

Donating once – Saving two lives

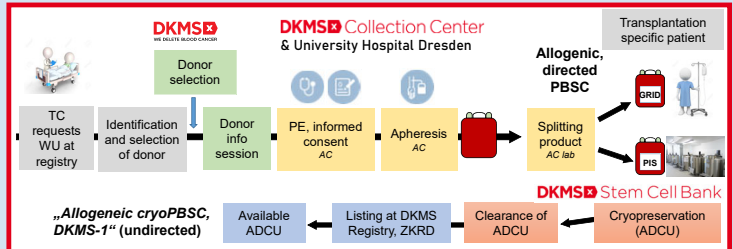
Adult donor cryopreserved units (ADCU) from the donor center perspective

Deborah Buk¹, Christian Welker³, Jürgen Sauter³, Karin Büttner², Gero Hütter⁴, Kristina Hölig⁵, Alexander Platz², Alexander H. Schmidt^{2,3}

¹DKMS Donor Center gGmbH, Tübingen, Germany; ²DKMS Stem Cell Bank gGmbH, Dresden, Germany; ³DKMS Group gGmbH, Tübingen, Germany; ⁴DKMS Collection Center gGmbH, Dresden, Germany; ⁵University Hospital Carl Gustav Carus, Medical Clinic I, Dept. of Transfusion Medicine, Dresden, Germany

Introduction

Many unrelated donors for PBSC collections have high CD34⁺ counts in the peripheral blood at start of apheresis, resulting in a CD34⁺ yield exceeding the amount requested by the transplant center (TC) significantly. In a defined setting, such products are split in the laboratory of the apheresis center (AC) and cryopreserved as undirected ADCUs at DKMS Stem Cell Bank. Here, we present the experiences we gained in the first 6 months of ADCU manufacturing from the donor center perspective.



Donor selection

- An algorithm checks whether a donor could be a candidate for an ADCU collection for each donor at DKMS Germany who is requested for PBSC.
- When eligible, donors are informed in the standard information session at workup that they are candidates to donate two products within their regular donation process.
- For that purpose, they have to be scheduled in specific ACs that hold respective approvals by authorities.
- At physical examination, the AC physician counsels the donor and retrieves additional consent for an ADCU donation.

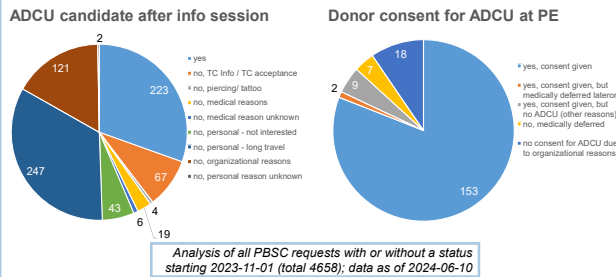
Donor	male	female
Age	≤ 40y	≤ 30y
Weight	≥ 70kg	≥ 60kg
HLA-type	1-20,000, 5-loci high res	

- Weight difference between donor and intended recipient
- No donor exclusion criteria/ need of special TC acceptance (according to guidelines of BÄK and approvals according to §25 AMG)

Donor experience

Donor safety throughout the whole collection procedure as well as the realization of the targeted PBSC product always have the highest priority and are not compromised by ADCU manufacturing. Safety for donors is ensured by strictly applying standard apheresis protocols. ADCUs are only manufactured if both products can be collected in one collection day without complications.

Candidates for PBSC with ADCU



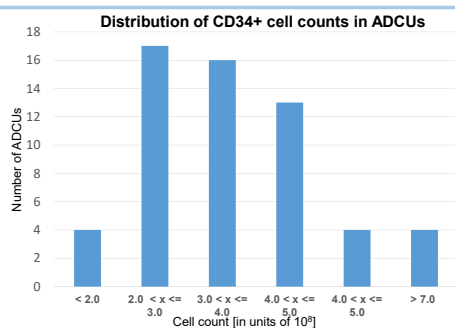
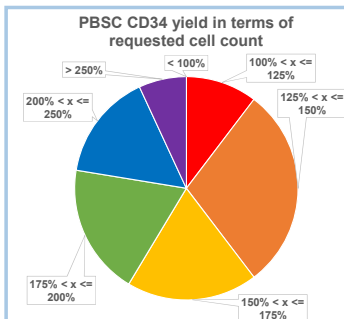
- By the algorithm, in approximately **16%** of all PBSC requests, the donor could potentially donate an ADCU.
- Donors are **motivated** to donate an ADCU (30.5%) and only a few are not interested (5.9%). Mostly, an ADCU could not be planned due to **organizational reasons** (too long travel time to AC 33.7%; capacity in AC/SCB 16.5%) and medical reasons 13.1%.
- At PE, **no donor declined** due to personal reasons. 86.8% signed the consent for ADCU at PE. Exclusions occurred due to medical or organizational reasons.

Donor ethics & safety

- Only **PBSC** collections
- Only within directed collection for a specific patient
- Prolonged apheresis** (max. 5h or 4-fold processed blood volume)
- No additional dose** of G-CSF
- Only if **good mobilization** and enough stem cells for two products can be collected in **one day**
- Only with **explicit consent** of the donor
- Thrombocyte counts ≥ 200,000/μl
- Venous status that allows sufficient flow velocity
- CD34⁺/CD45⁺ cell counts (on day of apheresis from donor blood)
- Continuous monitoring of general condition and well-being of donor during whole apheresis

Safe collection for the donor and priority of the directed donation.

Directed PBSC and undirected ADCUs



- All directed products were procured to the transplant center with at least the requested cell dose but the **majority contained much more CD34⁺ cells** than requested although an additional ADCU was obtained.
- Majority of ADCUs contained **over 2x10⁸ CD34⁺ cells**.
- Apheresis length was 3-5h in 84.5% of the cases (data not shown).

Analysis of 58 collections with ADCU 2023-11-01 to 2024-04-30

Conclusion

Up to now over 70 donors have consented and successfully donated for their patient and also for an ADCU. After the first 6 months of ADCU production, we show that all directed fresh PBSC stem cell products were procured with sufficient surplus CD34⁺ cells and that most of the ADCUs were stored with good cell counts – ready to be requested, shipped and transplanted. Length of aphereses were within normal ranges showing that with our donor selection we indeed approached donors with very good mobilization during G-CSF treatment and donor safety is ensured. When approached, donors react positively and only in rare cases are not interested but are rather highly motivated to donate an ADCU as well and help giving even more patients a second chance at life especially when time to transplant is crucial.

