



# **Impact of the SARS-CoV-2 Pandemic on HPC Donation and Transplantation**

EC Tissue and Cell Competent Authority meeting on COVID-19

2020-05-19

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# Impact of the SARS-CoV-2 Pandemic on HPC Donation and Transplantation

## Situation report

- Registries and Donor Centres
- Transports
- Collection units
- Donor safety and availability
- Cryopreservation

## Mitigation and potential actions on EU level

# Situation Report

Status 2020-05-19



## Situation in Donor Registries and Donor Centres

**Donor Registries and Donor Centres are fully operational for unrelated HPC donor searches and requests** and have been throughout the crisis even in heavily affected regions such as Northern Italy and the United Kingdom.

*Prolonged* restrictions could result in attrition of donor and financial base.

- Donor registry and donor centre staff is working from home since March 2020, with the exception of the medical staff and transport coordinators.
- No profound impact of COVID-19 infections on staff availability.

### **Pay attention to:**

- Less effective donor recruitment: donor recruitment is limited to online registration; no public donor drives (essential for recruiting underrepresented groups such as young males, ethnic minorities)
- Financial situation for registries and donor centres: increasing costs (IT hardware and licenses, personal protective equipment, tests, higher donor travel and accommodation costs), while simultaneously facing a (moderate) drop of requests and a (sharp) drop in money donations

# Transport between EU Member States and to EU Member States

**Exceptional international cooperation between EU SoHO team, Competent Authorities, WMDA, donor registries/donor centres, transplant centres, as well as courier companies and airlines resulted in working solutions for transports worldwide.**

New, alternative shipping options have been established in minimal time.

- Border closings
  - ⇒ Handover at airport hubs (Rome, London)
  - ⇒ Handover at the Polish-German border was established on March 16<sup>th</sup> to facilitate ground transport of hematopoietic stem cells to and from Poland, transit e.g. to Lithuania
  - ⇒ CDC travel waiver for European couriers travelling to United States
  - ⇒ EU travel waiver for couriers of SoHO, preceded by national waivers in European countries
- Passenger flight restrictions and widespread cancellations
  - ⇒ Products are handed over by freighter aircraft crews (current standard to transport hematopoietic stem cells from Europe to the United States)
- Cryopreservation at collection centre and unaccompanied shipping in dry shippers

# Transport – challenges observed

**Transport situation is generally stable, but far from optimal.**

Products arrive as scheduled, but not always under required conditions.

- Damage to cryopreserved hematopoietic stem cells during shipment
  - ⇒ Ongoing investigation of 3 incidents



Ruptured cryobag



Partial thaw; -37° instead of -150°C on arrival

- Prolonged transport times due to drastically reduced flight connections
  - ⇒ Even in excess of 72 hours
- Unclear sustainability of courier operations if staff is placed under quarantine after return (many couriers are volunteers)

# Collection Centres

**Due to protective measures such as screening donors before admission, personal protection equipment, and contingency planning, PBSC collection capacities could be maintained.**

Bone Marrow collections were locally not feasible during COVID pandemic.

- Bone Marrow Collection requires more staff and ICU care / ventilators. There is a limited capacity especially for collection centres at primary care hospitals. Bone marrow collections should be reserved for those donors or patients where bone marrow offers a clear benefit over PBSC.
- The percentage of bone marrow donations dropped >50% compared to Jan / Feb 2020 (DKMS 8% in April vs 17% on average 2019).
- Only moderate decrease of PBSC collections, *if at all* (DKMS +5% in March, -10% in April; Easter?)
- All collection centres screen donors for COVID-19 symptoms before admission; where required by local policies, healthy donors are tested for SARS-CoV-2.
- Some collection centres do not allow companions in the collection centre.
- WMDA has not received reports about SARS-CoV-2 transmission from donors to collection unit staff or vice versa.

## **Pay attention to:**

- Many transplantations only *postponed*; unclear if capacities will suffice in the coming months, especially for bone marrow collections.

## Donor safety and availability

**Donors stay highly committed. Donor safety is ensured by consistent eligibility guidelines and minimizing risk exposure.**

### **WMDA recommendation** [Novel Coronavirus - SARS-CoV-2 & COVID-19](#)

- Donors with confirmed SARS-CoV-2 infection must not donate and should be deferred for at least 28 days after full recovery.
- Donors with COVID-19 symptoms or risk exposure will be tested and/or deferred.
- To avoid unnecessary blood draws and contact to health providers, some donor registries and donor centres have implemented Health & Availability Check. In that case the donor donates blood for confirmatory typing at work-up stage instead of verification stage. In some countries the Health & Availability Check is the only option to proceed.
- Local collection or adapting travel and accommodation standards, e.g., issue personal protection equipment.
- WMDA has no reports of donor harm due to COVID-19.

