

Where do we first start? From following
standards to successfully obtaining
accreditation

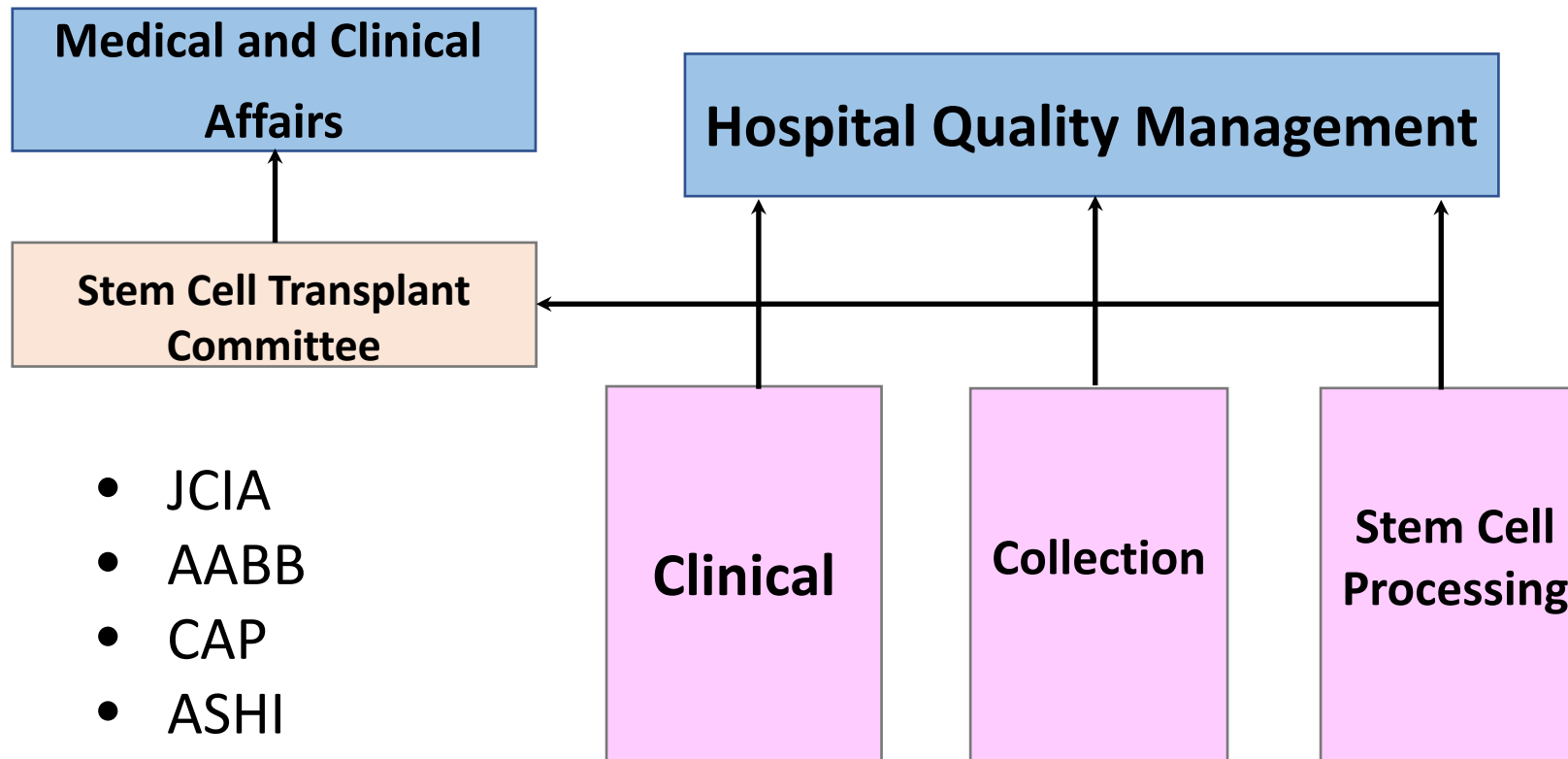
Dr. Amal Al-Seraihy

Director of Pediatric SCT program

Chairman of SCT Quality Management Committee

KFSHRC-Riyadh- KSA

Stem Cell Transplant (SCT) Program Management & Quality Pre-Accreditation 2008



Stem Cell Transplant Program Staff and Activities

| | | |
|--|------------|---|
| Stem Cell Transplant Staff | | Beds= 14 pediatric =19 adult Transplants = 323 transplants Allogeneic = 256 Stem Cell processing procedure = 882 Apheresis = 200 Bone Marrow harvest = 137 |
| Physicians (3 Program Directors) | 36 | |
| Nursing (including Coordinators and Quality Management) | 80 | |
| Apheresis Stem Cell Transplant Laboratory | 24 | |
| Others (Pharmacists, Data Managers, Health Educators, etc.) | 10 | |
| Total | 150 | |

Reporting Data to CIBMTR and EBMT since 1993

Why JACIE Accreditation ?

- Performing all SCT activities in accordance with agreed standards of excellence .
- Certify that program operates an effective QMS
- KFSHRC-SCT program mission is to ensure the highest quality of care to patients undergoing transplant procedure and to seek continuous improvement.
- Strategic organizational goals aiming for program of excellence in cell therapy

How did we start?

2008

JAN decision

Aug. application

Nov. inspection

March 2008

**PRE-
INSPECTION
EVALUATION
JACIE OFFICE**

JACIE COORDINATOR

PROJECT CHAMPIONS

Consultant SCT
SCT coordinators adult & pediatric
Clinical supervisor of Apheresis and BB
Senior Tech staff SC processing Lab

400 hrs./3months

JACIE CORE TEAM

- Program Directors
- Representative hospital QMD
- Head nurses of SCT unit and outpatients
- Representative hospital organization procedure
- Representative pharmacy, Social, services

