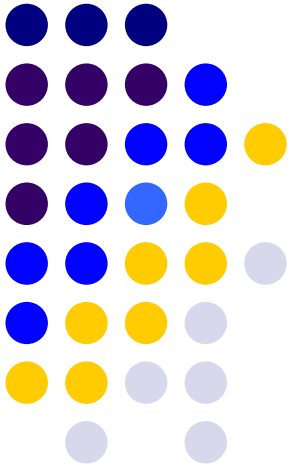
JACIE

16 October 2007

JACIE Kursu



Turkish Society of Hematology

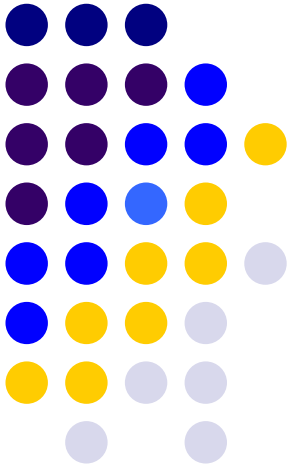
JACIE joint accreditation committee isct-ebmt

09.00 – 09.15	Welcome and goals of the day *Osman İlhan*
09.15 – 09.45	Current Status of Accreditation in Europe *Eoin McGrath*
09.45 – 10.15	Current and future regulatory environment for transplant teams *Evren Özdemir*
10.15 – 10.30	*Break*
10.30 – 11.00	Resources available to assist centres in preparation *Eoin McGrath*
11.00 – 12.30	Working Groups – Topic: What are the main challenges to establishing a Quality Management System in our units?
	Processing
	Clinical + Collection (incl. Nurses)
	Quality Manager + Data Manager
12.30 – 14.00	*Lunch*
14.00 – 14.45	Common deficiencies found in JACIE inspections.
14.45 – 15.45	Experience of an accredited centre *Nina Som, Bristol, UK*
15.45 – 16.00	*Break*
16.00 – 16.30	Presentations by working groups + discussion
16.15 – 16.30	Summary

Current status of accreditation in EU

Eoin McGrath

JACIE Office, Barcelona



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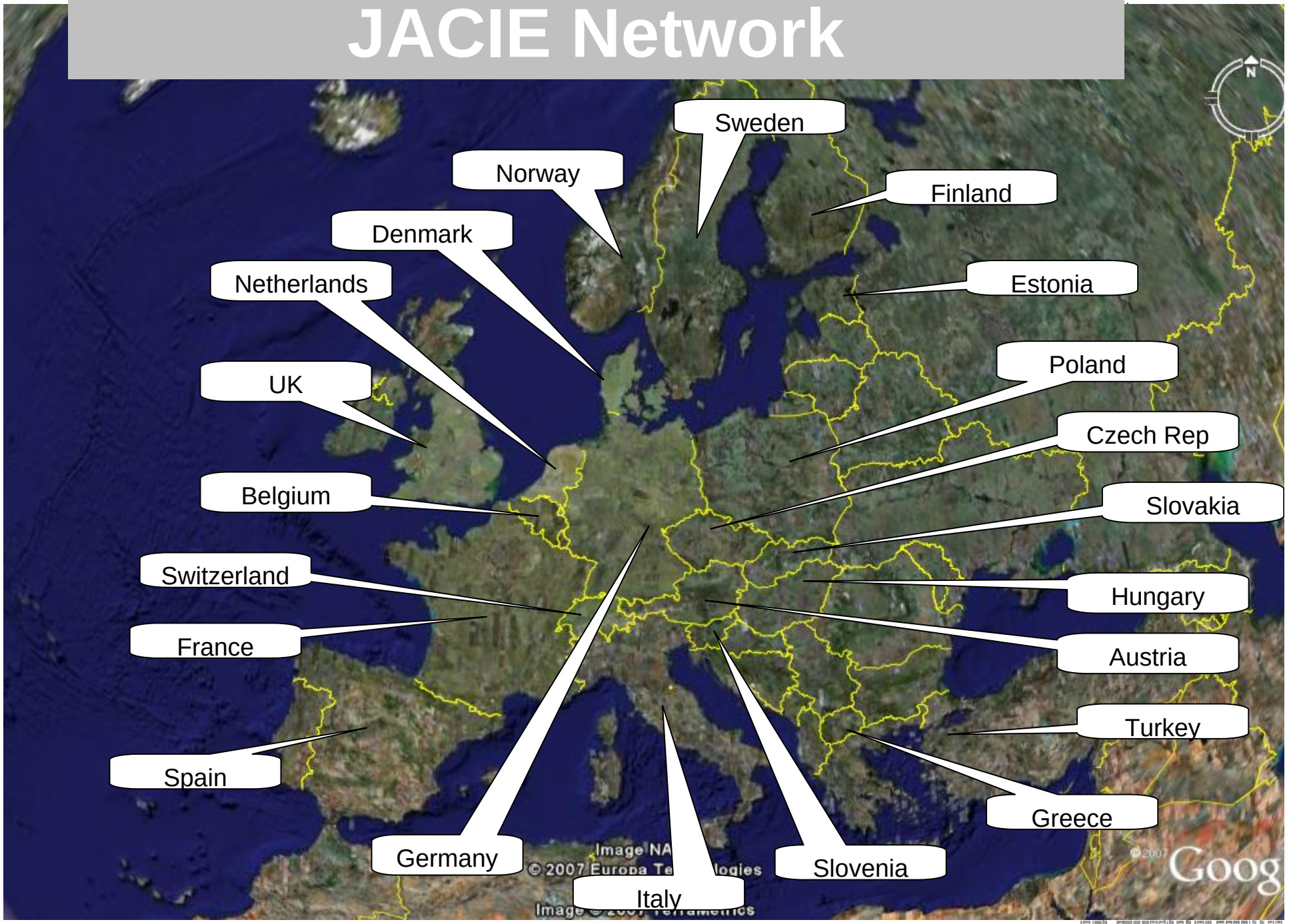
JACIE Network

