Crucial steps to “set up” the first Pediatric BMT center in Tanzania

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BMKH meeting (DODOMA)

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SCD in Tanzania up to 2019

- **SCD birth prevalence /year**:

  6-10 per 1000 births (**around 20.000**)

- **SCD children MR/year** = 10.500 (J. Makani)

- **U5-MR for SCD = 50 to 90 %**

- **U5-MR for Malaria = 10 % (WHO data)**

Estimated yearly Incidence of childhood leukemia and lymphoma in "Tanzania"

NEW LEUKEMIAS/YEAR

- **2000** children **in Tanzania**
- **500 in the areas of**
  - Mwanza
  - Dodoma
  - Zanzibar

NEW LYMPHOMAS/YEAR

- **2500** children **in Tanzania**
- **600 in the areas of**
  - Mwanza
  - Dodoma
  - Zanzibar

We have a dream… a BMT Center

to cure SCD and other childhood hematologic diseases in Tanzania

Mandatory for a BMT Center

- ***BMT Center*** must carry out at least 10 allogeneic sibling donor transplant a year

- *Adequate space, design with "protective environment"* and location for BMT Center
- *Adequate number of the personnel* with a good "expertise"
- *Adequate facilities to minimize risks* to the health of employees,patients, donors visitors and volunteers

BMT and PEDIATRIC Hematologic Center

with a system of "environment protection" and need of:

- **3 doctors ; 15 nurses; 1 chief of nurse**
- 4 single rooms (with bathroom) and 3 double bed rooms (each with bathroom inside)
- **One nurse station,** 1 protective cabinet for preparation of immunosuppressive therapy
- **Doctors rooms with Internet/Intranet**
- **Storage room** *(scales, monitors, needles for BM aspiration, any other supplies for post-BMT complications….)*

Plasma air Sentinel

CHARACTERISTICS

- **PlasmairT2006:** *It is a new mobile system to protect immunosuppressive patients against airborne contamination by HEPA with Microbial Destruction*
- **Evidence Based Clinical Efficacy1**
- **Safety** (Class II medical device) *due to a room air cleaner*
- **Patient Comfort 3**

OUTPATIENT for transplanted children

- **6 single beds rooms** for infusions, chemotherapy…..(+ 3 bathrooms)
- **One large common room** with 10 beds for IV infusions plus 3 bathrooms (at least)
- **2 rooms for procedures** (BM aspiration, lumbar puncture……..
- **1 Nurse station** for preparation of infusions and any kind of procedure (+ Internet/Intranet)
- One protective cabinet
- Storage room (for drugs….)
- **Doctors station** with Internet/Intranet
- 1 “Play/rest room” for patients and/or parents
- 1 room for “social worker and psycologyst
- Various (scales, monitors…..)

BMT facility : the Team

- "Program Director" responsible for clinical transplant activities
- Attending physicians and other personnel (nurses) with specific training and expertise for BMT
- Mid-Level practitioners (chief of nurses, research nurses....)
- Medical Directors of "Collection and Processing Facilities", Pharmacy.....
- Data manager

BMT Accreditation: consulting and certified Units and/or physicians

- **Blood Bank and HLA Lab**
- **Instrument for irradiation of Blood Products**
- **Pathology/Hematology LAB**
- **Pharmacy**
- Surgery
- Intensive care Unit
- Nephrology (dialysis),Cardiology,Pneumology
- Radiology
- Infectious disease Unit/LAB
- Neurology /Psychiatry

BMT strategy

- To optimize the clinical activity of doctors and nurses involved in stem cells transplantation
- To promote quality medical and laboratory practice in BMT
- To provide continuously the guidance to all the professionals *by a "quality management system"*

Quality management System: what does it means?

- A system to document initial qualifications and training of the personnel
- Provision for continuing education and “annual review “of the competence
- A system for clinical care of donor and recipient
- A system for conducting and reviewing “audits”and BMT internal meetings
- A system for detecting errors,accidents,adverse events and their correction or prevention

How to improve the "Education" of BMT Team of BMKH

** **At distance training** (Teleconference with BMT Experts)

Pre-start up **Local training (by Italian BMT experts)

** **Internship** in an abroad BMT qualified Center

<u>Training** since the "start up" by Italian BMT experts" for at least 3 years</u>

****Continuous evaluation of competences** by a quality management plan

Education and quality management of the "BMT Center" Personnel

EDUCATION

Initial Competencies evaluation

Continuous evaluation : at least once a year

Documents

Improvement plans

Audit

Outcome.