**MANGEMNET
MEDICAL CLINICAL AFFAIR**

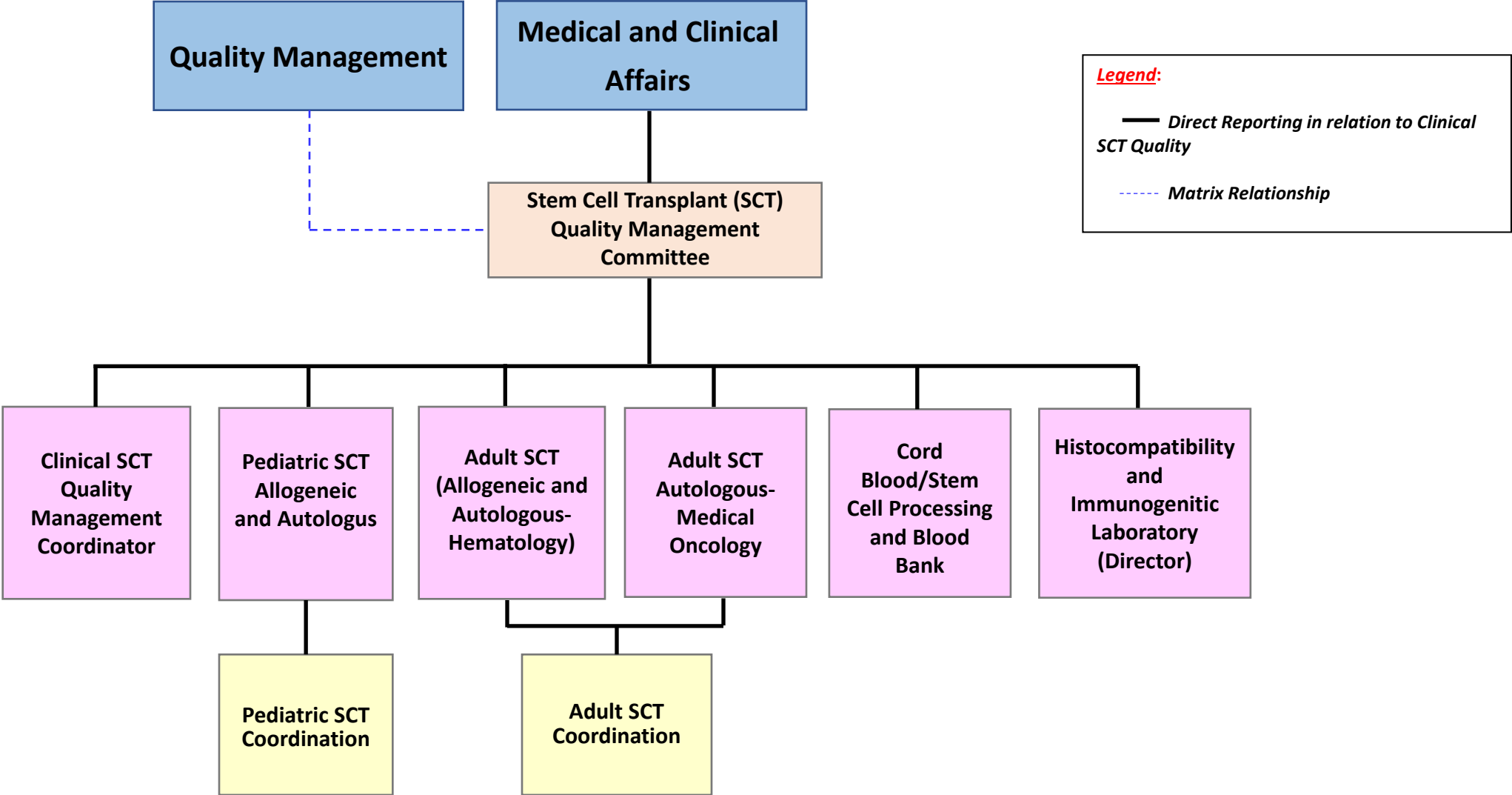
June 2009

**POST INSPECTION
EXTRENA ASSISTANT
QM-UK accredited SCT**

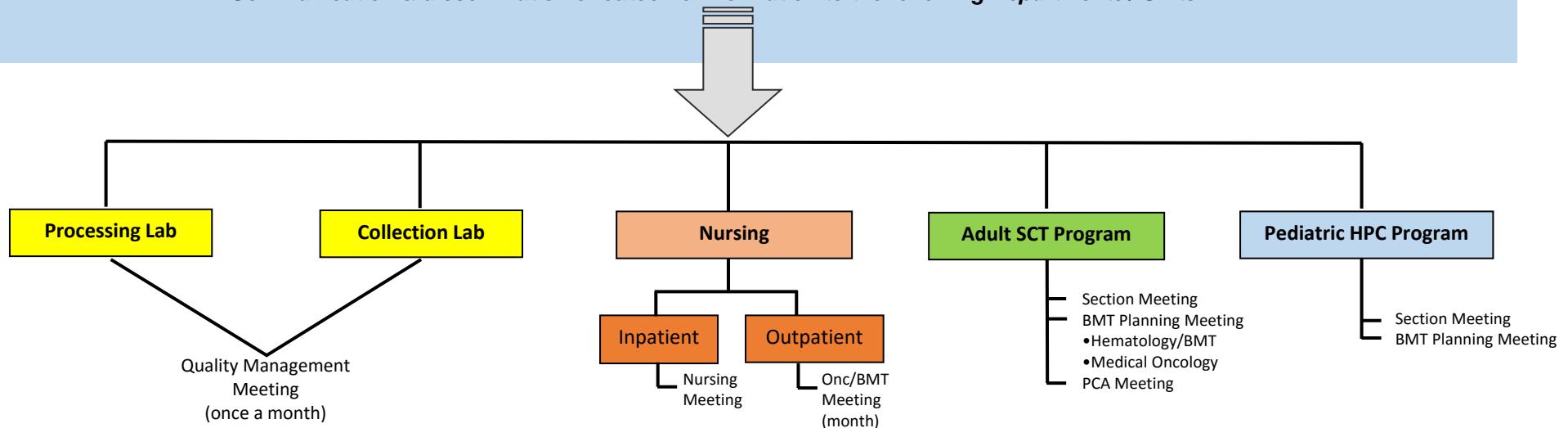
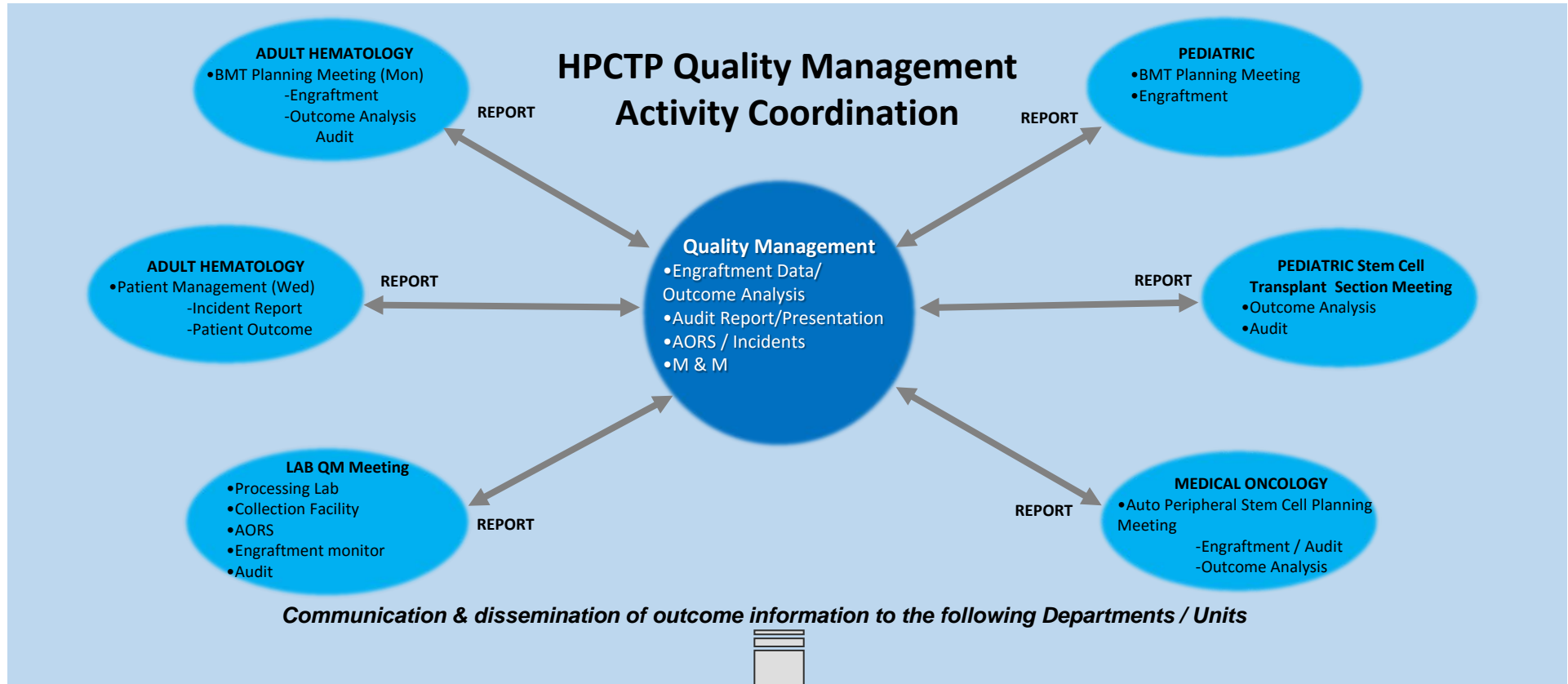
First JACIE Accreditation 2008-2010

- Common Themes in **deficiencies** found in all 3 facilities
 - Quality Management system need to be more robust
 - Communication issues
 - Audit
 - Adverse occurrence reporting/ follow up
- Labeling ISBT 128
- SCP Lab Space(HPC products/staff safety)

SCT Quality Management Committee Program Hierarchy



Communication Pathway in the SCT Quality Management Committee



Safety Reporting System Flow Chart

Stem Cell Transplantation Quality Management Program (Revised May 2014)

Errors, Accidents, Adverse Events , Biological Product Deviations and Complaints

Incidents are reported by staff within the Clinical, Collecting and Processing Facility thru the hospital reporting system "SRS" via Quality Information System "QIS"
The incident is analyzed and reviewed according to the APP:
1434-01- Reporting and Management of Incidents"

Incidents and corrective actions are discussed as standing agenda items in the following committees:

1. Stem Cell Transplant (HCT) Quality Management Committee
2. Clinical Stem Cell Transplantation (SCRT) Quality Management Nursing Subgroup

Depend on the type and severity of incident, the incident and its corrective actions will be disseminated to the SCT involved staff thru email, memo, IPP, guideline, Education and Training ect...

SCT Quality Manager from each facility keeps track of all related incidences: (Appendix A)

