Calling All Super Heroes

# Marrow Masters:
# To Harvest and Beyond

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November 10, 2018

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Let's go!

# Disclosures

The following faculty and planning committee staff have the following financial disclosures:

| Name | Institution | Disclosure |
|---|---|---|
| Robert M. Rifkin, MD, FACP | Presbyterian/St. Luke's Medical Center | None |
| John Miller, MD, PhD | NMDP/Be The Match | None |
| Alicia Kasper | NMDP/Be The Match | None |
| Jennifer Hintze-Olson | NMDP/Be The Match | None |
| Sue Reichling | NMDP/Be The Match | None |
| Amy McGarrity | NMDP/Be The Match | None |
| Gretta Stritesky, PhD | NMDP/Be The Match | None |
| Betsy Blunk, BSN, RN, CHTC,BMTCN | Sarah Cannon Blood Cancer Network | None |

# Learning objectives

- At the conclusion of this session, attendees will be able to:
  - Identify FACT requirements pertaining to marrow harvests
  - Discover efficiencies to reduce harvest time
  - Support current best practices for marrow harvest procedures

# Marrow Masters - Agenda

- Collection Center Snapshot
- Marrow Harvest Procedure
- NMDP 24th Edition Standards
- FACT/JACIE 7th Edition Standards
- Current Issues Surrounding Marrow Harvesting

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# Progenitor Cell Collections at Presbyterian/St. Luke's Medical Center

| Collections at Presbyterian Saint Luke's by Calendar Year | Marrow Center - 2266 | PBSC Center - 9864 | Total Collections |
|---|---|---|---|
| 2008 | 10 | 30 | 40 |
| 2009 | 15 | 35 | 50 |
| 2010 | 20 | 42 | 62 |
| 2011 | 30 | 56 | 86 |
| 2012 | 19 | 68 | 87 |
| 2013 | 13 | 81 | 94 |
| 2014 | 9 | 61 | 70 |
| 2015 | 11 | 77 | 88 |
| 2016 | 13 | 70 | 83 |
| 2017 | 3 | 41 | 44 |

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# The Lee-Lok Disposable Marrow Harvest Needle

# The Bone Marrow Collection Kit

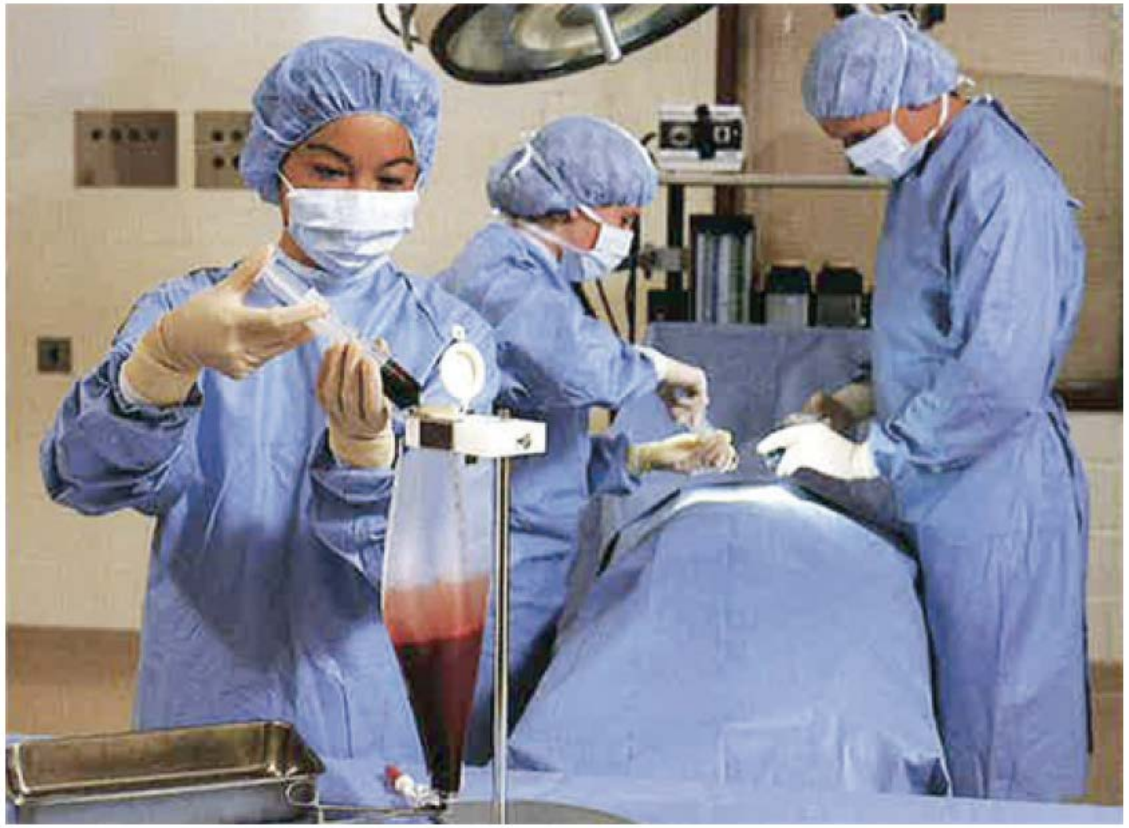
## Collection and Gravity-flow Filtration System