Errors

Corrective actions

Validation

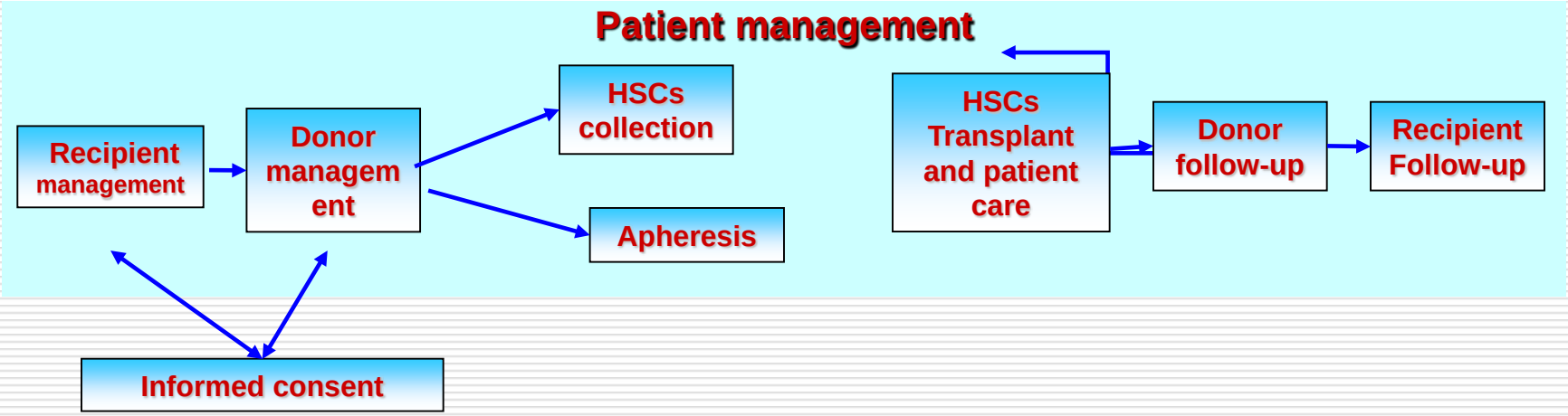
Privacy

Product deviations

"Nurses competence" in BMT process

- Infection prevention and control
- Administration of the preparative regimen and immunosuppressive drugs
- Transplantation of "stem cells" and supportive care (nutrition…..)
- CVC care and Blood product tranfusion
- Knowledge and prevention of adverse events

Competence of primary physicians on BMT Process



BMT "work metodology"

Interaction among different departments and "staff"dedicated to BMT by:

- **Quality management system** who provides several critical "standard operating procedures"(SOPs) which control any process before and after BMT

- **The use** of International Standards for *"cellular therapy product Collection, Processing and Administration*

JACIE in EUROPE : a promising result in more than 220 BMT Centers

- **BMT "Jacie accreditated " Centers** provide better results in terms of EFS *(more than 14%)* compared to BMT Centres non accreditated
- **Jacie International Standards** for BMT activity make safer all procedures concerning "*collection, manipulation, processing and administration of haemopoietic stem cells*

EBMT REVIEW , JCO, 2010

BMT Unit at BMKH : it's feasable

With the right “task force”

WITH A DEDICATED TEAM at BMKH !

After 1- 2 years of strong "training" to doctors/nurses and Lab staff

Only in the setting of specific BMT structure and collaborative support facilities

Only if there is a strong maintenance of the training to the BMT staff members

With determined collaborators !

WHEN?

It depends from :

- **our will-power and commitment**
- **a continued “training”**
- **a comprehensive financial support!**
- **assuring the maintenance of the BMT activity**

POSSIBLE ROAD MAP

Up to Feb 2020

Completion of :

- BMT UNIT
- Pharmacy
- LAB
- BLOOD BANK
- Other Services

Up to June 2020

Assessment of:

- Acquired competences
- Facilities availability

and ..launching of first BMT

and ...have a nice job!

a special thanks to Italian Charities and to all professionals and/or the authorithies in Tanzania

ELP3

8 per mille
CHIESA VALDESE
UNIONE DELLE CHIESE METODISTE E VALDESI

Azienda Ospedaliera San Gerardo

ISTITUTO MARIA LETIZIA VERGA
Per la salute del Bambino e della Mamma

Mountain top is approaching……

Jacie on site Inspections

When?