1. SR -Reference Number
2. Incident Date
3. Location
4. Incidents Type
5. Level of Harm
6. Brief Description
7. Corrective Actions
8. ID number of staff initiating SRS (Optional)



**Joint Accreditation Committee ISCT-EBMT
certifies that**

**Oncology / Haematology / BMT
King Faisal Specialist Hospital & Research Centre
Riyadh, Saudi Arabia**

Jane A Apperley

Jane Apperley
President, JACIE

Christian Chabannon

Christian Chabannon
Vice-President, JACIE

comply with the requirements of JACIE and are granted accreditation for

**Autologous & Allogeneic Transplantation in Adult Patients
Autologous & Allogeneic Transplantation in Paediatrics Patients
Collection of HPC, Marrow
Collection of HPC, Apheresis
Cell Processing**

Programme Directors: M. Aljurf & M. Ayas

CERTIFICATE NUMBER:
SA-001-2010

DATE OF ISSUE:
01/02/2010

DATE OF EXPIRY:
31/01/2014



Changes after JACIE accreditation and the Road to Reaccreditation

- Fulltime quality manager for clinical program
- Both collection and SCP assigned two their senior staff for this role
- Clinical SCT –QM nursing subcommittee
- JACIE-*i* Learn online module in hospital info-gate



Changes after JACIE accreditation and the Road to Reaccreditation

- Building culture awareness of QM program in SCT.
- Staff motivations, role models and leadership
- Improve implementation QMS, maintaining number of meetings, document and data management
- Audit and adverse event are required more attention in reporting and tracking action plan.
- The process of auditing does not end with completion, reporting and action. (Plan-Do-Study-Act) cycle.

