

Graft Processing in Japan

Cell / donor banking	No. of Pool	No. of Transplant	Courier
BM	510,526	BMT: 13,278 PBSCT: 1	Medical doctor from transplant center
CB	32,805	7,707	Shipping company

Transplant center

Perform 10-20 SCT/year (“walking distant SCT”)

No processing lab

No controlled-rate freezer (mechanical freezer -80)

No inspection for related SCT

I&A for unrelated SCT does not include regulation for graft processing

CB bank

11 local banks, no unified protocol for CB processing

Guideline for blood processing in hospitals

Issued by Japan society of blood and marrow transplant
and Japan society of blood transfusion and cell therapy in 2010

**Aim: Safety / quality control
also for international shipping of the graft**

**Subject: PBSC collection
Depletion of RBC or plasma
Freeze/thaw**

**Minimum Requirement (but all Optional):
Involvement of Blood transfusion service
Graft processing Lab
Clean bench
Microbial testing
Label printer
Automated cell counter
Flow cytometry (CD34 Single Platform Methods)
Traceability**

Cons

- ✓ **SCT has been performed safely without regulation.**
- ✓ **Insufficient man power**
 - Average 3 hematologists per center**
 - BM / PBSC harvests**
 - Freeze**
 - Long-distant hand-carry of BM**
- ✓ **Small center does not pay for Lab/equipment.**
- ✓ **Risk for suspension of SCT in small centers, resulting in no more “walking distant SCT”**

Proposal

- ✓ **Currently all optional, but will become requirements in future for inspection of SCT center only for unrelated SCT.**
- ✓ **May apply to all transplant center (but no consensus)**
- ✓ **Give sufficient time to each hospital to buy necessary machines or equipment.**
- ✓ **To create awareness among the top-ranking officer of hospitals and policy makers.**