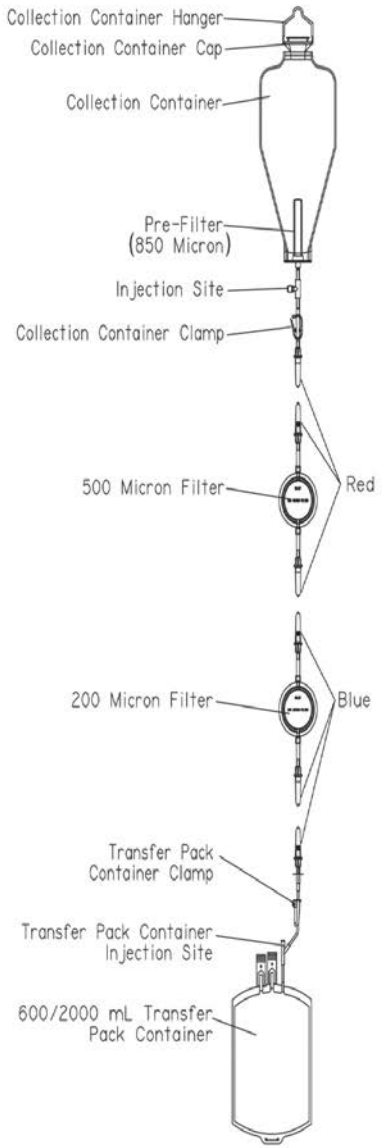
- Consists of separate components that are assembled with large connectors for filtration
- One 1.2 liter collection container with an 850 micron pre-filter
- Two 500 micron filter assemblies
- One 200 micron filter assembly
- Three 600 mL Transfer-Pack containers
- One 2 L Transfer-Pack container
- Four additional tip protectors
- Two sterile wraps

**Don’t Forget to Buy the Collection Kit Stand !!!**

# The Bone Marrow Collection Kit

# Bone Marrow Harvest
# The Operating Room





# The Bone Marrow Collection Kit

## Key Features and Benefits

- Minimal set up: includes components needed for collection and filtration in one sterile package.
- Easily disposable: single-use plastic components.
- Simple collection: wide opening on collection container with cap closure.
- Allows for pre- and post-filtration samples: injection sites on collection containers and Transfer-Pack containers.
- Pre-filter in collection container removes large aggregates: 850 micron pre-filter reduces likelihood of clogging.
- Gravity flow-through medical grade, mesh filters: includes two 500 micron filters, in case clogging occurs.

# Bone Marrow Harvest – The Realistic Approach

ORIGINAL ARTICLE

WILEY European Journal of Haematology

## Bone marrow harvest from unrelated donors—up-to-date methodology

Katarzyna Pruszczyk[1] | Kamila Skwierawska[1] | Małgorzata Król[1] | Albert Moskowicz[1] | Dariusz Jabłoński[2] | Tigran Torosian[3] | Iwona Piotrowska[3] | Elżbieta Urbanowska[1] | Wiesław Wiktor-Jędrzejczak[1] | Emilian Snarski[1]

*Eur J Haematol.* 2017;99:357–365.