Changes after JACIE accreditation and the Road to Reaccreditation

The program was inspected on **January 2014 for reaccreditation**

- ISBT 128 software installed and implemented July 2014
- Renovation of new space processing laboratory to meet safety standards in stem cell processing completed in September 2015.

Program was re-inspected on March 2016 and granted the second accreditation by May 2016.



Riccardo Saccardi
JACIE Medical Director

Maria Vittoria Gazzola
Chair, JACIE Accreditation Committee

The Joint Accreditation Committee ISCT-EBMT (JACIE)

hereby declares that

**Clinical Stem Cell Transplantation,
King Faisal Specialist Hospital & Research Centre
Riyadh, Saudi Arabia**

has been found to meet the standards as set out in the FACT-JACIE International Standards for Cellular Therapy, edition 5 in the following area(s):

**Autologous & Allogeneic Transplantation in Adult Patients
Autologous & Allogeneic Transplantation in Paediatric Patients
Collection of HPC, Marrow
Collection of HPC, Apheresis
Cell Processing - minimally manipulated**

Programme Director: Dr. Al Seraihy, Dr. Aljurfi and Dr. Al Humaid

CERTIFICATE NUMBER:

466

DATE OF ISSUE:

20/05/2016

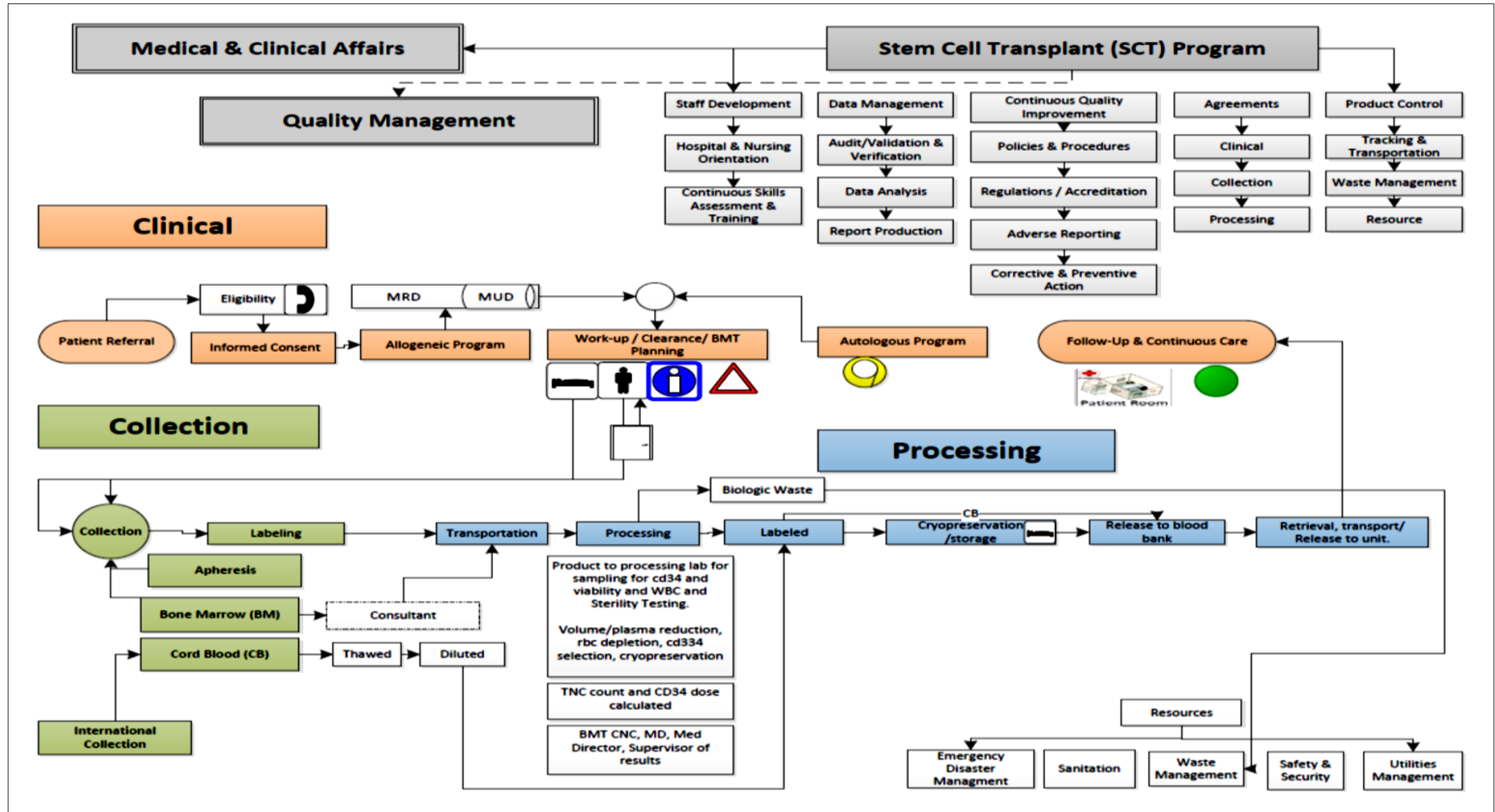
DATE OF EXPIRY:

19/05/2020



Where we are today ?

