FACT-JACIE International Standards: 5th Edition

Standards

- First edition 1998
- 4th edition released 31 October 2008
- 5th edition due for release March 2012

- International standards

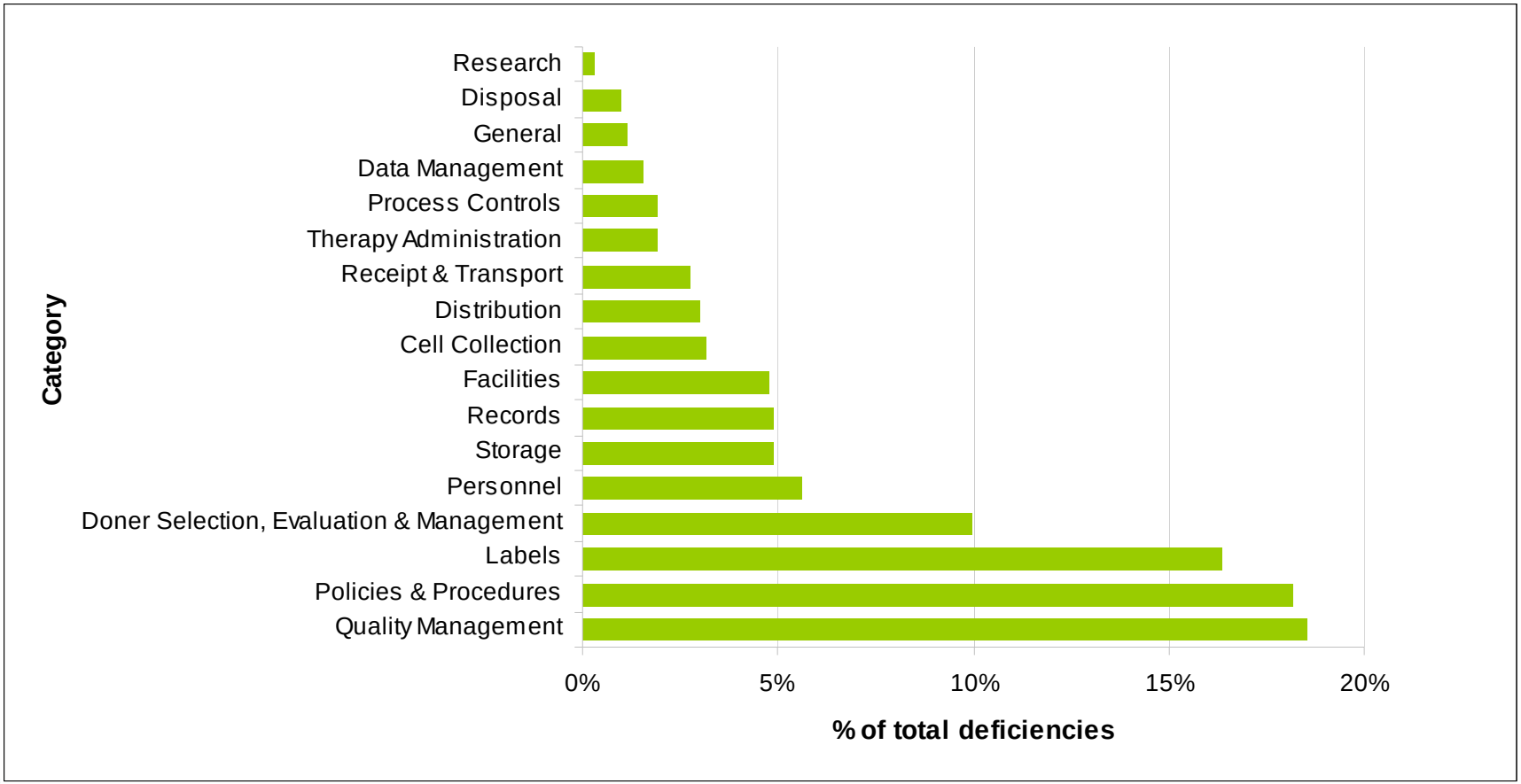
Common deficiencies

Deficiencies cited by JACIE Inspectors

- Total number of inspections 43
- Total number of citations 1267
- Average citations per inspection 29
- Breakdown by part of standards (citations / total number of standards)
  - Part B Clincal 137 / 315 (43%)
  - Part C Collection 187 / 354 (53%)
  - Part D Processing 285 / 585 (49%)

Areas of deficiencies

Expressed as % of total deficiencies. Based on analysis of 1732 deficiencies encountered in inspections