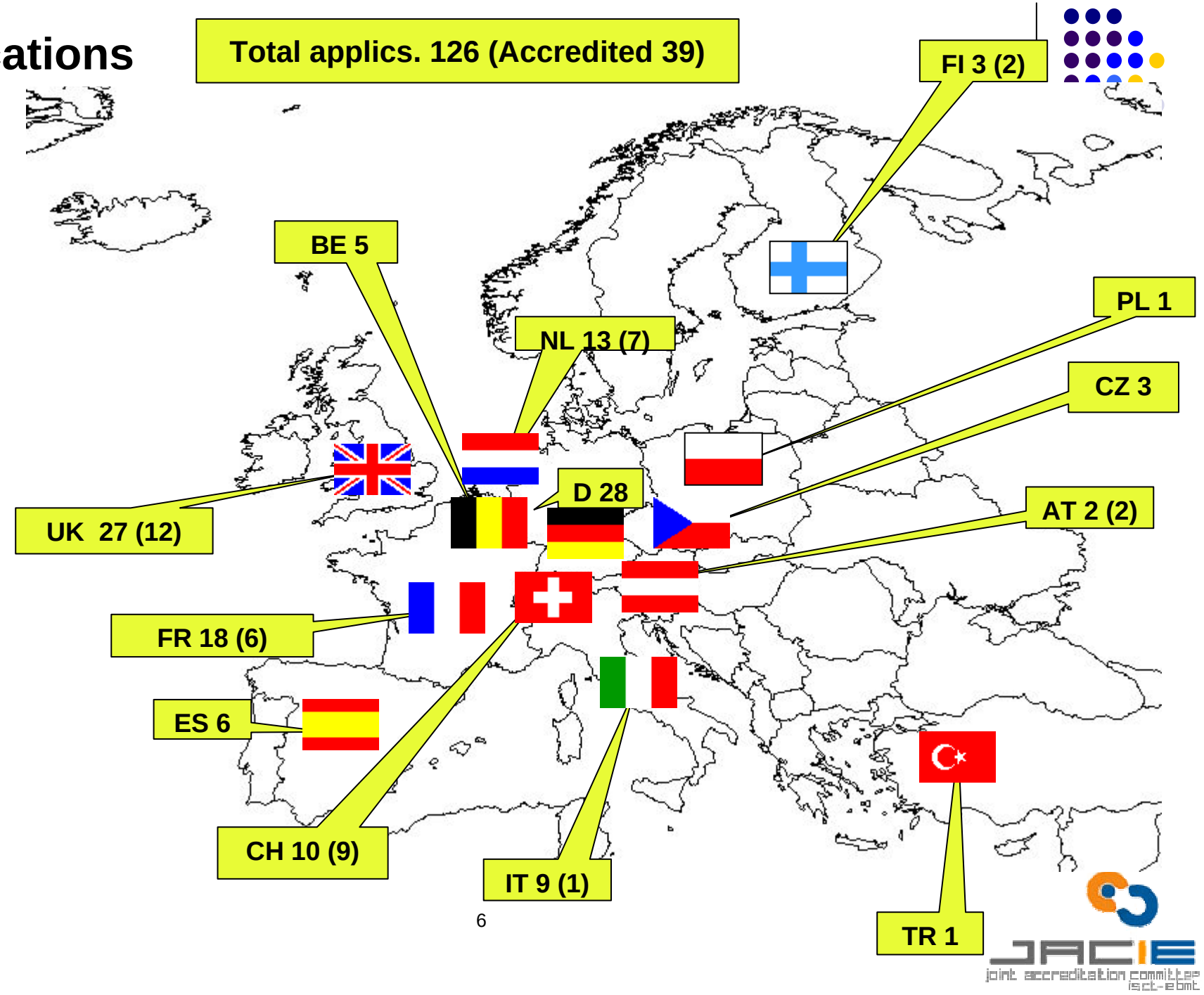


Inspections since 2003

- Centres registered: 126
- Centres in progress: 48
- Centres inspected: 78
  - Facilities accredited: 39
  - Post-inspection, not accredited 37
  - Accreditation expired 2 *(Spanish pilot programme)*
- Countries: 13

- 9 audits scheduled up to end 2007.

Applications



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Structure

21 Countries: Austria; Belgium; Czech Republic; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Italy; The Netherlands; Norway; Poland; Switzerland; Slovakia; Slovenia; Spain; Sweden; Turkey; United Kingdom; Sectoral representatives for Cord Blood, Nursing & Paediatrics

President: Ineke Slaper-Cortenbach (ISCT)
Vice-President: Jane Apperley (EBMT)
Medical Director: Diana Samson, Accreditation chair: Derwood Pamphilon

EBMT - ISCT

JACIE Office

Accreditation Committee

Eoin James MacHale

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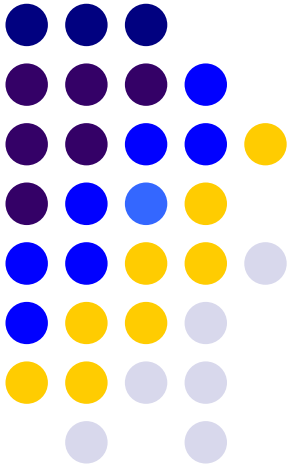
International status



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Contacts

- Contacts with
  - EU
  - WHO
  - EUSTITE project
  - Council of Europe
  - National health authorities
  - Other accrediting bodies

Regulatory context -EU

- Directive 2004/23/EC Effective 7 April 2006
  - quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Directive 2006/17/EC Effective Nov 2006
  - donation, procurement and testing of human tissues and cells
- Directive 2006/86/EC Effective Sept 2007
  - traceability requirements
  - serious adverse reactions and events
  - coding, processing, preservation, storage and distribution of human tissues and cells
- Directives in progress
  - Import/export
  - Coding Effective Sept 2008

International status

Spain

The Spanish National Transplant Organisation (ONT) is the Competent Authority.

Agreement signed 30 Oct 2006 between ONT, Spanish scientific societies and JACIE officially supporting voluntary accreditation for HSC centres

International status

The Netherlands

Dutch Health Care Inspectorate (IGZ) underlines the importance of JACIE accreditation as a tool to show compliance with the EU directive for tissue banks.

Agreement with CCKL (national lab accreditation body) to manage JACIE inspections.

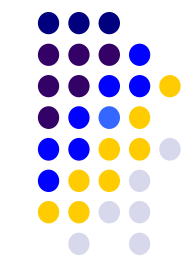
October 25th 2006: Min of Health issues document on ‘Arrangement of Stem Cell Transplantation’. Establishes rules to licence centers to perform stem cell transplantation.
- Includes condition that centers must have JACIE accreditation within 2 years from now.

International status

Italy

The Centro Nazionale Trapianti (CNT) considering assigning JACIE inspectors, via Italian Bone Marrow Transplant Group (GITMO), to perform inspections of HSC transplant programs and investigate that any additional EU directive requirements are checked during the inspections.

International status



France

The French Health Authority (HAS) recognises JACIE as an exemplary and innovative process.

HAS policy is to recognise different evaluation systems in order to benefit from complementary aspects and avoid duplication and includes JACIE within this policy.
ANAES Accreditation Manual For Healthcare Organisations, Sept 2004

International status

United Kingdom

Human Tissue Authority (HTA) propose to use JACIE inspectors as advisors when visiting SCT facilities and two have now been trained as HTA Specialist Assessors.

JACIE accredited centres have been classified as low-risk by HTA.

NHS service commissioners are considering JACIE accreditation as a quality standard for provision of HSCT services to the NHS.