- *QM program of SCT program is still under hospital QM department but with time and productivity, the program develop more reactivity, decisional “power and autonomy and recognized as one of the top quality programs that inspected in the last few years as commented by inspectors. March 2015*

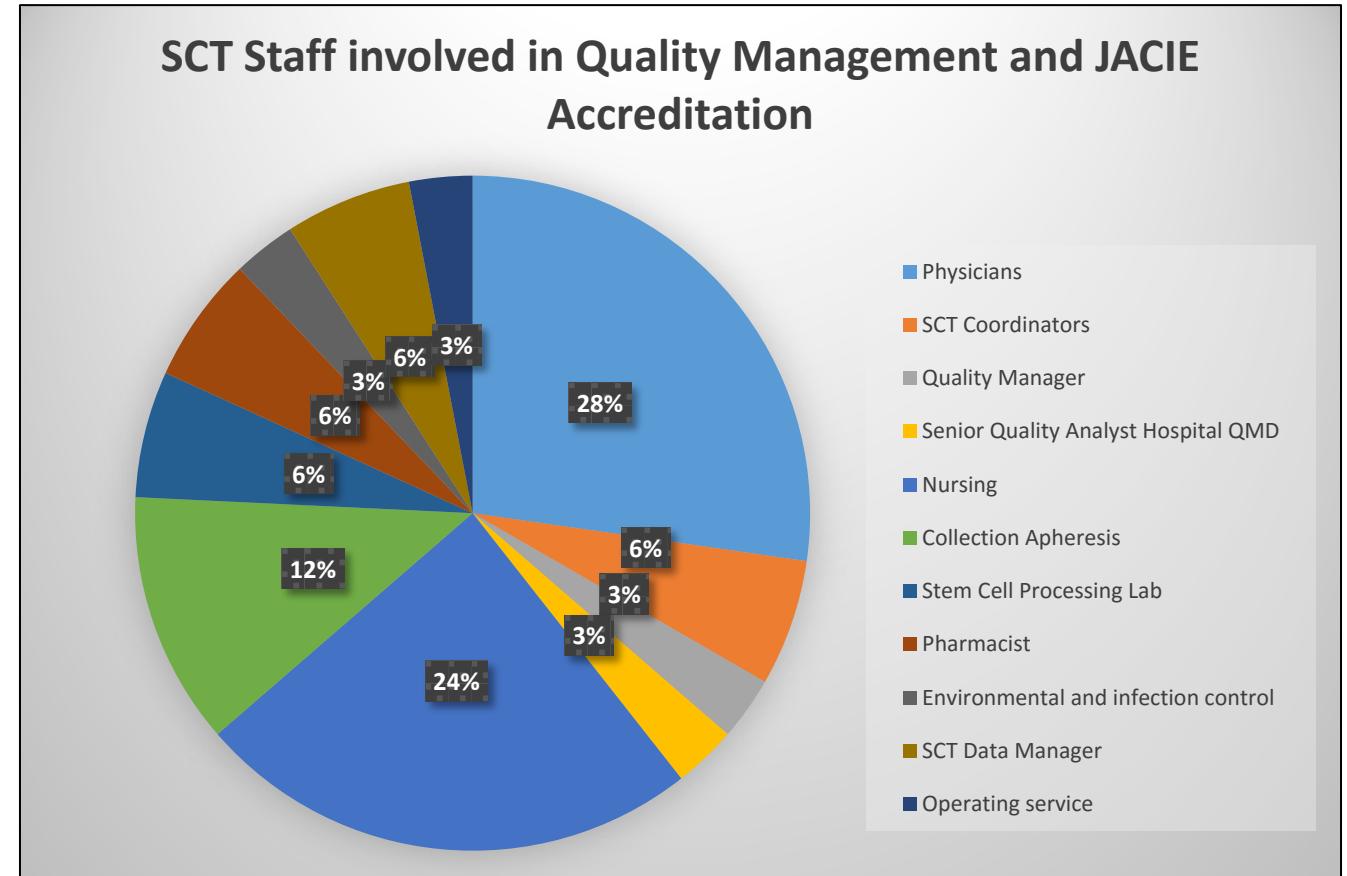


Stem Cell Transplant Program Staff and Activities

| Working committee | Pre accreditation 2008 | First JACIE Accreditation 2010 | JACIE Re-Accreditation 2015 |
|--|---------------------------|-----------------------------------|--------------------------------|
| Stem Cell Transplant Quality Management Committee | | | |
| Members | 12 | 18 | 33 |
| Number of meeting per month | 1 | 1 | 2 |
| Stem Cell Transplant Stem Cell Transplant Quality Management Clinical Nursing Sub-committee | | | |
| Members | | 12 | 19 |
| Number of meeting per month | | 1 | 1 |
| Stem Cell Transplant Collection Processing Sub-committee | | | |
| Members | | 10 | 12 |
| Number of meeting per month | | 1 | 1 |

Stem Cell Transplant Staff involved in the Quality Management and JACIE Accreditation

