

**Preregistration and five-year
follow-up system for bone marrow
and peripheral blood stem cell
family donors – the interim report**

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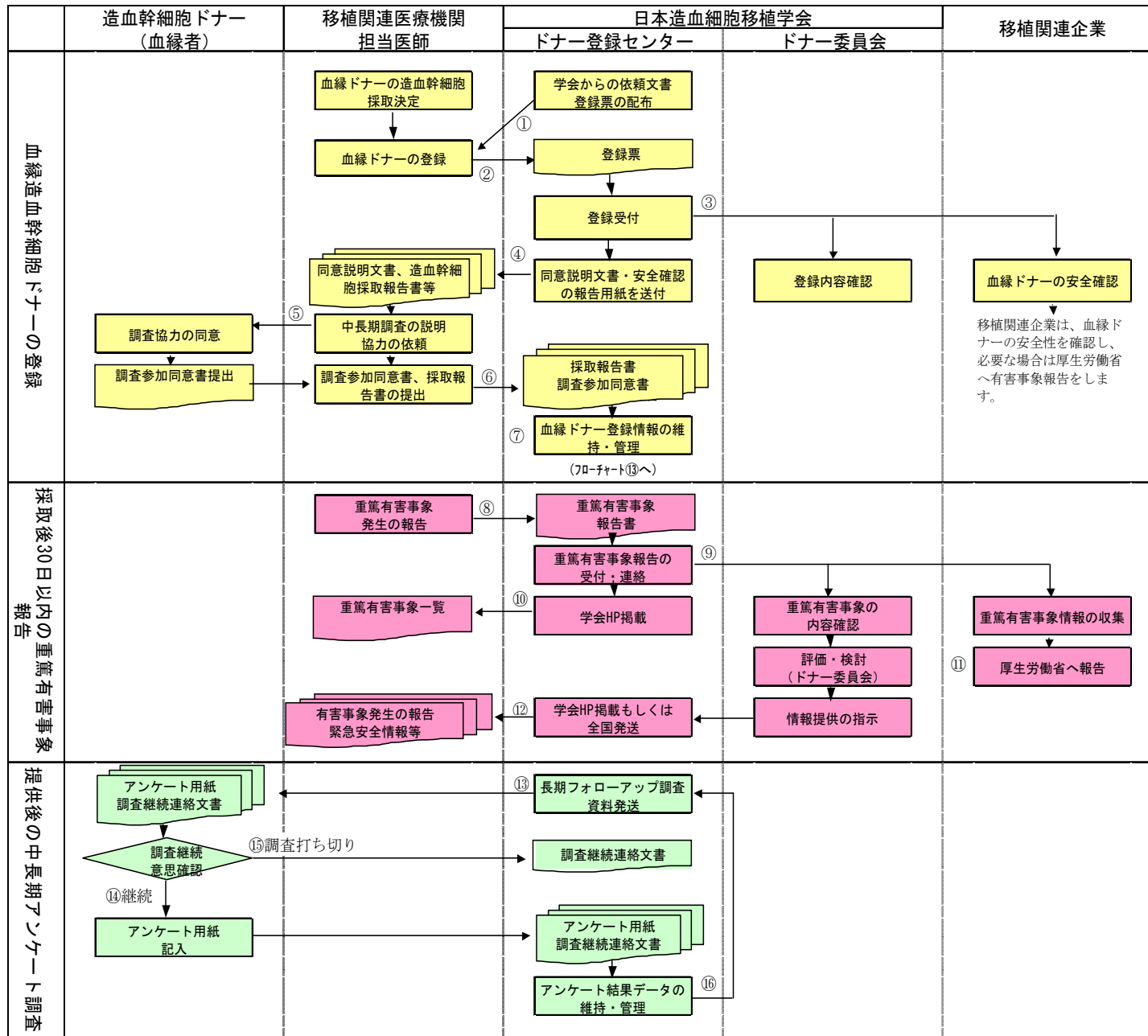
Background