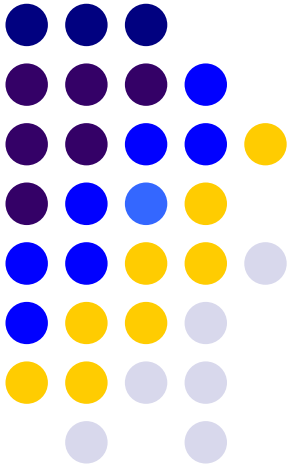
International status

Austria
The Austrian Health Institute (ÖBIG) provided financial support to centres preparing for JACIE accreditation

Belgium
Health authorities have asked that JACIE inspectors act as advisors on implementation of Directive and Belgian regulations will take JACIE Standards as a base

Poland
Ministry of Health plans to support accreditation expenses within the scope of the POLGRAFT program

JACIE developments



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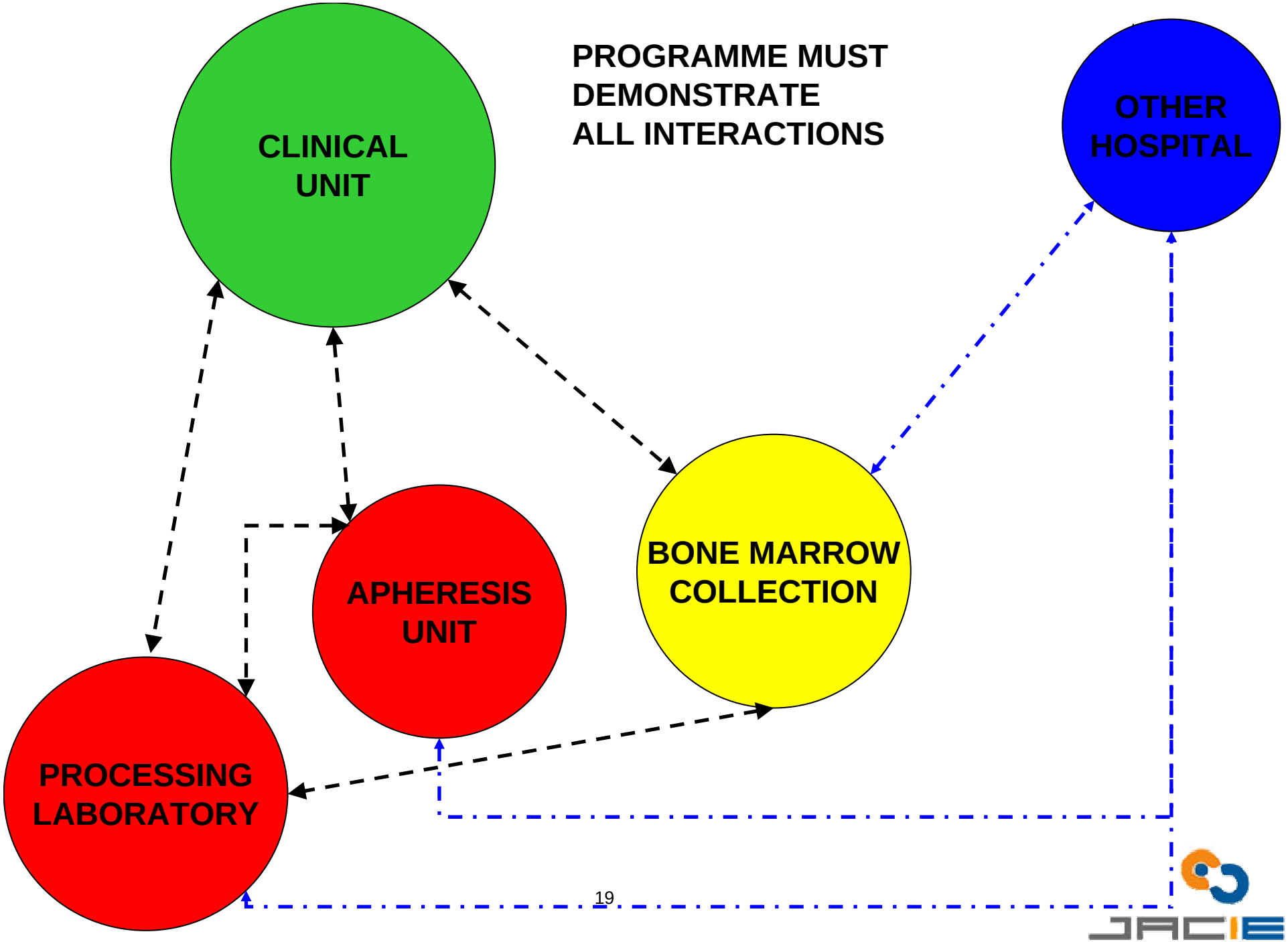
Standards

- Designed to cover all phases/tasks in transplantation from donor to infusion
- **Interaction** between clinical unit, cell collection facility and laboratory fundamental



Standards: 3rd edition

- In effect since 19th August
- First inspection using 3rd edition took place in UK, September
- Manual:
  - FACT Office coordinating drafting and release
  - JACIE contribution
  - Provisional date November 9 for release

Major changes

1. **Restructure of Document**
   Three sections compared and aligned to be parallel and consistent throughout.
2. **International Language and Content**
   "FACT-JACIE International Standards…"
3. **Regulatory requirements (FDA and EU Directive) included**
   Includes labeling requirements – 2 tables as appendices
4. **Redefined numbers requirements**
   B1.5 for clinical programs
   C1.3, C1.4, C1.5 for collection facilities (12 months, 30 aphereses/3 years; 3 marrows/3 years)
   D1.3 for Processing facilities (12 months)
5. **Expanded Quality Management section (B4; C4; D4)**
6. **Collection:**
   Added Pediatric competencies
   Duplicated Donor Selection, Evaluation and Management
7. **Processing Facility**
   GTP issues, primarily of donor eligibility, documentation, and labeling

Inspectors

- 141 certified inspectors in total
- 18 countries
- All inspectors required to have attended training course and submitted CV, qualifications, exam and registration
- Half-day refresher course planned for Florence EBMT meeting

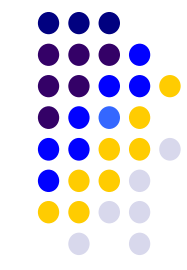
ahcta | alliance for harmonisation of cellular therapy accreditation

The Alliance for Harmonisation of Cellular Therapy Accreditation (AHCTA) is formed by representatives of the following organisations:

- American Association of Blood Banks (AABB)
- American Society for Blood & Marrow Transplantation (ASBMT)
- European Group for Blood & Marrow Transplantation (EBMT)
- Foundation for the Accreditation of Cellular Therapy (FACT)
- International NETCORD Foundation
- International Society for Cellular Therapy (Europe) (ISCT)
- Joint Accreditation Committee ISCT-EBMT (JACIE)
- World Marrow Donor Association (WMDA)

ahcta | alliance for harmonisation of cellular therapy accreditation

Mission statement



- harmonisation of respective standards
- single set of quality, safety and professional requirements for cellular therapy including haematopoietic stem cell (HSC) transplantation.
- all aspects of the process from donor recruitment to transplantation and clinical outcome.
- Supported by
  - complementary standards and guidelines,
  - promotion of the concept of a global set of standards
- inform and support authorities in the area of cellular therapy regulation

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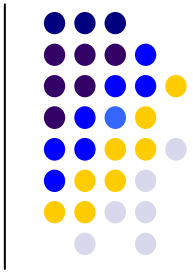

- Import/export discussion document
  - Min guidelines to support TC Directive
  - Input on cord blood from NetCord
- Crosswalk of respective standards to highlight areas of discrepency

- Any questions?