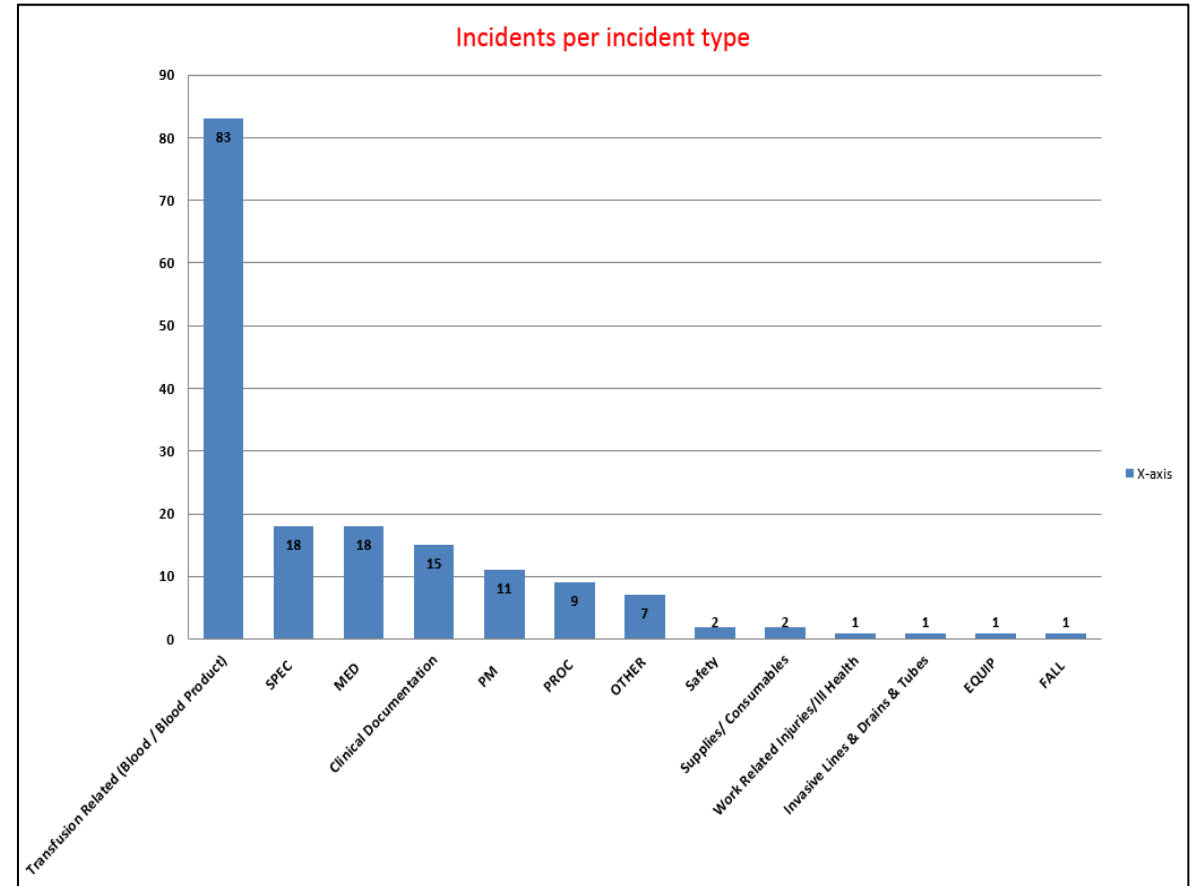
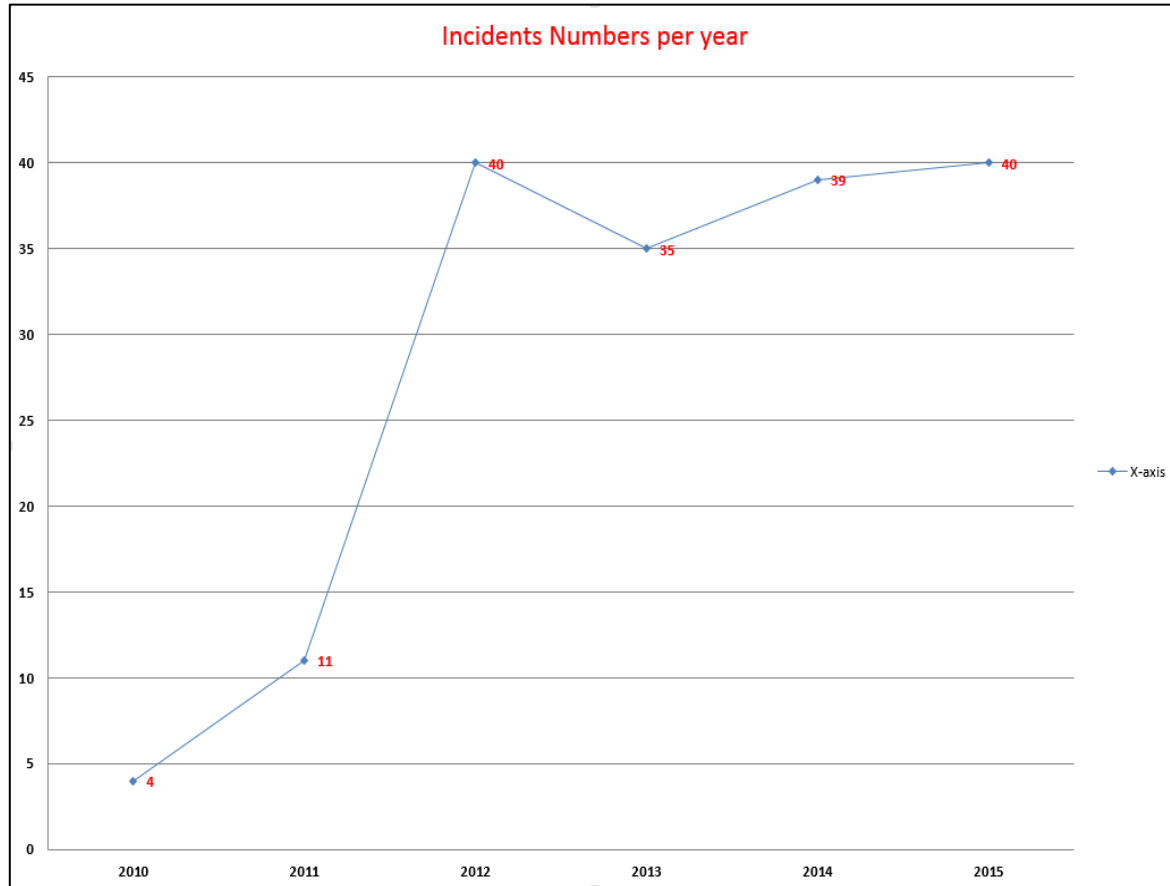
| Staff | Number |
|---|-----------|
| Physicians | 9 |
| Stem Cell Transplant Coordinators | 2 |
| Quality Manager | 1 |
| Senior Quality Analyst Hospital (Quality Management Department) | 1 |
| Nursing | 8 |
| Collection Apheresis | 4 |
| Stem Cell Processing Lab | 2 |
| Pharmacist | 2 |
| Environmental and Infection Control | 1 |
| Stem Cell Transplant Data Manager | 2 |
| Operating Service | 1 |
| Total | 33 |