**At the time of first accreditation

**Interim inspection on 2nd year

**Reaccreditation every 4 years

About what?

** Three HSCT “facilities” (i.e. AUDIT)

** Patients clinical outcome

** Organization standards (In and Outpatient Unit)

** Documents, policies,procedures(high dose chemotherapy, HSCs infusion, management of errors and/or adverse events..)

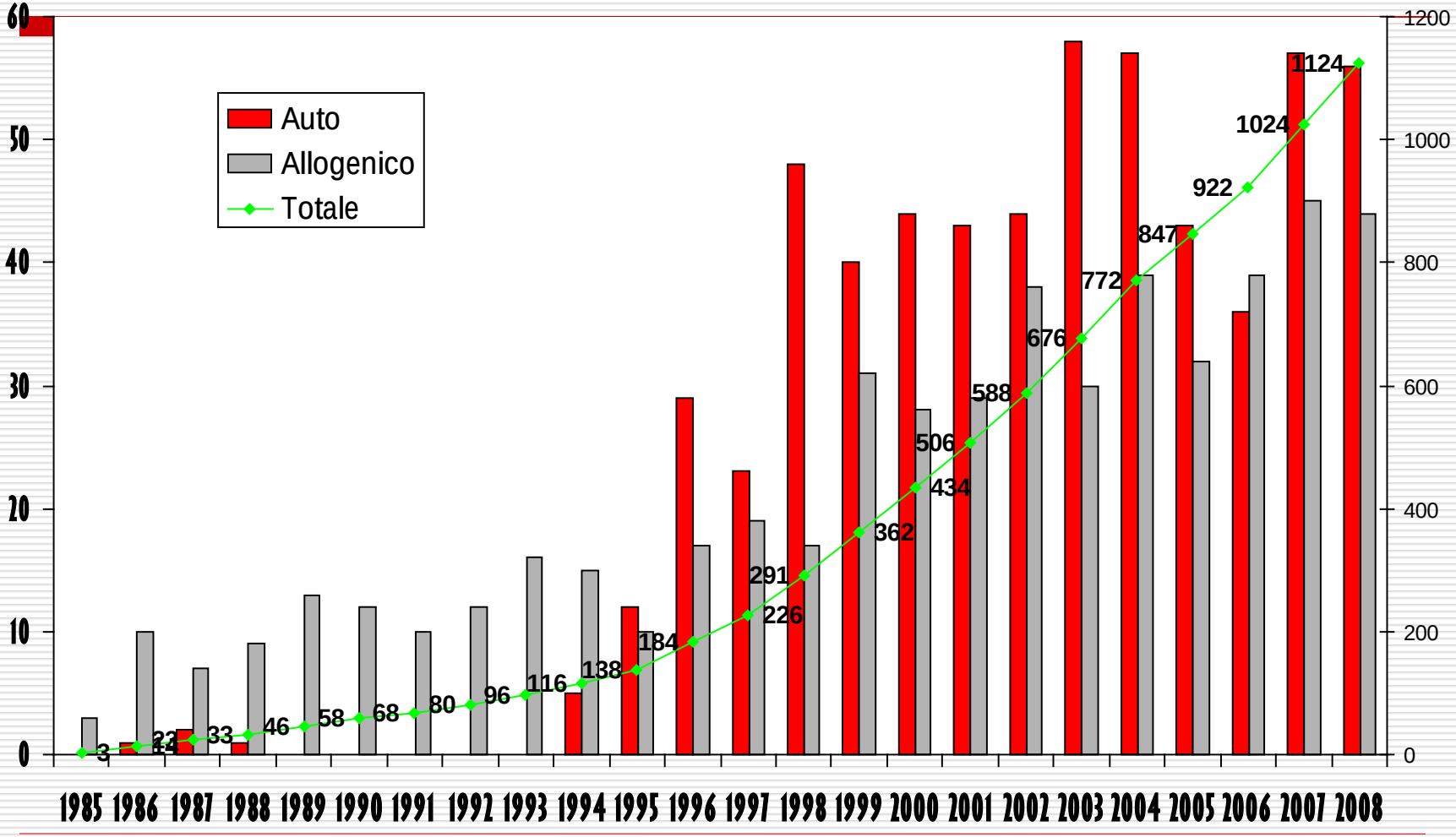
** Personnel education and training

Monza "adult and pediatric Centers" : Jacie Accreditation Process

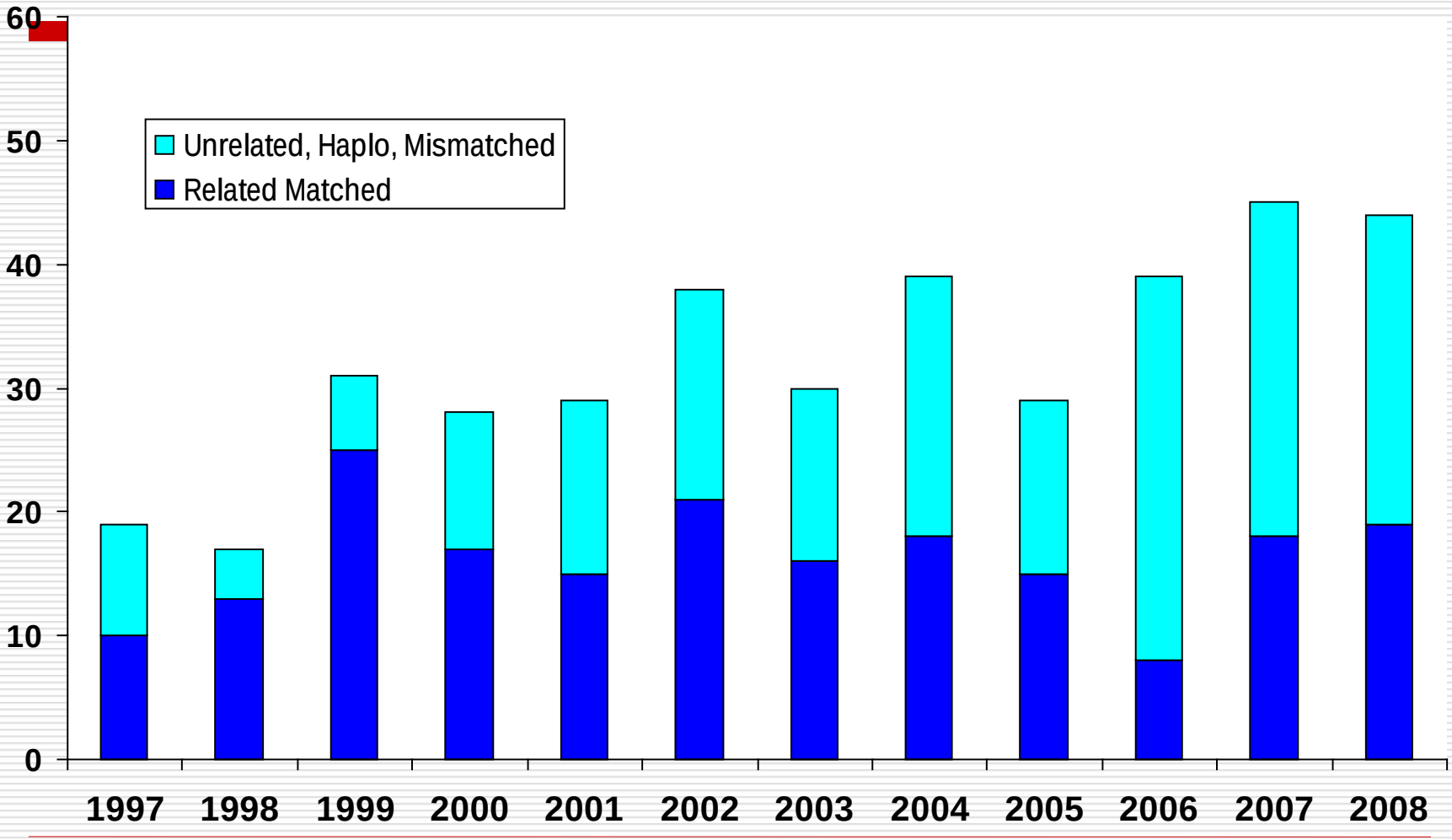
- First Accreditation : June 2008
- Reaccreditation : June 2012