Resources Available to Assist Centers in Preparation

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Tools & assistance

- Standards
- Manual
- Inspection Guide
- JACIE Office
- JACIE Online
- Medical Director
- Other inspectors
- Online documentation

Documents on web site

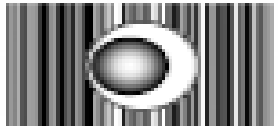
- Inspection Checklist
- 3rd ed FACT-JACIE Standards
- Significant Changes
- Online Guide
- Accreditation deficiencies v2.0
- Accreditation process
- Pre-inspection Document Checklist
- Inspection guide 2.5
- JACIE CV template
- Potential Inspection Outcomes July 2006
- JACIE information leaflet

International Cellular Therapy Coding and Labelling Advisory Group

- Review existing regulation regarding labeling
- Design product label templates that satisfy regulatory requirements;
- Provide a focus for the standardization of terminology and product naming;
- Promote the adoption of the ISBT 128 standard in cellular therapy facilities around the world;
- Provide advice and support to facilities introducing the standard;
- Advise on the ongoing development of the ISBT 128 standard to support new developments in cellular therapy.


fact
Foundation for the Accreditation of Cellular Therapy


ICCBBA

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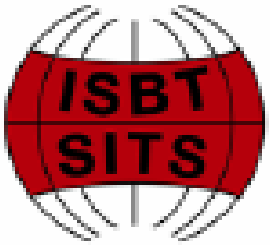
International Society for Cellular Therapy
ISCT


ASBMT
American Society for Blood and Marrow Transplantation


ISBT
SITS


EBMT


NATIONAL MARROW DONOR PROGRAM


AABB
Advancing Transfusion and Cellular Therapies Worldwide

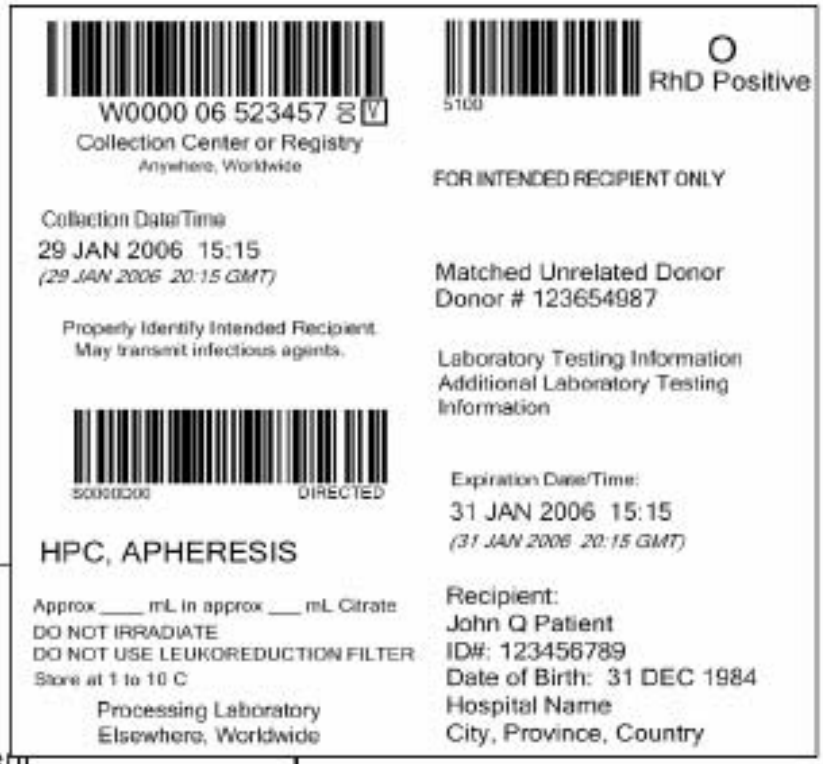

ISCT
EUROPE

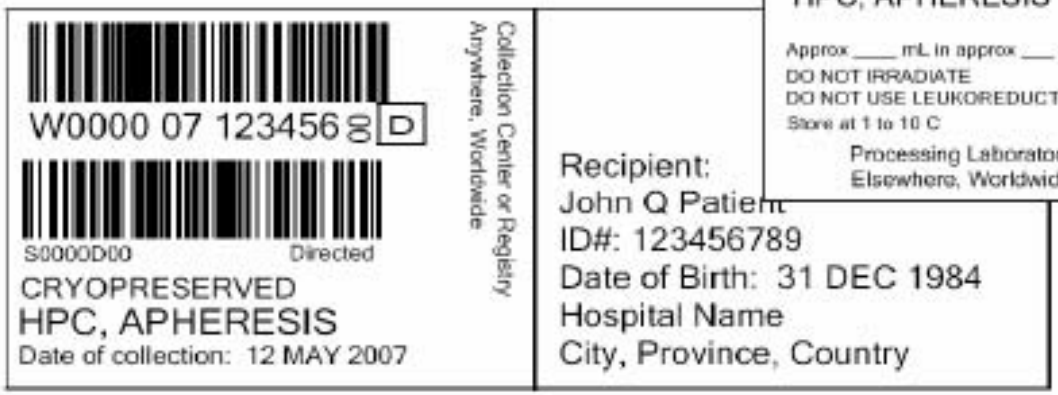

ASFA
American Society for Apheresis


WMDA

International Cellular Therapy Coding and Labelling Advisory Group

- Final release of terminology and label design at ISCT meeting, June 2007
- http://iccbba.org/cellulartherapy_educationalmaterial.html
- Contribute to the work of the CEN (European Committee for Standardization): CEN/ISSS Workshop on Coding of Information and Traceability of human Tissues and Cells (WS/Tissues & Cells)





ISBT 128
More than Identification

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

ISBT 128
More than Identification

CEN/ISSS Workshop on Coding of Information and Traceability of human Tissues and Cells (WS/Tissues & Cells)

- "…..propose guidelines and recommendations to permit the implementation of the European Coding System respecting the Tissue and Cells Directive's requirements."

http://www.cen.eu/nr/cen/doc/PDF/575060.pdf

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CEN/ISSS Workshop on Coding of Information and Traceability of human Tissues and Cells (WS/Tissues & Cells)

- 11 months duration
- Expect to complete work in mid-March 2008
- Recommendation to the EU Commission
  - Commission decides on adoption
  - In place by September 2008

Quality Management Guide

- ‘Practical reference guide to implementing quality management in a stem cell transplantation (SCT) programme in accordance with JACIE Standards’

- Phase 1: To write and publish a guide to implementing quality systems in stem cell transplant programmes in line with the JACIE Standards on quality management
- Phase 2: To update the guide on a regular basis based on continued accrual of experience and best practice

- The project to be fully funded by an unrestricted educational grant from Chugai Sanofi Aventis.