Documents of SCT Quality Management System

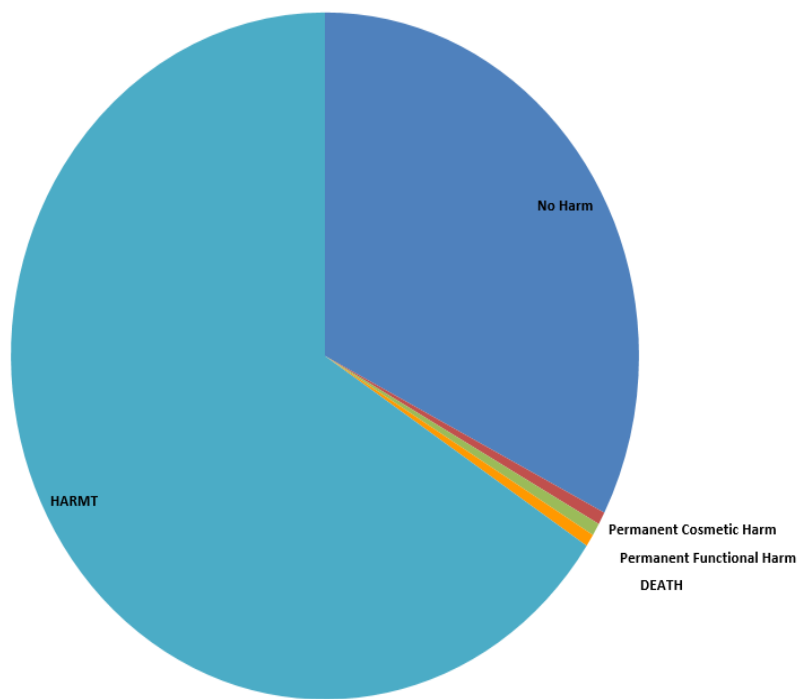
| Document | Pre accreditation 2008 | First JACIE Accreditation 2010 | JACIE Re-Accreditation 2015 | Total of 273 documents |
|----------------------|---------------------------|-----------------------------------|--------------------------------|---------------------------|
| Clinical program | | | | |
| QM plan | 0 | 1 revised every 2 yrs. | 1 | |
| SOP | 5 | 33 | 85 | |
| Forms | 2 | 5 | 15 | |
| Consents | 2 | 4 | 6 | |
| Agreement | 1 | 1 | 1 | |
| Organizational | 10 | | | |
| Collection Apheresis | | | | |
| QM plan | 0 | 1 | 1 | |
| SOP | 24 | 25 | 25 | |
| Forms | 31 | 33 | 33 | |
| Stem Cell Processing | | | | |
| QM plan | 0 | 1 | 1 | |
| SOP | 21 | 21 | 58 | |
| Forms | 10 | 43 | 43 | |