- Total HSCTs = 1223 (since 1984)
- Allo :630 (60% MUD)
- Auto:583 (79% PBSC)

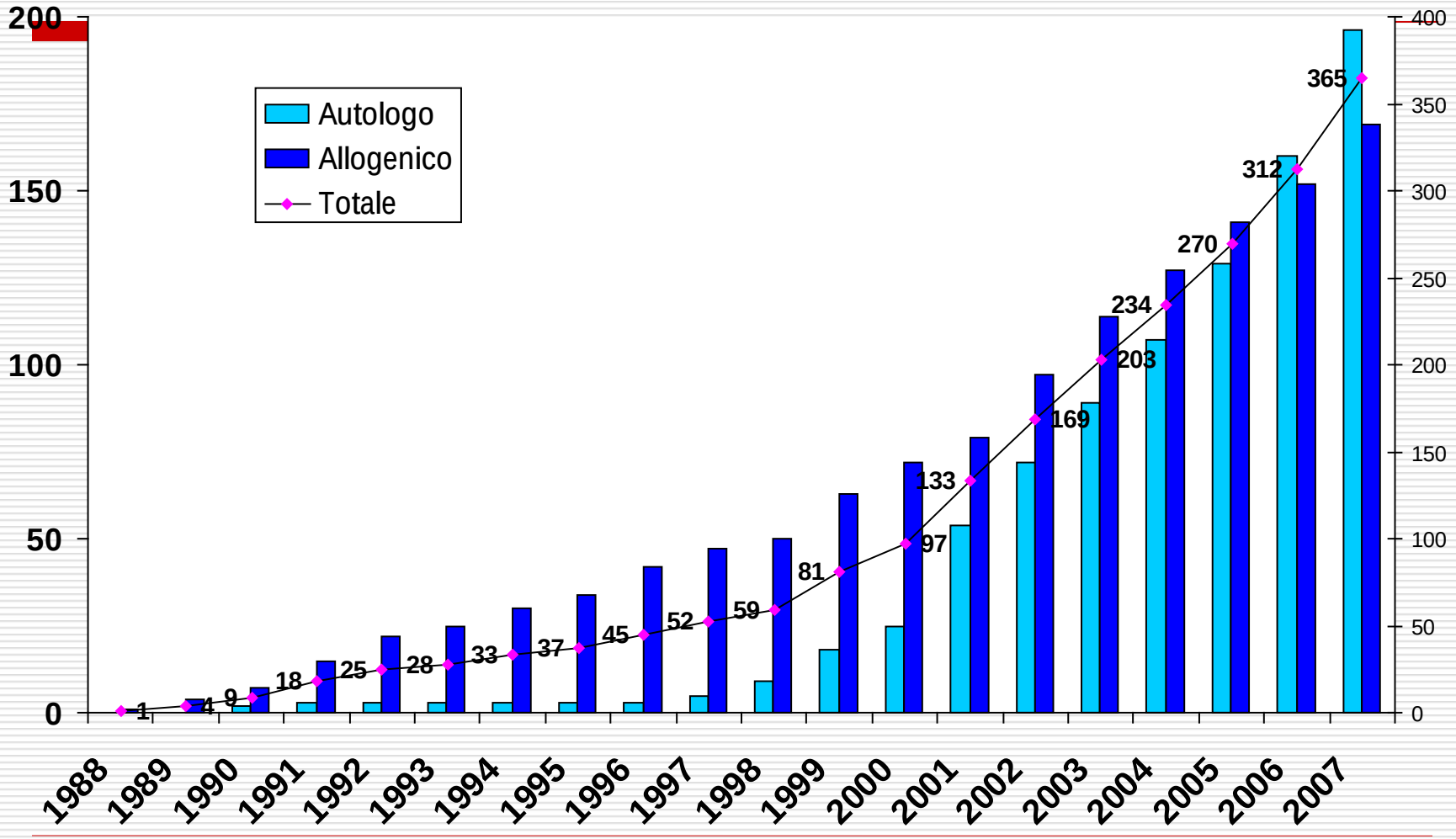
Monza HSCTs Activity per year : 1985-2008



Different types of Allo HSCTs performed in the period 1997 - 2008



Patients cured per year in Monza HSCT Centers (= 700 PTS. alive and well with a follow up >3 years) 1988-2008