# Bone Marrow Harvest – Key Points

**Background:** Bone marrow harvesting is one of the essential sources of stem cells for hematopoietic stem cell transplantation. Today, we will review the current "up-to-date" standard of the bone marrow harvest in unrelated stem cell donors.

**The Data:** Medical data of 187 unrelated hematopoietic stem cell donors who underwent bone marrow harvest without previous peripheral blood stem collection at the center between 2011 and 2015 will be reviewed .The methodology of marrow collection includes multiple cells aimed at safety of the procedure. For example, educational movie, modified skin disinfection protocol, cell enumeration during the procedure, reduction of the contamination surfaces, and ongoing monitoring of the quality of work of the doctors will be reviewed.

**The Goal:** The total nucleated cell count over $2x10^8$ per kg of recipient has been reached in 93.6% of harvests. All of the donors harvested more than $1\ x10^8$ per kg of the recipient. There were no donors who required transfusions or had serious adverse events during and after the harvest.

**Conclusion:** We describe here the current up-to-date standard of bone marrow harvest, which leads to excellent results in majority of donors without causing significant complications during the donation.

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*Eur J Haematol.* 2017;99:357–365.

# Bone Marrow Harvest: Donor vs Recipient Weight

| | Sufficient BM donations[a] | *P*-value | TNC/kg recipient body mass | *P*-value |
|---|---|---|---|---|
| Total | 93.7% (133/142) | | 4.587 (1.043-19.25) | |
| Recipient's body mass > donor's body mass | 70.8% (17/24) | <.0001 | 2.67 (1.479-3.743) | <.0001 |
| Recipient's body mass ≤ donor's body mass | 98.3% (116/118) | | 5.334 (1.043-19.25) | |
| Recipient <50 kg | 98.9% (87/88) | .0019 | 6.719 (1.043-19.25) | <.0001 |
| Recipient ≥50 kg | 85.2% (46/54) | | 2.822 (1.479-4.62) | |

TNC=total nucleated cell count.
[a]Sufficient BM donations (TNC/kg recipient >$2\times10^8$).

**TABLE 1** The impact of recipients weight on chances of obtaining total nucleated cell count of more than $2\times10^8$ per kilogram of recipient weight (median values with ranges in brackets), Mann-Whitney test

*Eur J Haematol*. 2017;99:357–365.

# Bone Marrow Harvest Yields

| Characteristic | Number | TNC >4×10$^8$ | *P*-value |
|---|---|---|---|
| Donor sex | | | |
| Female | 61 | 33 (54%) | .7329 |
| Male | 81 | 47 (58%) | |
| Weight difference | | | |
| Recipient heavier | 24 | 0 (0%) | ***<.0001*** |
| Equal weight | 1 | 0 (0%) | |
| Donor heavier | 117 | 80 (68.4%) | |
| BM harvest volume (mL) | | | |
| 414-811 | 36 | 34 (94.4%) | ***<.0001*** |
| 830-1075 | 36 | 29 (80.6%) | |
| 1085-1507 | 35 | 10 (28.6%) | |
| 1513-2051 | 35 | 7 (20%) | |
| **Characteristic** | **Number** | **TNC >2×10$^8$** | ***P*-value** |
| BM harvest volume (mL) | | | |
| 414-811 | 36 | 35/36 (97.2%) | ***.0182*** |
| 830-1075 | 36 | 36/36 (100%) | |
| 1085-1507 | 35 | 33/35 (94.3%) | |
| 1513-2051 | 35 | 29/35 (82.9%) | |

Statistically significant values shown in bold italic

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# Key Check Points Prior to the Bone Marrow Harvest

- Donor qualification
- Material preparation for the harvest
- Personnel preparation for the harvest
- Choice of experienced operator
- Preoperative donor assessment
- Donor positioning
- Staff and material preparation immediately prior to harvest

# Key Check Points During the Bone Marrow Harvest

- Skin disinfection
- Reduction of the risk of contamination
- Reduction of needle accidents
- Reduction of bleeding risk during the harvest
- Intra-harvest collection assessment
- Deviations from the procedure and serious adverse events (SAE)
- Observation – Encourage staff to visit other centers to see harvests
- Research projects

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# National Marrow Donor Program®/Be The Match®