- **Preregistration and 5 year follow-up for peripheral blood stem cell (PBSC) family donors conducted by JSHCT from 2000 to 2005 revealed that certain severe adverse events not necessarily unrelated with donation occurred during donation period, within 30days and even more than years after donation. To know the real figure of safety and risk of PB donation and bone marrow (BM) donation, a prospective comparative study for two stem cell harvest methods was required.**

Purpose

- **To compare the frequency, severity and characteristics of adverse events during and after stem cell donation (PBSC and BM) up to 5 years by using a single preregistration system for family donors.**

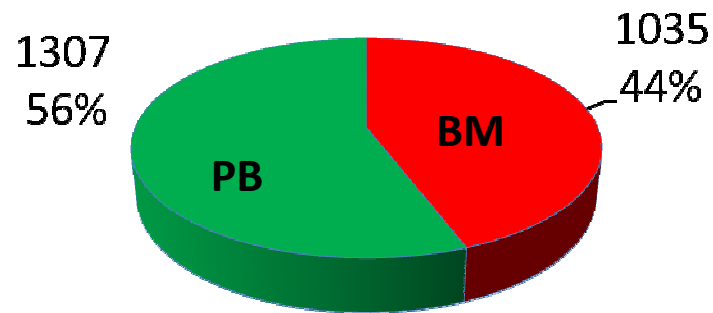
Flow-chart for HSC family donor follow up