SRS Incidents 2010-2015

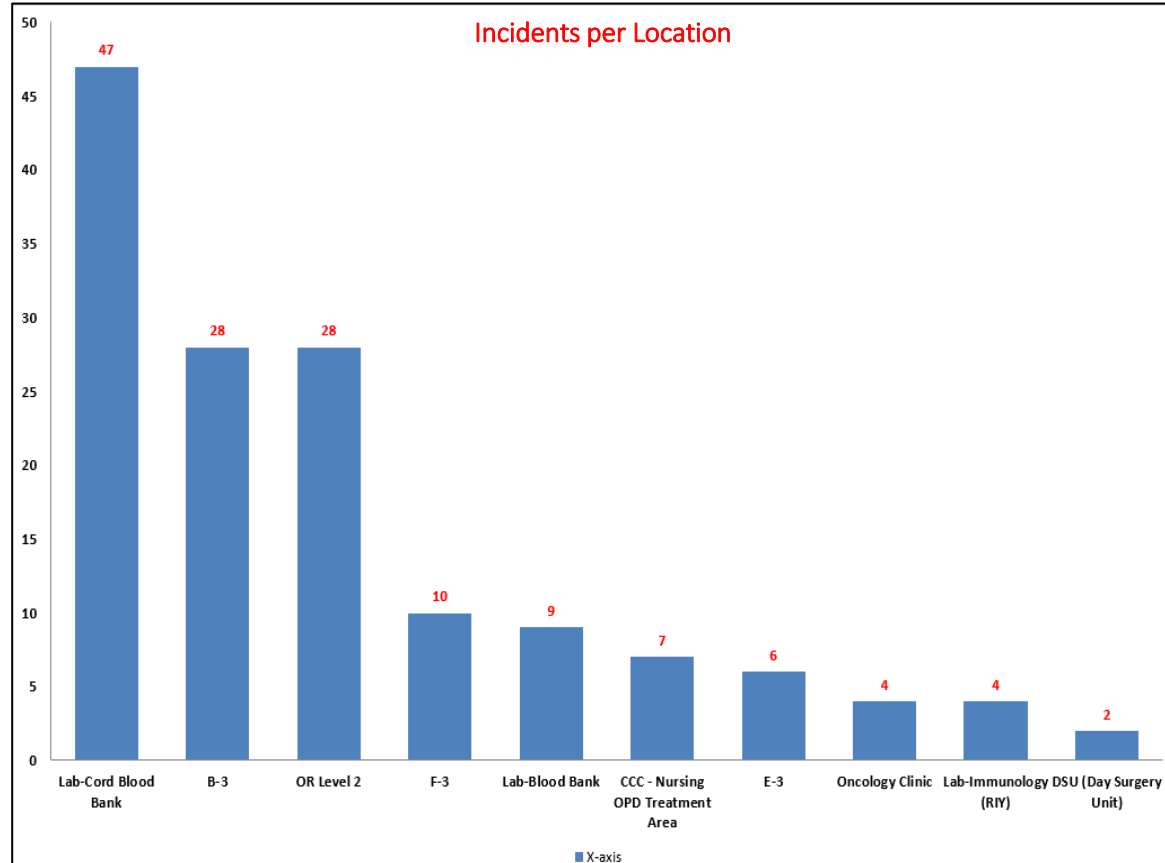


SRS Incidents

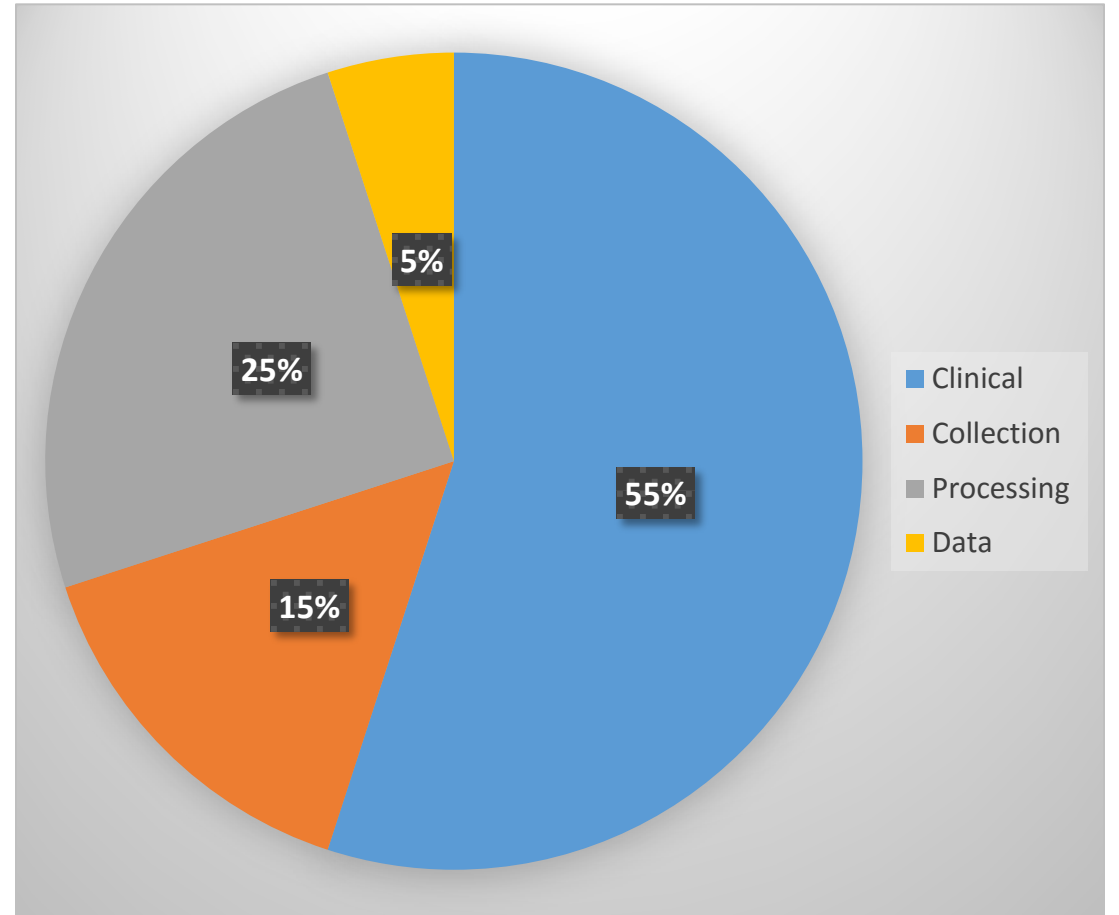
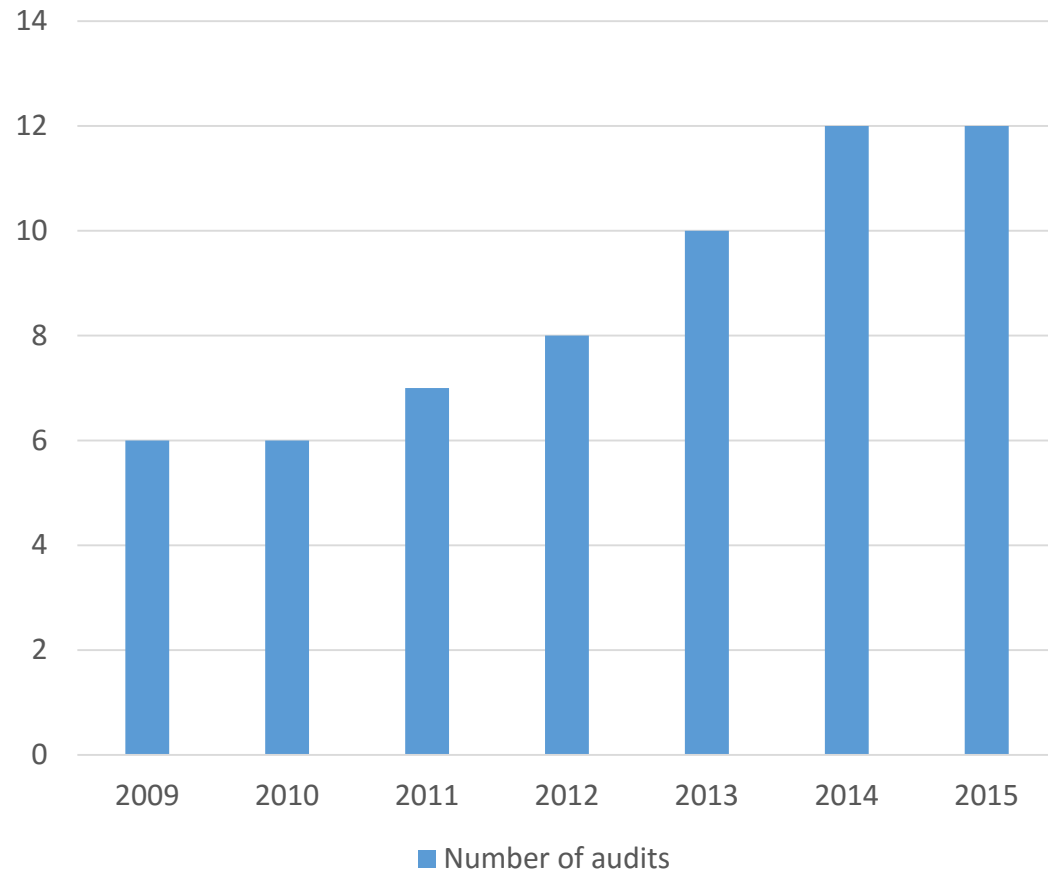
Incidents per Level of Harm



Incidents per Location



Audit Number/Service 2009-2015



Impact of JACIE Accreditation on SCT at KFSHRC

- New attitudes, culture and new thinking strategy – working, controlling the work, validation, analyzing outcome and starting corrective measure
- Demanding and it creates additional workload and documentations
- Staff education about SCT-QM
- **Reliable documentation, communication and Standardization of care**
- **Safety, Satisfaction, more efficiency and effectiveness**

Impact of JACIE Accreditation on SCT at KFSHRC

- **Outcome Analysis and Measures**

- Number microbial contamination of HPC
- 100 days morality and end of year survival for each type of SCT
- Intensive care admission within 100 days from transplants
- Hospital readmission within 100 days from transplants.
- SRS number and severity

- **Cost/Cost efficiency**

- *Does JACIE Accreditation Drive the Quality in SCT Program at KFSHRC?*