# 24th Edition

# Standards

## And

# Glossary

**January 1, 2018**

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# NMDP Section 5.0000

## Criteria for Participating Marrow Collection Centers

| | |
|---|---|
| 5.1000 | Facility Characteristics |
| 5.2000 | Medical Director |
| 5.3000 | Personnel |
| 5.4000 | Support Services |
| 5.5000 | Policies and Procedures |

# 5.1000 Facility Characteristics

5.11 Center shall be accredited by an organization granted deemed status by CMS or non-US equivalent.

5.12 Center shall have an experienced team that has collected HPC(M) at least three times in the past three years.

5.13 Center shall have written agreement(s) defining roles and responsibilities with participating donor center(s).

# 5.2000 Medical Director

5.21 Center medical director shall have postdoctoral training in hematopoietic stem cell collection or transplantation.

5.22 Center medical director shall have at least one year experience in the collection procedure.

5.23 Center medical director or designee shall perform and/or review a complete medical evaluation of the donor to determine if the donor is acceptable candidate for HPC(M) collection including evaluation for the donor for risks of donation and evidence of disease transmissible by transplantation.

# 5.3000 Personnel

5.31 Center physician performing the HPC(M) collection shall have performed at least 10 prior collections of HPC(M) for transplantation with at least three collections in the previous three years. Any person assisting in the marrow aspiration (physician, nurse, technician) shall have documented adequate training in HPC(M) collections for transplantation.

5.32 Center shall provide daily and emergency coverage by designated coordinator(s), sufficient in number to meet the needs of the center's activities.

5.33 Center shall provide anesthesia under supervision of a licensed, board-certified anesthesiologist or certified nurse anesthetist.

# 5.4000 Support Services

5.41 Center shall have a surgical operating room and a medical or surgical intensive care unit.

5.42 Center shall have irradiated and leuko-reduced blood components available in the event that the use of allogeneic blood products cannot be avoided.

# 5.5000 Policies and Procedures

5.51 Center shall maintain written procedures for the collection, testing, and labeling of HPC(M).

5.52 Center shall verify that if autologous units have been collected the units are available prior to the HPC(M) collection.

5.5210 The center should have the capability to collect and store autologous red blood cells prior to the HPC(M) collection if necessary.

5.53 Physician responsible for the collection shall be present for the duration of the HPC(M) collection.

5.54 Donor shall be admitted and discharged from the collection center on the same day unless medical status precludes this.

5.5410 Physician shall be responsible for determining that the donor's health is appropriate for discharge.

5.55 At the time of discharge, the center shall provide to the donor post-donation care instructions with contact names and phone numbers.

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# FACT Manual #1: The Standards

**INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION**



**Seventh Edition**
**Version 7.0**
**March 2018**

# FACT Manual #2: The Guidance

INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

**ACCREDITATION MANUAL**



**Guidance to Accompany the**
**FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Seventh Edition**

**Seventh Edition**
**Version 7.0**
**March 2018**

# Marrow Collection Facility Standards (Part CM)

| | |
|---|---|
| CM1 | General |
| CM2 | Marrow Collection Facility |
| CM3 | Personnel |
| CM4 | Quality Management |
| CM5 | Policies and Standard Operating Procedures |
| CM6 | Allogeneic and Autologous Donor Evaluation and Management |
| CM7 | Coding and Labeling of Cellular Therapy Products |
| CM8 | Process Controls |
| CM9 | Cellular Therapy Product Storage |
| CM10 | Cellular Therapy Product Transportation and shipping |
| CM11 | Records |
| Cm12 | Direct Distribution to Clinical Program |

# Key Differences: FACT vs NMDP

- CM1.4 The Marrow Collection Facility shall have a Marrow Collection Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.

- CM1.5 A Minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month prior preceding initial accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within each accreditation cycle.

# Key Differences: FACT vs NMDP

- CM3.1.3 The Marrow Collection Facility Medical Director shall have at least two (2) years experience in cellular therapy product collection procedures.

- CM3.1.4 The Marrow Collection Facility Medical Director shall have performed or supervised ten (10) marrow collection procedures within his/her career at a minimum.

- CM3.1.5 The Marrow Collection Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to the field of HPC transplantation.