Minor v Significant Deficiencies

- Difference between a minor deficiency and a significant deficiency is a matter of judgement
- Minor deficiencies
  - generally involve correction to existing SOPs or other documentation
- Significant deficiencies - examples
  - Inpatient isolation facilities inadequate
  - No continuous temperature monitoring of freezers
  - Inadequate quality management programme

Clinical programmes deficiencies: the top six

- Donors
- Infectious disease markers not tested within 30 days of collection
- Data management
- Corrective actions
- Outpatient area
- Discharge

B6.000 Donors - Problems

- Lack of written donor information

  e.g. collection procedures and risks of G-CSF, central lines
- Missing/inconsistent donor info e.g. travel, transfusion, immunisation histories
- Lack of clear selection criteria
- No clear ‘final authorisation’
- Not relaying donor info to collection facility
- No record in patient record of donor suitability e.g. HLA, CMV, ABO

SOLUTIONS

- **Clear, comprehensive and unambiguous policies and procedures**
- **Checklists**
- **Final approval documents**

Testing for IDMs

- B6.3.2 “Within 30 d prior to collection all HPC donors shall be tested for evidence of clinically relevant infection – HIV 1/2, HBV, HCV, HTLV 1/2*, syphilis

- B6.3 states that “there shall be donor evaluation procedures to protect the recipient from the risk of disease transmission from the donor”

- Deficiencies – medical history doesn’t include the correct questions
  - specific tests e.g. syphilis omitted
  - not repeated if SCT delayed

Corrective actions

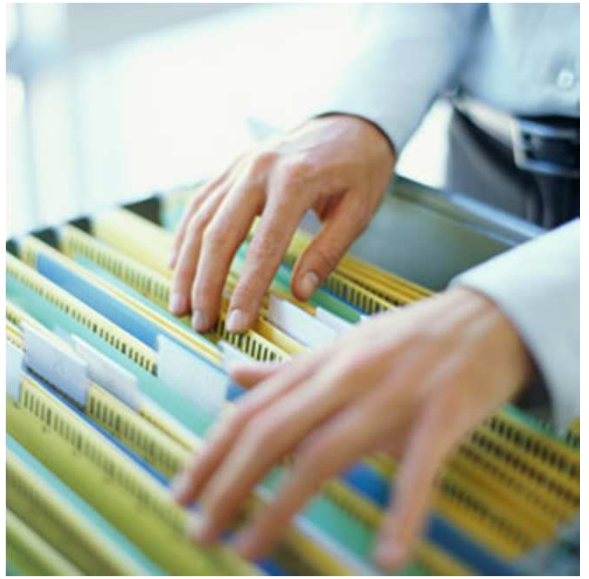
- B4.10.4 – “corrective action shall be implemented as appropriate”
- Deficiencies recorded
  - lack of audit
  - audit not regular
  - critical endpoints not defined
  - not disseminated
- Adverse events and clinical incidents not reported/recorded; absence of corrective actions

Data Management

- B9.1 and B9.2 describe the requirement to collect all TED/MED-A data and audit this regularly

- At a minimum – patient outcomes, donor screening and testing and recipient 100d mortality

- Deficits
  - incomplete or incorrect forms, lack of engraftment data
  - clinical status at SCT not well recorded
  - lack of chemo prescription, date of administration not recorded

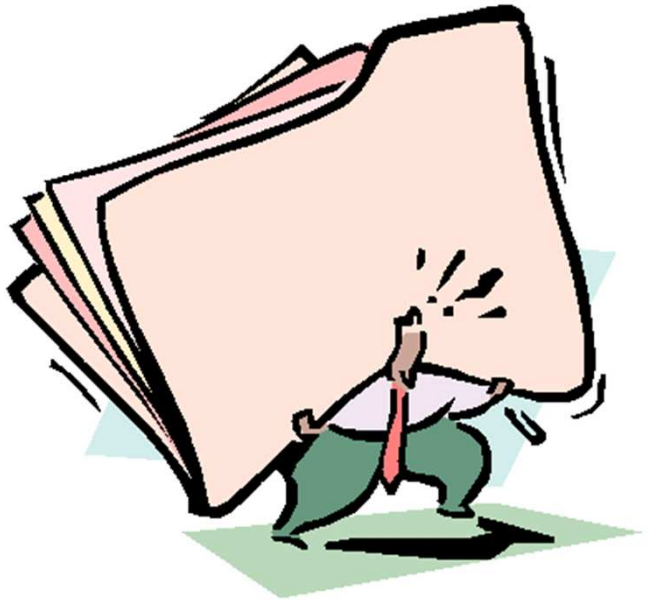


Donor Selection & Management

- No written orders for collection
- Absence of written consent
- No arrangements for assessment of (interim) donor suitability
- No formal policy / SOP for assessment of venous line placement
- Assessment of venous line placement not documented in patient/donor record