Quality Management Guide

- To help applicants move from the ‘blank page’ when they start preparing
- To distribute experience and best practice
- To train inspectors
- Release early 2008
- Copies sent to EBMT member centres and ISCT Europe members

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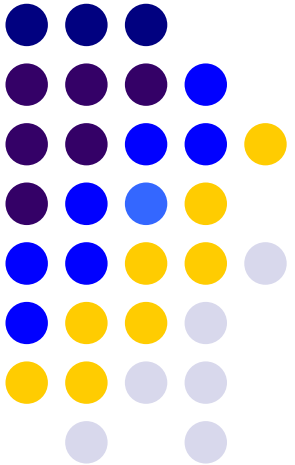
Deficiencies data



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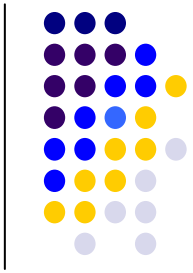
Deficiencies library



- Currently 570 items from 35 reports
- Very useful for applicant centres, inspectors
- Helps JACIE maintain consistency in recommendations
- Public anonymous version will be on web site.

Deficiency library Excel file

B	C	E	G	H	J
MainSection	Edition2	Markers D / I / S	Inspectors Comment	Med Dir Comment	General classification
B03000	3421	D	•The Programme has used CPD and programme participation as evidence of competency for attending physicians. There is no clear indication of how competency is judged. A number of the activities listed in this standard are generic to haemato-oncology, but others are more specific to allogeneic BMT. A checklist for attending paediatricians was not available. Dr McVerry indicated he was not competent in all areas but this may be clinically appropriate as he only attends SCT patients on an on call basis. •Assessment of competencies for trainees is ongoing during their training period. We did not see detailed records of participation in educational activities related to the field of haematopoietic stem cell transplantation.	–there was no clear indication of how competency is judged (see General Comments). There are training portfolios for junior staff but it is not clear whether these include a record of competency for the tasks that junior staff regularly perform in relation to the BMT programme, e.g. marrow harvests. The centre should clarify this with JO.	Training
B03000	3422	D	All physician in program have clinical training and competency regarding items of paragraph B 3.422 but some of them ask for education to improve their competency in some fields (e.g. management of ABO incompatible haematopoietic progenitor cells components, methodology of HLA typing, identification and selection of haematopoietic progenitor cell source...)	There should be a regular programme of continuing education covering areas such as management of ABO incompatible haematopoietic progenitor cells components, methodology of HLA typing, identification and selection of haematopoietic progenitor cell source.	Training
B03000	3432	I	The answer given by the team is NO. Bone marrow harvest is becoming increasingly less frequent and is replaced by peripheral blood progenitor cells harvest. Nevertheless, the auditors had proof that the team has enough trained physicians to perform bone marrow harvest when requested. Transplant physicians in the clinical program are proficient in HPC infusions	Not all the transplant physicians are proficient in bone marrow harvest. However the team had sufficient trained staff to carry out marrow harvests when requested. In fact the standards (section 3.4) state that the transplant physicians should be knowledgeable in bone marrow harvest, it does not specify they need to be proficient.	Staffing
B03000	3600	D	Not all physicians provided evidence of certification and subspeciality training.	documentation of higher specialist accreditation and certification was not always available. Documentation should be provided to JO; copies of GMC registry entries will suffice.	Training
B03000	3600	D	No access to clinical psychology.	There should be access to clinical psychology. Presumably this can be accessed through psychiatric referral. The applicant should clarify this.	Staffing
B03000	3610	D	Based on the PDF files received via JACIE website the liaison consultants for Infectious Disease and Psychiatry were "not in the specialist register". It is unclear who produced this PDF file – I suspect this may be an administrative error; the Consultant staff at the Hammersmith have a high academic reputation.	The inspector noted that the consultant senior physicians for infectious disease and psychiatry were not found in the specialist register. Evidence of their correct registration as consultants should be submitted for review.	Staffing
B03000	3710	D	Nurses and nurse supervisors in the program have		Training

- Experience generally same as FACT in US
- Listing of deficencies
  - On web site shortly

EBMT Annual Meeting, 2008

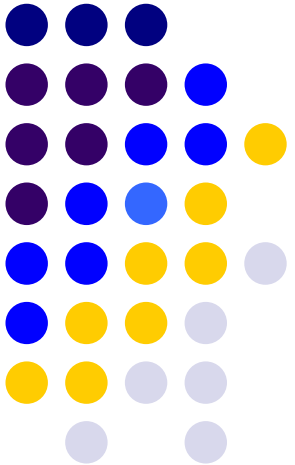
Florence • Italy • March 30 – April 2, 2008

1. JACIE Session: Monday 12.30-13.30 (to be confirmed)

2. JACIE & Nursing: time and day to be advised

3. Quality management workshop : Monday (to be confirmed)

Work groups



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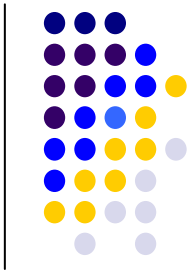
WORKING GROUPS



- Processing
- Clinical + Collection (incl. Nurses)
- Quality Manager + Data Manager

- “Challenges in establishing a quality system in my facility”

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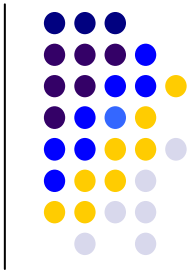
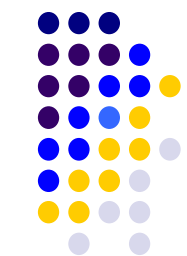
Discuss in groups



"Challenges in establishing a quality system in my facility"

- What is objective?
- Who should be involved?
- What resources and support do we need?
- What methodology will we use?
- What/who are potential **threats** to success?