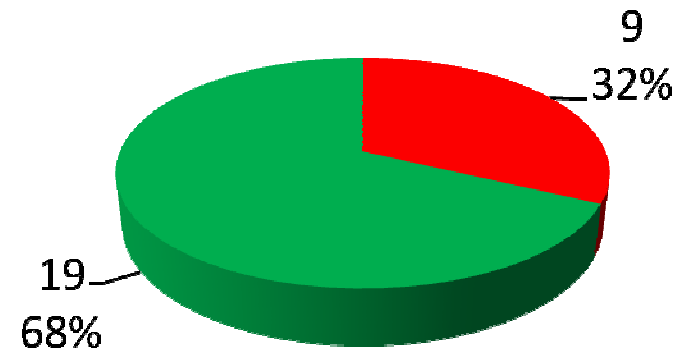
Result

BMH VS PBSCH 2006,3~2008,12 JSHCT

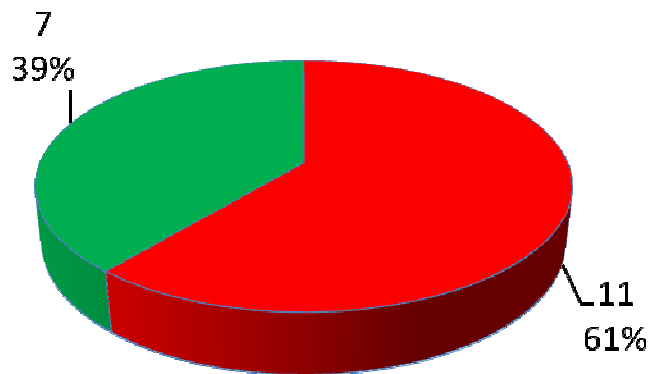
Registered



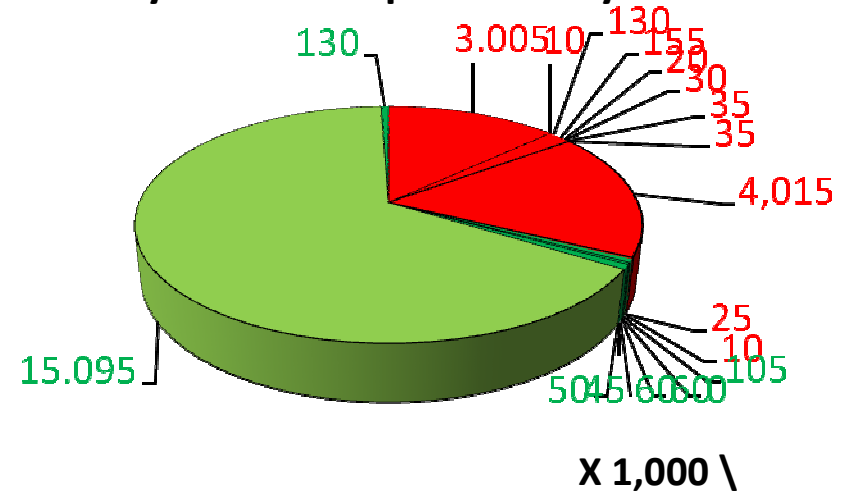
Acute adverse events reported



Casualty insurance-case number base



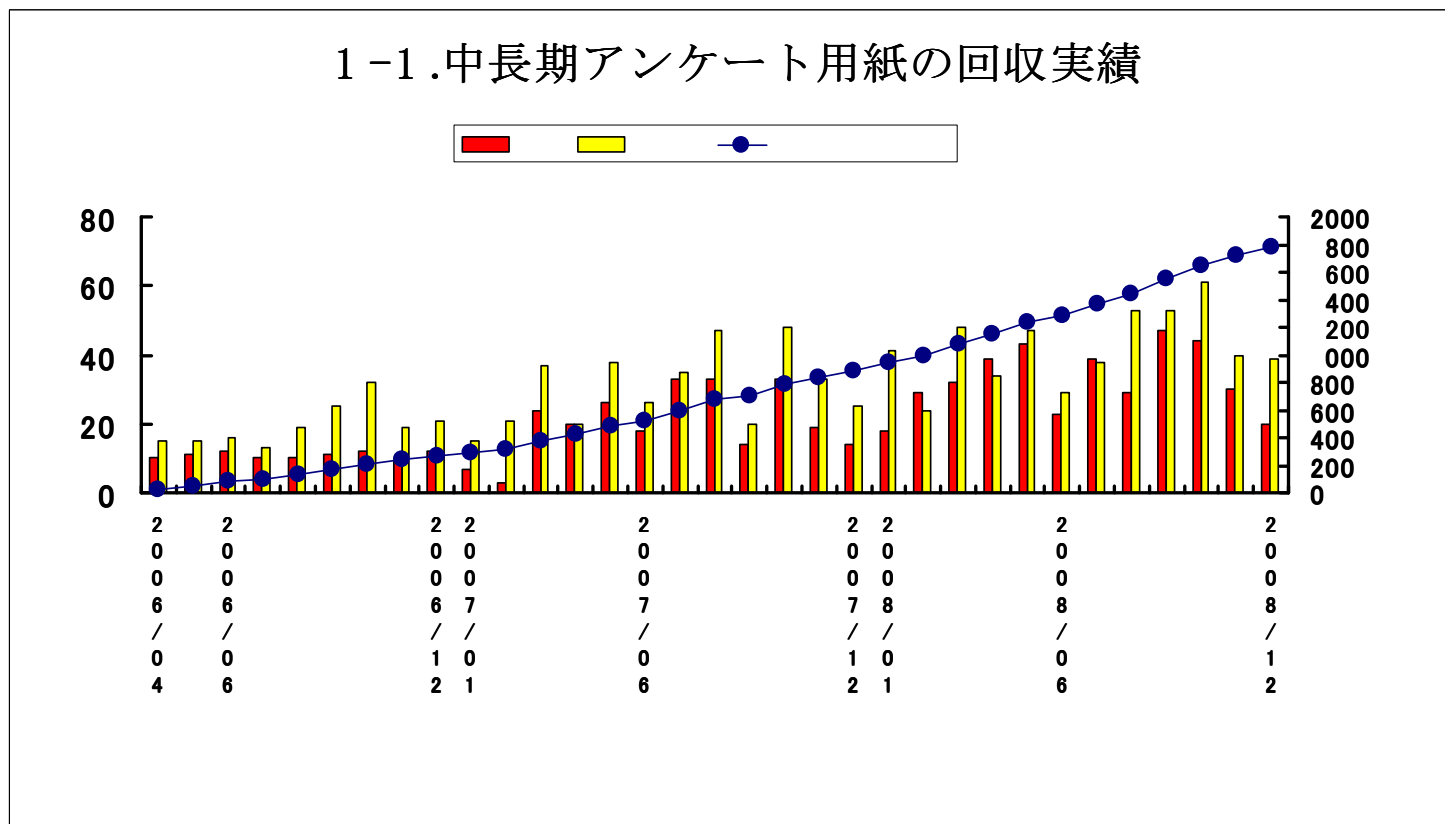
Casualty insurance-paid money base



Result

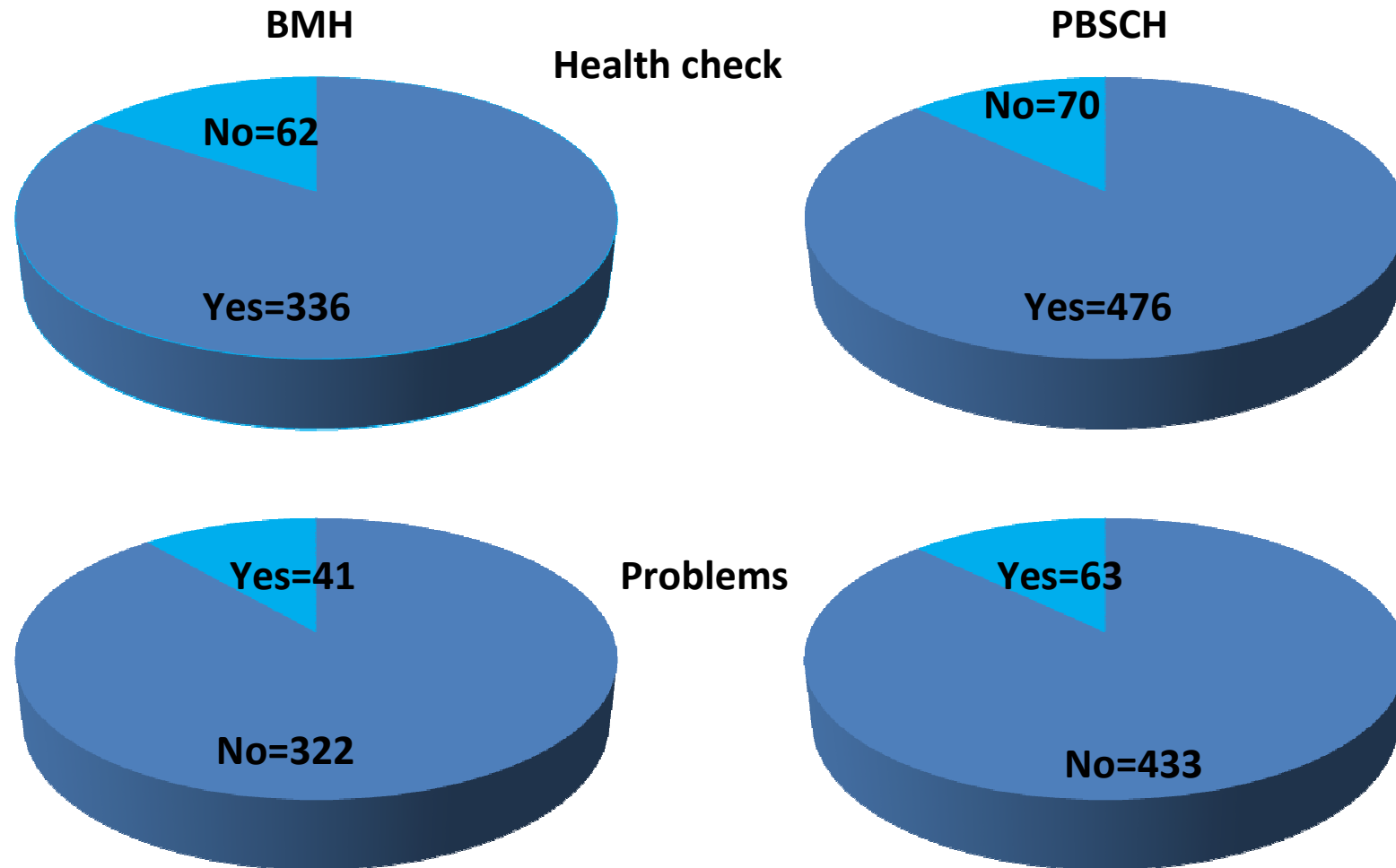
Status of annual questionnaires

Response rate: BM: 497/1035=48%, PB: 651/1307=50%

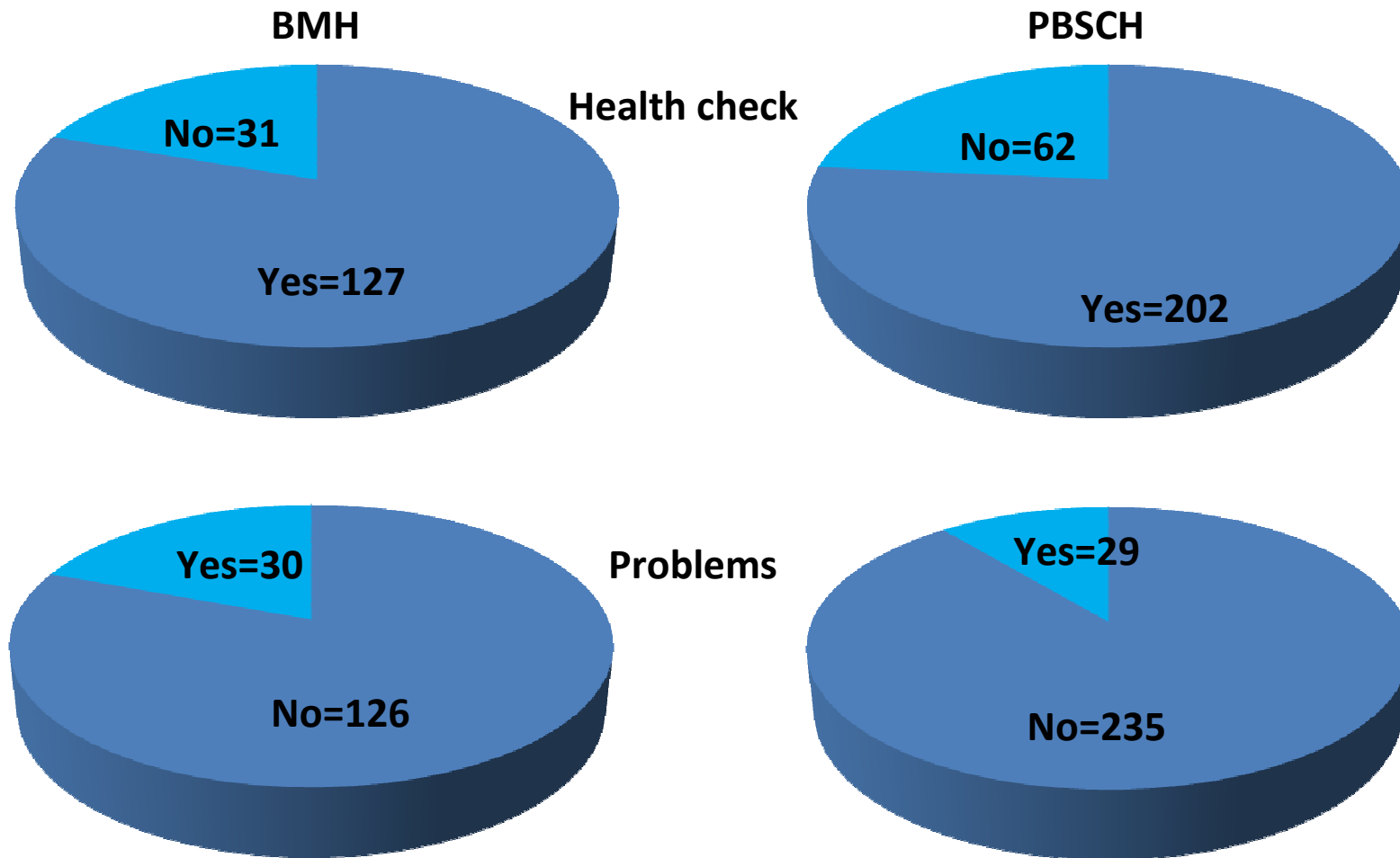


From April 2006 ~ December 2008

Result: The answers to annual letters –Within the first year of post donation



Result: The answers to annual letters –After more than the second year of post donation



Importance of pre-registration

-Especially from the view of donor safety-

System	Pre-registration	Fatal event within 30 days
Unrelated		
BM Japan	yes	0
World	yes	0