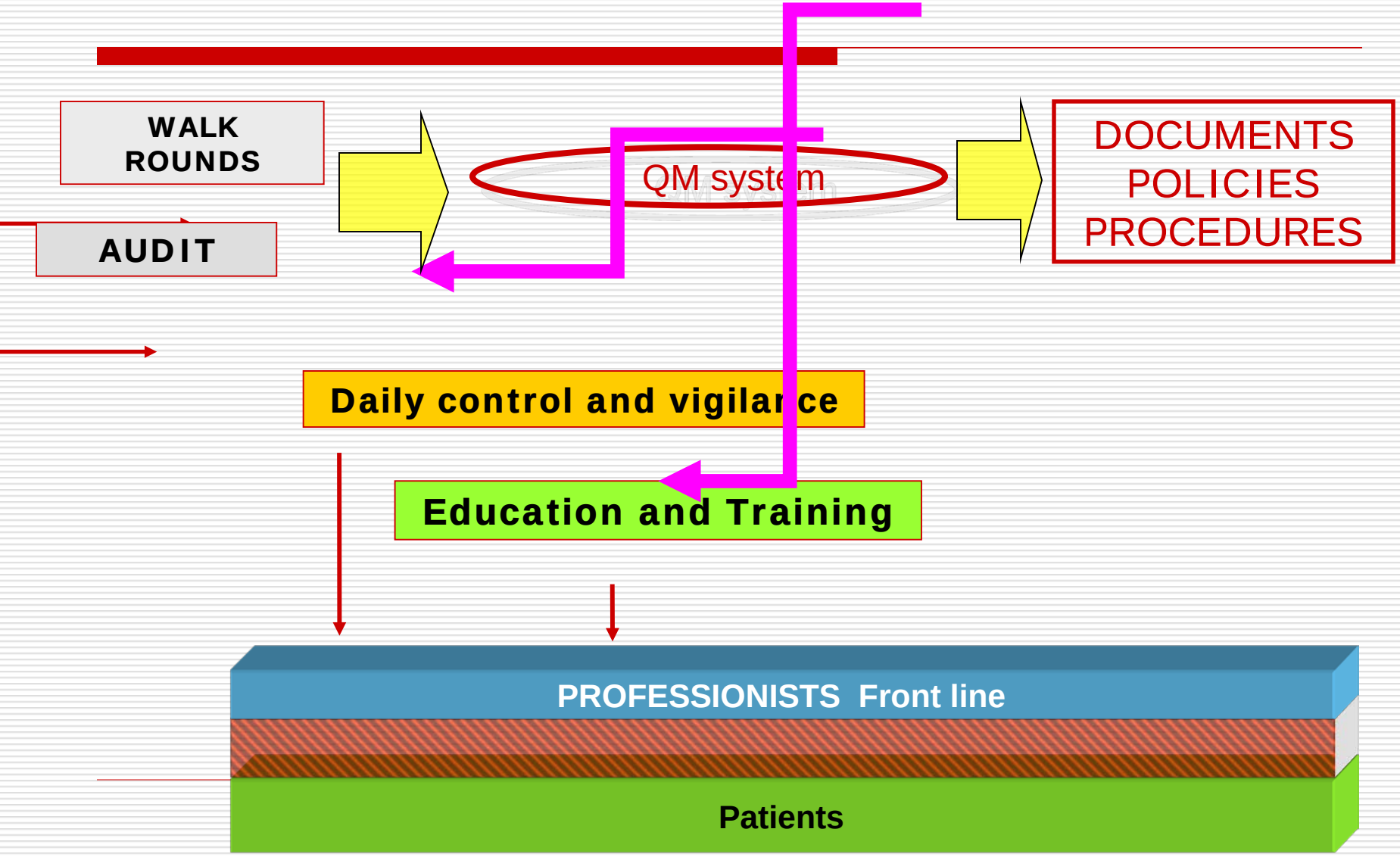


Conclusion

JACIE means :

- ✓A common approach for taking care of HSCT patients (see protocol, guidelines, procedures..)
- ✓To guarantee the best results in terms of EFS and quality of life after HSCT
- ✓A continuous improving for quality medical and laboratory practice in HSCT

From the procedures to the actions of all HSCT personnel



PATOLOGIE TRATTATE NEI DUE CENTRI TRAPIANTO (1985-2008)