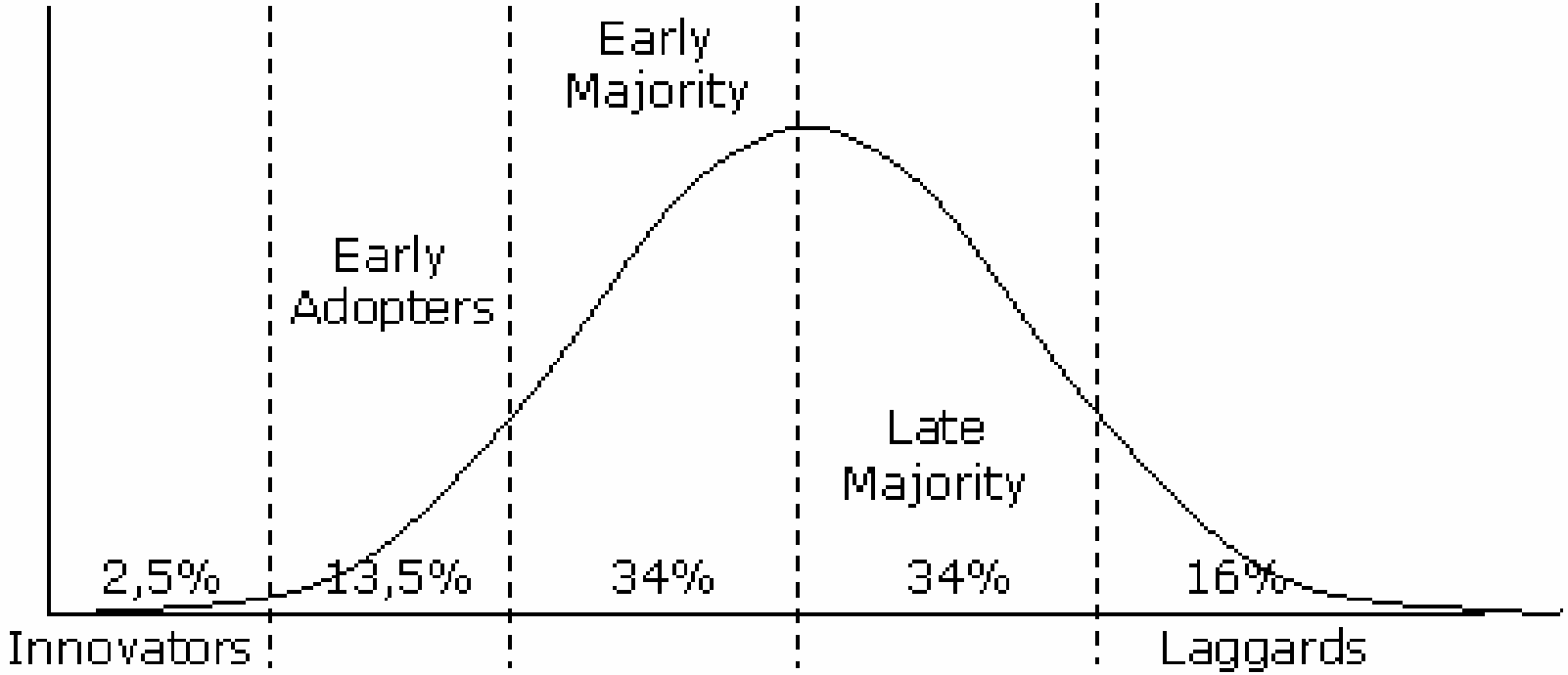
Rogers adoption/innovation curve



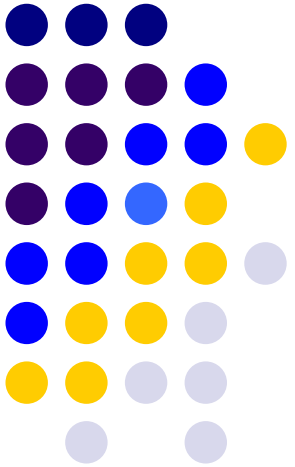
- Rogers achieved academic fame for his Diffusion of innovations theory
- He proposed that adopters of any new innovation or idea could be categorized as innovators, early adopters, early majority, late majority and laggards