PB Japan	-	-
World	yes	0
Family		
BM Japan	No	1
World	No	several
PB Japan	yes	0
World	No	11

Discussion-1

- **The system of preregistration for hematopoietic stem cell (BM & PB) family donors has worked under the collaboration of the participating institutes. The frequency and the severity of adverse events were, so far, not significantly different between BM and PB donors.**

Discussion-2

- **The fact that no life-threatening acute adverse events have been observed in this study suggests that pre-registration of donors with eligibility criteria is useful to prevent such events.**

Introduction of Tiny Booklet for donors

Our prospective survey revealed that certain acute severe adverse events occurred even in donors who had been confirmed to be healthy at the time of donation. However, no mortality cases were found so far, suggesting that the pre-registration system with its standards for donor eligibility has been effective in preventing real life-threatening adverse events. The results of the annual health check for 5 years showed that the incidence of hematological malignancies among PBSC donors was not high compared with that among retrospectively surveyed bone marrow donors.

Introduction of Tiny Booklet for donors

- **To elucidate the frequencies of short and long-term effects of HSCT harvest, international systematic survey is warranted and we proposed “Tiny Booklet for donors ” which will help donors to received the appropriate treatment and also will help docors to collect the data of adverse events.**



The Japan Society for Hematopoietic Cell Transplantation

骨髄・末梢血幹細胞 ドナー手帳

初版
(2010.06.21)最終修正

案

一般社団法人日本造血細胞移植学会
財団法人骨髄移植推進財団

目次 1/2

ドナーの方へ	3
1. この手帳の目的と使い方	4
2. ドナー(あなた様)の情報	5
3. 連絡方法(血縁ドナーの方)	6
(非血縁ドナーの方)	7