# Key Differences: FACT vs NMDP

- CM3.2 Quality Manager
- CM4: Quality Management
- CM5.1 The Marrow Collection Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in CM4. These documents shall include all elements required by these Standards and shall address at a minimum: …

# Key Differences: FACT vs NMDP

- CM6 Allogeneic and Autologous Donor Evaluation and Management
- CM7: Coding and Labeling of Cellular Therapy Products
- CM8: Process Controls
- CM9/10: Cellular Therapy Product Storage, Transportation, and Shipping

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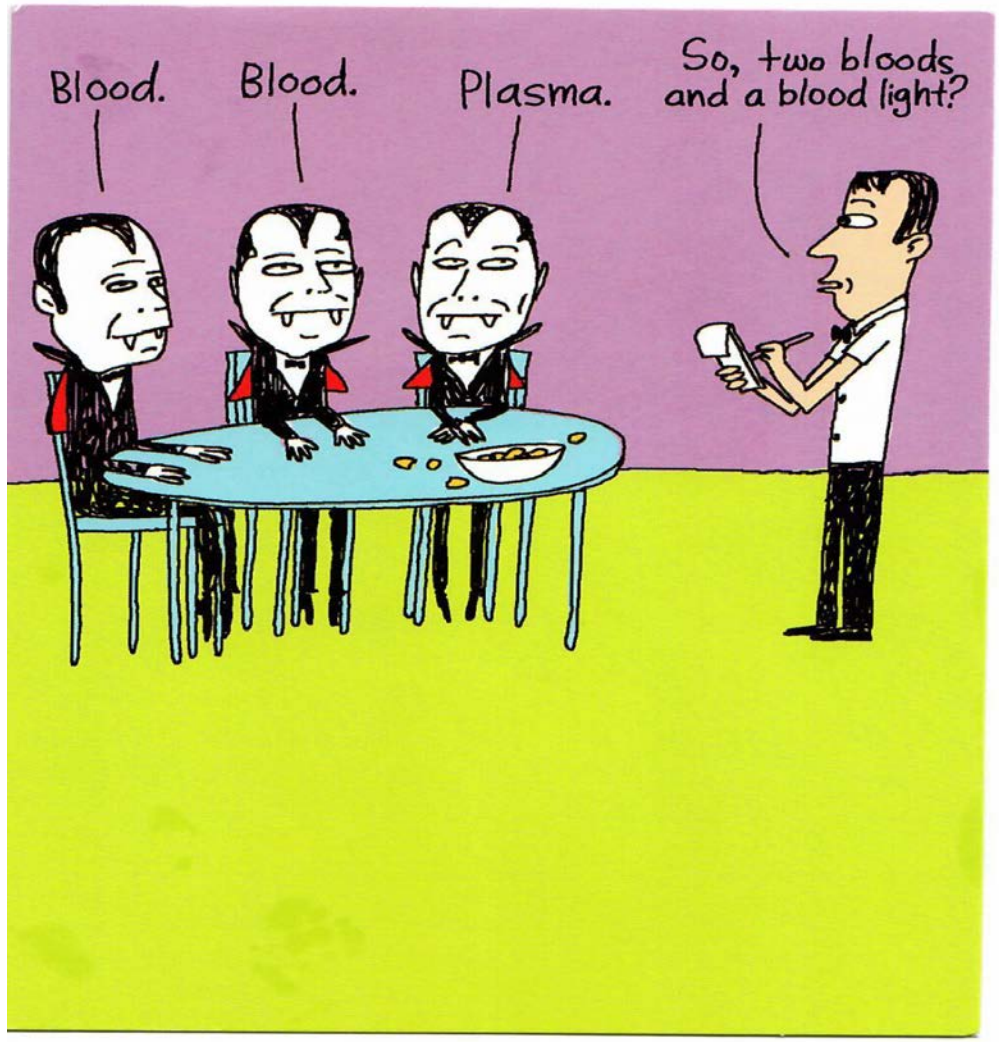
# Current Issues Surrounding Marrow Harvesting

- ✓ Increasing use of mobilized PBPC's
- ✓ Increasingly rare indications for bone marrow as source of stem cells
- ✓ Frequent cancellation of harvests
- ✓ Availability of operating rooms and experienced teams
- ✓ Reimbursement rates
- ✓ Lack of experience of collection team
- ✓ Difficulty complying with the standards
- ✓ Should marrow collection centers be regionalized?

# Thank you!

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