www.valuebasedmanagement.net

Rogers Adoption / Innovation Curve



Common deficiencies found in JACIE inspections



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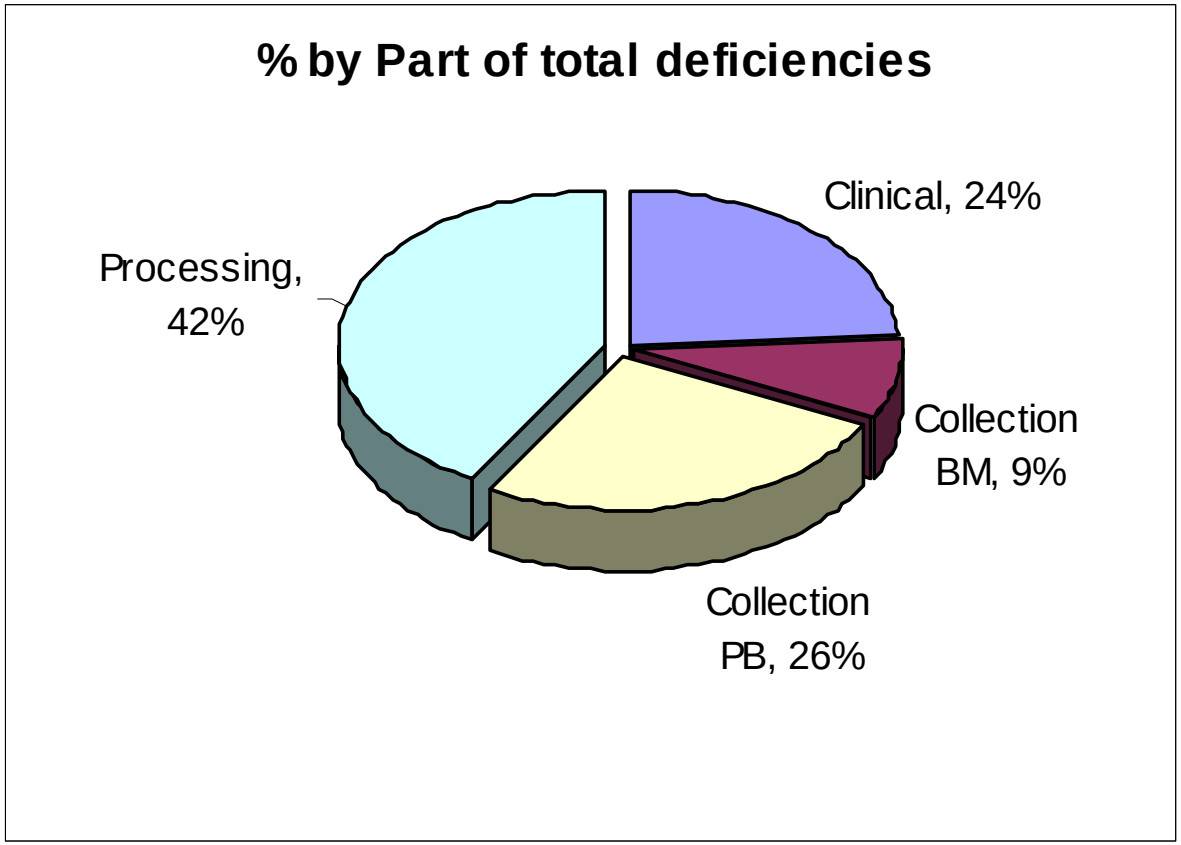
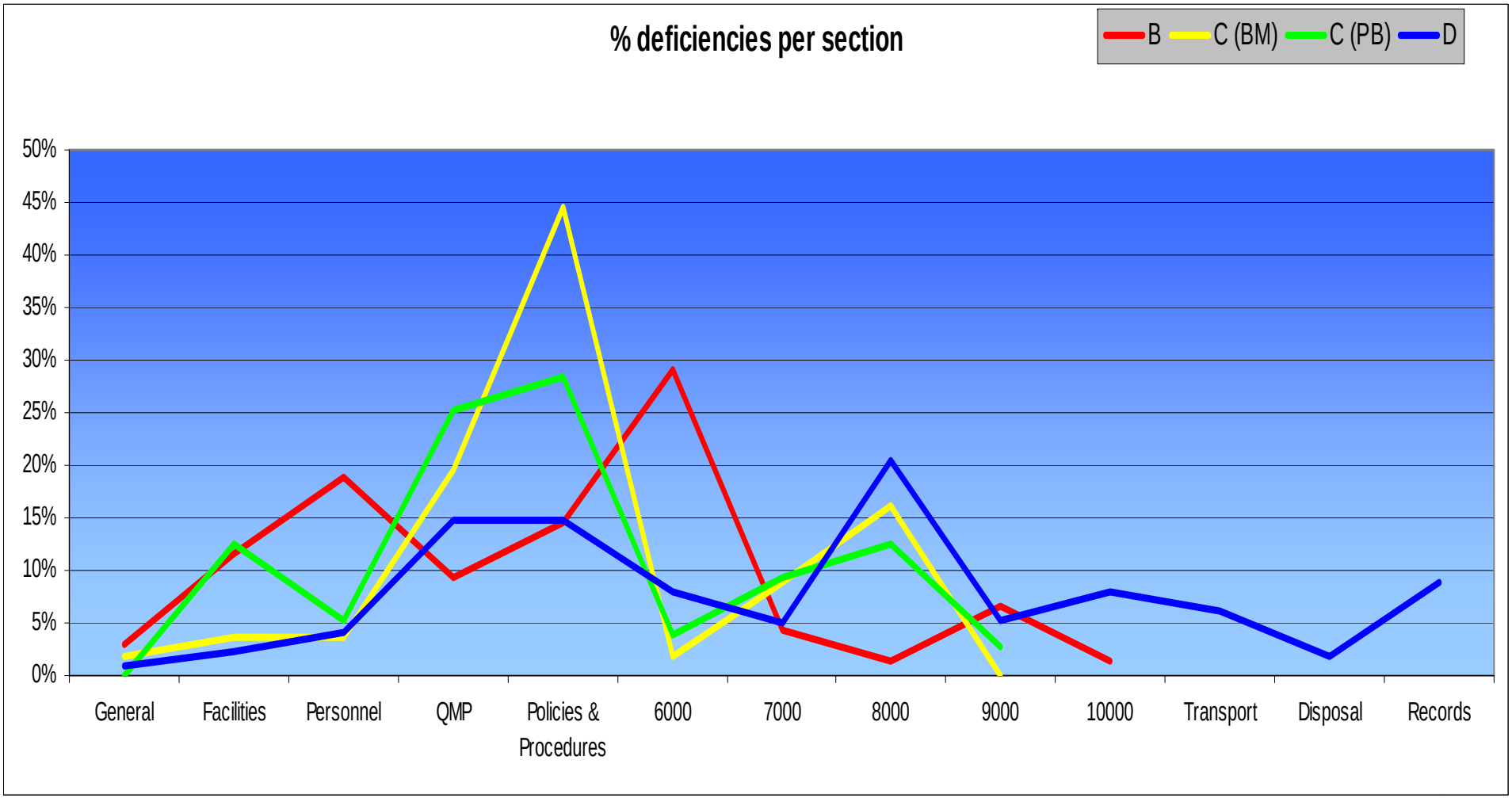
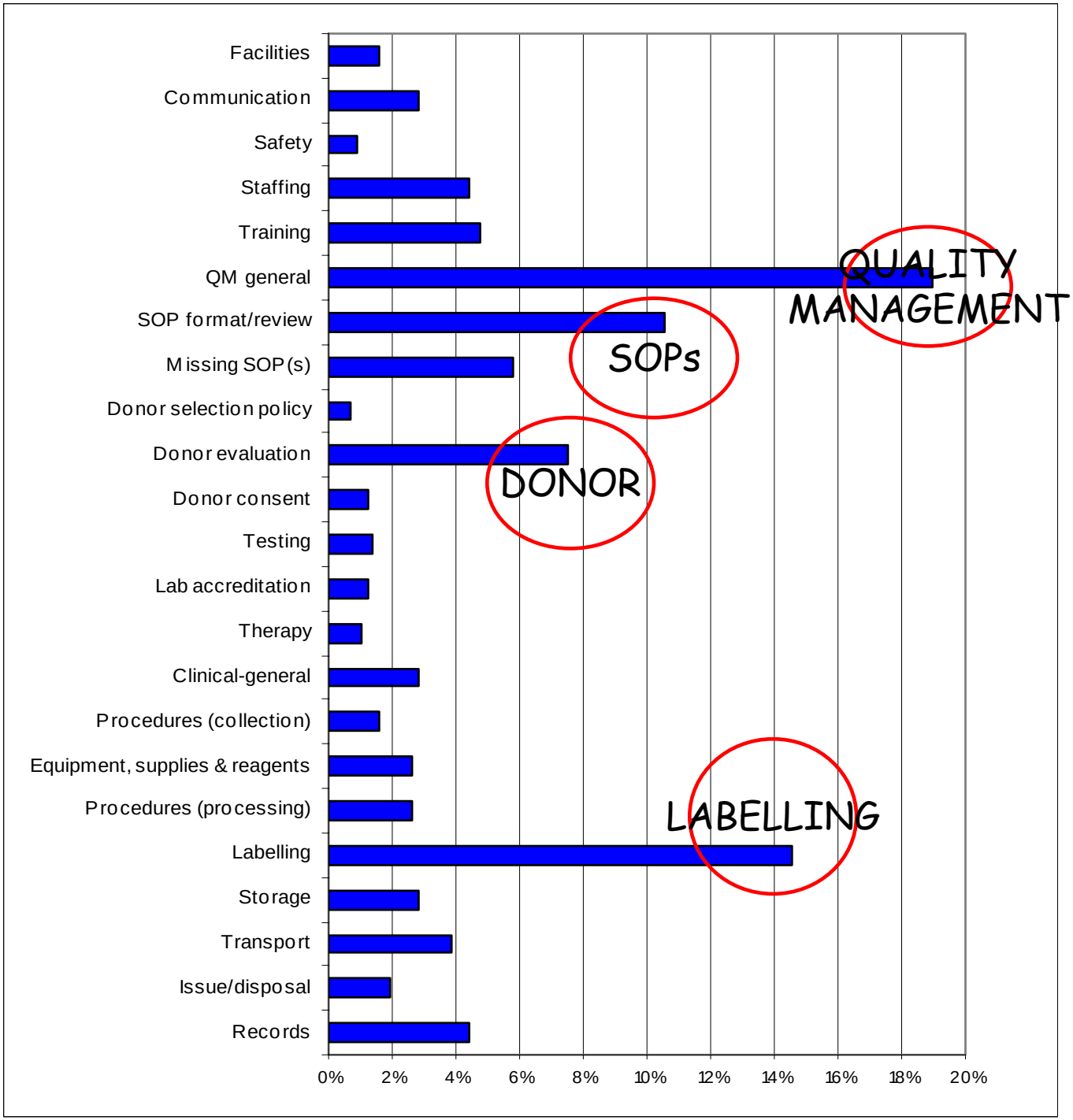
Breakdown of deficiencies by section



% of deficiencies per section of standards





Categories of deficiencies as % of total deficiences across all parts of standards

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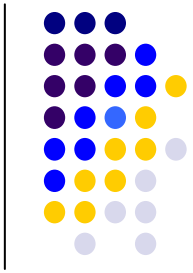
Minor vs Significant Deficiencies

- 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 Programme



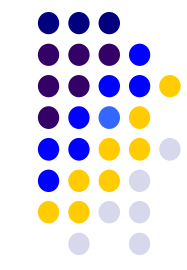
- Single Clinical Programmes
- Consultants/Attending Physicians
- Adverse Event Reporting
- Audits & Outcome Reviews
- Donor Evaluation, Selection and Care
- Therapy Administration

Single Clinical Programmes

B1 “
…integrated medical team…
single PD..common staff training programmes, protocols & QMS”

- Lack of integration
- Poor interaction between staff in the 2 units
- Little sharing of expertise
- QMP’s essentially separate
- Who is the designated person for QM?