Policies and Procedures

- Document control system inadequate
- Specific policies missing e.g. storage, transportation
- Lack or approval or regular review
- Format incorrect, no range of expected results or acceptable endpoints
- No references given
- No examples of associated worksheets or forms
- No documented training to new/revised SOPs



Recent Hot Topics for JACIE

- Early discharge from the transplant centre
- Air quality
- BM harvesting
- Extra-corporeal photopheresis
- ICU Service provision

Early Discharge

- Against spirit of standards to accredit the centre performing the infusion as the “Transplant centre” without considering post-transplant care

- 4th and 5th edition
  - B2.4.5 “The Clinical Program shall ensure planned discharges are to facilities adequate for post-transplant care”

- Responsibility of the TC to ensure compliance with items such as - Isolation facilities
  - Staffing and training
  - Policies and procedures

- JACIE will require documentation of compliance and may include inspection of the hospital providing post-transplant care

Clinical Units and Air Quality

- B2.1 There shall be a designated inpatient unit that minimizes airborne microbial contamination
- B2.2 There shall be a designated area for outpatient care that reasonably protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation, and administration of intravenous fluids, medications, and/or blood products
- B2.4.1 There shall be provisions for prompt evaluation and treatment by a transplant attending physician available on a 24-hour basis

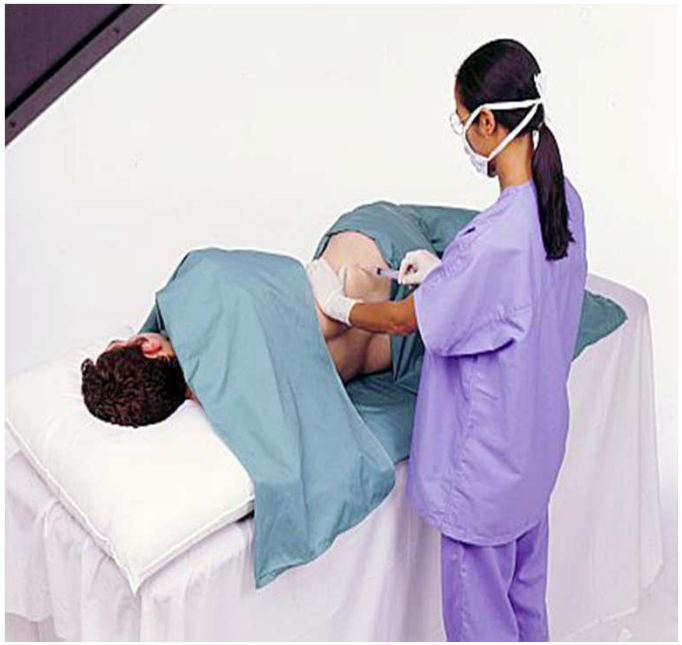
4th Edition - Minimising Airborne Contamination

Standards recognise:

- Variation in unit facilities – number, case mix, prevalence of opportunistic infections
- Increased use of ambulatory approaches with frequent day case review
- Do not imply that all units must have LAF
- Important to provide data on effectiveness of approaches used

Bone Marrow Harvesting

- Minimum is 1 in 12 months before initial accreditation and 1 per yr of each re-accreditation cycle
- Full Part C checklist e.g. Licensed physicians, good facilities
- Incorporate into QM e.g.SOPs
- Staff competency and experience
- If numbers too small Part C checklist not required



4th Edition - Admission to Intensive Care

- B2.2.1The inpatient program shall have an intensive care unit or equivalent coverage available
- An ICU on the same site represents the optimal standard of care
- Centres with on-site access should have a contingency for when the on-site unit is full or unavailable
- Access to ICU in terms of response time and time-in-transit should be very carefully monitored and documentation of this should be available at inspection

Intensive Care Unit Access

- B2.1.1.1 There shall be written criteria for transfer of patients to an ICU or equivalent coverage

- A concise description of access to ICU is now requested among the pre-inspection documentation e.g. SOPs describing the process for accessing ICU services

- Inspectors will meet with ITU staff and visit the facility