** - Aligns with patient/donor care guidelines
- **COMMON INTERNATIONAL LANGUAGE** : “ Quality ”
- **COMMON GOAL** - Bring together clinicians & other specialists
- **REDUCE BIAS** : the effect of individual experiential bias or ‘agenda’ & the influence of dominant local financial, clinical or academic conflicts of interest
- Legal and regulatory requirements in some countries
- Improvements in patient survival & reduction in procedural mortality

Snowden et al, Bone Marrow Transplantation 2017



Our Experience



Developing a Multi-stakeholder Initiative to overcome barriers in implementing FACT mandated Quality Management System (QMS) in an Indian transplant center

Rizwan Javed , Mita Roychowdhury, Jeevan Kumar, Saurabh Bhave, Arijit Nag A, Soumita Ghosh S, Aseem Mahajan, Reena Nair, Mammen Chandy



Implementation of Quality Management System (QMS) Improves Peripheral Stem Cell Collection Service in an Indian Center

Rizwan Javed , Mita Roychowdhury, Jeevan Kumar, Saurabh Bhave, Arijit Nag A, Soumita Ghosh S, Aseem Mahajan, Reena Nair, Mammen Chandy

FACT Accreditation in India: Challenges & Opportunities



Rapid Growth

- 110+ Transplant Centers
- CAR-T Expansion



Need for Standardization & Global Credibility



FACT Accreditation FACT-JACIE Standards

Key Challenges

Infrastructure & Cost

- GMP Facilities
- Upfront Costs



Human Resources

- Skilled Workforce Shortage
- Retention Issues



Multidisciplinary Coordination

- Siloed Systems



Regulatory Complexity

- NABH vs. Global Standards



Key Opportunities

Quality & Safety

- Standardized Care



Capacity Building

- Training & Education



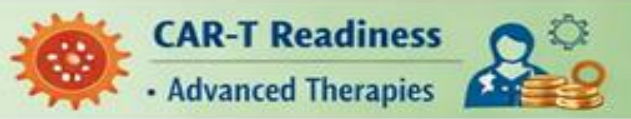
Global Collaboration

- Intl. Trials & Exchanges



CAR-T Readiness

- Advanced Therapies



TAKE HOME MESSAGE



Toward Value-Based, Globally Aligned Care

• Enhanced Outcomes



• International Credibility

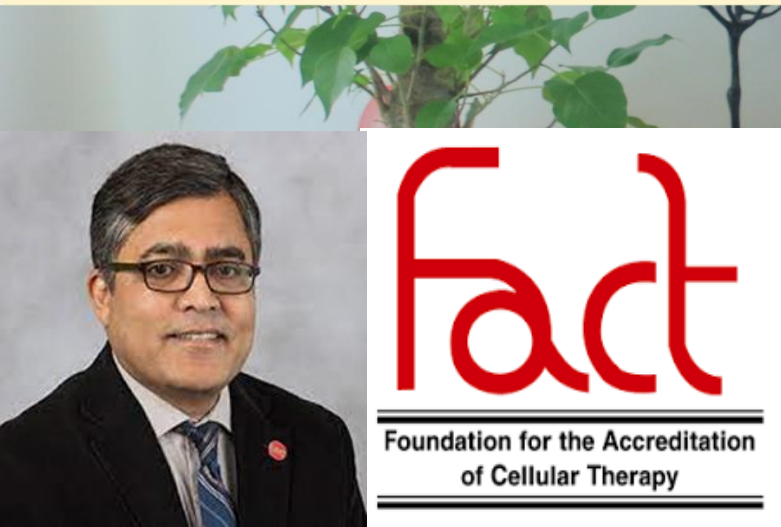


• Sustainable Growth



- Faculties of Clinical Hematology & Pediatrics
- Admin & allied departments
- IT, MRD, HMS, F&B, Estates
- Dr Aseem Mahajan & QA team
- Laboratory Services
- House-keeping team
- Nursing team
- FACT Team

ACKNOWLEDGEMENTS



Foundation for the Accreditation
of Cellular Therapy



Through the eyes of gratitude everything is a miracle !



Thank you everyone !

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