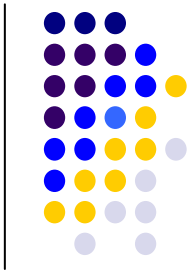
Senior Clinical Staff



- **B3.1..”dedicated BMT team including PD + 1 physician trained or experienced in HPC therapy for 1 year”**
- **Also adult and paeds expertise as appropriate**
- **BMH proficiency**

- Not all 1 year experience
- Not correct speciality
- CV’s - documentation of appropriate training
- Are they competent?
- Not proficient in BMH

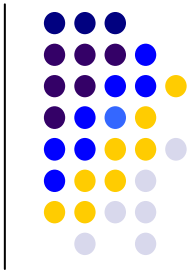
QM: Adverse Event Reporting



- **B4.10 "must have a system, document corrective actions & review, evaluate promptly**
- **Report to regulatory agency"**

- Uses hospital based system: under-reporting
- No SOP: PD/patients physician
- No evidence of AE evaluation
- Must include in quality review

Audit and Outcome Review



B4.8 "collect, analyse & audit performance data"

- Should include TRM, engraftment, line infections
- No plan for review
- Range of acceptability?
- Deviation - ? what action
- No SOP for audits - communicate results

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Donor Evaluation, Selection & Management

B6 Donor evaluation testing & consent

- Patient / Donor issues -1
  - no record of verification of patients diagnosis
  - no formally documented criteria for defining suitable donor
  - no explicit documentation of suitability of donors
  - not clear how the decision is made to use a donor not meeting the programme's selection criteria
  - donor's medical record does not record where applicable that the donor was informed of any abnormalities and of recommended follow-up
  - policy for disposal not mentioned in donor consent forms

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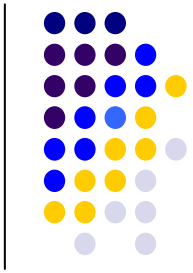
Donor Evaluation, Selection & Management

B6 Donor evaluation testing & consent

- Patient / Donor issues 2
  - pregnancy assessment not routinely performed
  - donor medical history does not include a travel history
  - donor medical history does not include questions to identify persons at high risk of significant transmissible infections.
  - HLTV I and 2 serology not performed
  - no SOP or controlled document for transmitting the results of donor evaluation from the clinical team to the collection facility

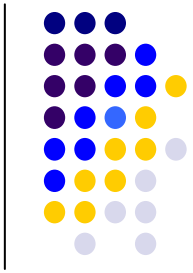
Therapy Administration



B7 Written policies for HD therapy and HPC products

- No SOP's for all regimes
- Dose of drugs not checked by 2 people
- Instructions for infusion not clear
- No documentation in notes of unit identifiers for all products

Stem Cell Collection



Bone Marrow

- Personnel
- Protocols and procedures
- Cell collection

Peripheral Blood

- Personnel
- Labels
- Collection facilities

Bone Marrow Collection

C3 Personnel

- BMH - documented training & proficiency
- MD responsible for donor evaluation & safety
- How many procedures are done

Bone Marrow Collection Policies and Procedures

C5

- BM Collection Procedures
  - no SOP for BM collection
  - SOP present but inadequate e.g. no acceptable results and tolerance limits / no instruction for action if these are not met
  - no procedure for recording deviation from the SOPs relating to marrow collection, or whether and how such deviations are approved
  - expiration dates and lot numbers of the reagents/equipment used for BM harvest not recorded
  - records of collection not regularly reviewed by CF Director
  - no systematic outcome review / audit

Bone Marrow Collection: cells and labels

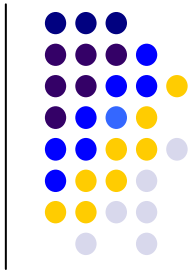
C7 & C8

- No written orders
- SOP must cover transportation
- Labels must be alphanumeric
- Must give proper name
- CF and PL need to agree HPC identifiers

PBSC Collection

- no formal policy /SOP for assessment of venous line placement
- assessment of venous line placement not documented in patient record
- range of expected results not defined in SOP for stem cell collection
- tolerance limits and corrective actions for collection not defined
- No SOP covering transportation from the apheresis unit to the processing facility
- no procedure / documentation relating to validation of equipment / procedures
- Records of collection not regularly reviewed by CF Director
- No systematic outcome review / audit

PBSC Collection:



- Inadequate documentation of training
- MD does not have appropriate contract with facility
- QMP should cover H&S
- TTI testing by clinical programme - communication
- Reporting AE's to clinical unit - SOP

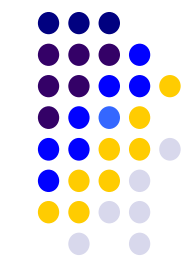
- Communication from clinical to collection team
- Suitable space for donor examination
- Proper disposal of apheresis kits

PBSC Collection : Labels

C7 Operations, product identification and label content

- Examples appended to SOP
- Unique alphanumeric identifier
- SOP to include Biohazard label
- Pre- or demand -printed labels
  'Human HPC-A
- Name + volume of AC/additives

Cell Processing Laboratory



- Quality Management
- Labels
- Storage Conditions

Quality Management

- Processing Facility
  - no written request for processing
  - methods used for processing not validated
  - no SOP for handling ABO incompatible graft
  - alarm system not adequate
  - temperature not monitored during transport
  - engraftment data not regularly monitored
  - no formal criteria for acceptable engraftment

LABELS

- Labelling
  - components labelled only with the donor name. (A unique alphanumeric code must be used)
  - proper component name not used (Haematopoietic Progenitor Cells, Marrow / Apheresis - HPC-M / HPC-A)
  - Biohazard label not used as specified
  - missing information
    - date / time / volume of collection
    - name and volume of anticoagulant / other additives
    - donor ABO and Rh group
    - instruction ‘Do not irradiate’
    - instruction ‘ for autologous use only’
    - time of expiry

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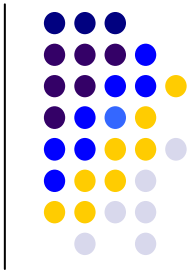
Conditions for Storage



D9 Cryopreservation samples, procedures and cooling rate

- Continuous monitoring required
- Procedure for notifying personnel
- Room must be secure
- 'No provision for back up storage'
- 'No storage temp records'

Typical Deficiencies - General

- Interactions must be documented
  - written request for collection
    - From clinical programme to collection facility
  - written request for processing
    - From clinical programme to processing facility
  - results of infections disease marker testing
    - must be available to both collection and processing facilities
  - engraftment data
    - must be available to both collection and processing facilities
  - report of adverse events
    - Must be available to all relevant facilities
  - transport log form
    - For handover between collection/processing and processing /clinical facilities

Don’t forget….

- Listing of deficencies
  - On web site

THE END

Teşekkür ederim

Thank you for listening