4. 主として採取・移植施設以外の医療関係者の方へ	8
5. 骨髄提供スケジュール表	10
6. 末梢血幹細胞提供スケジュール表	11
7. 骨髄・末梢血幹細胞採取前にお願しいたいこと	12~16
8. 骨髄提供について	
(1) 自己血採血について	17~19
①採血前の注意	
②採血当日の注意	
③採血後の注意	
(2) 骨髄採取の方法	20

Collaborators

- **Donor Committee JSHCT 2000~2007**
- Koderu Y, Asano S, Ikeda Y, Imamura M, Kato S, Kawa K, Tanimoto M, Dohy H, Nakahata T, Harada M, Morishima Y, Kanda Y, Shiobara S, Tanosaki R, Mitamura M, Yamamoto K
- **Donor Committee JSHCT 2008~**
- Suzuki R, Miyamura K, Nagafuji K, Hino M, Kim S, Mitamura M,
- Isogawa E, Kanemoto M
- **Donor Registration Center**
- EPS Co.
- **Japan Marrow Donor Program**
- **Grant-in-aid** for Human genome, Tissue engineering and Regenerative medicine , 2000~2007, **Ministry of Health, Labor and Welfare, Japan**
- **Grant-in-aid** for prevention and treatment for immunoallergy disease , 2008~2011, **Ministry of Health, Labor and Welfare, Japan**