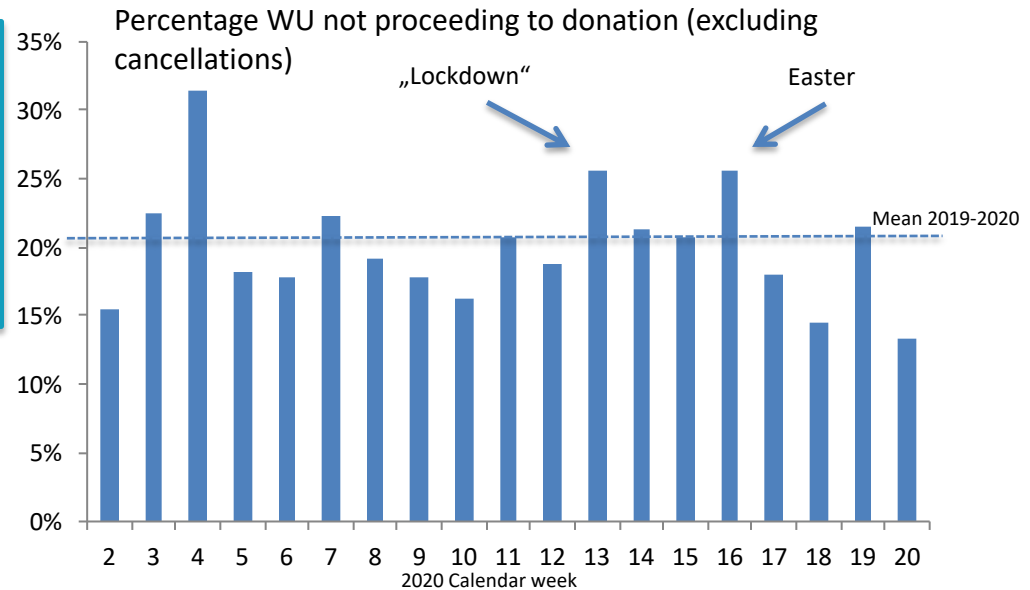


# Donor availability, work-up (WU) cancellations and postponements

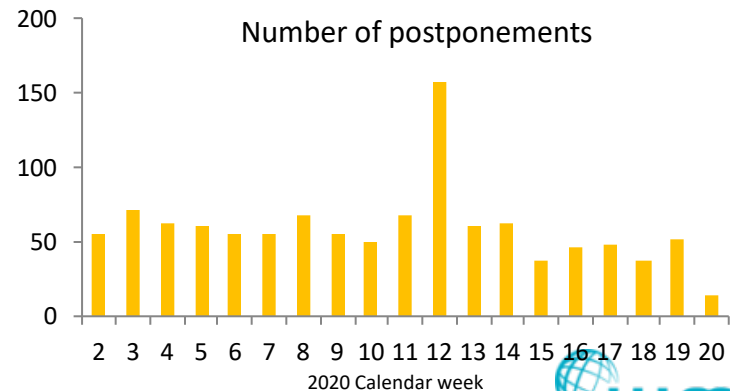
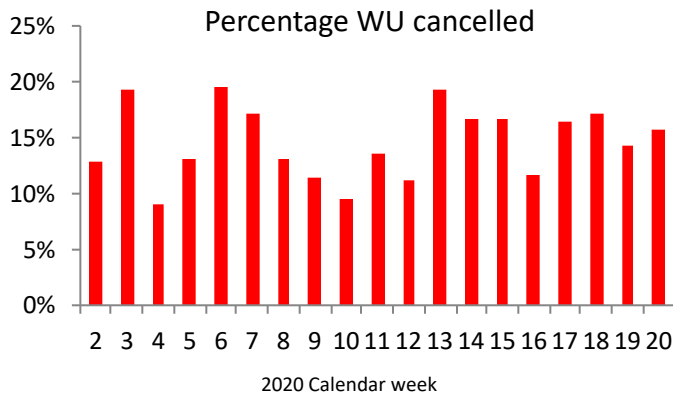
(all figures DKMS Germany) CA = Cancellation, NI = Not Interested (withdraw), TU = Temporally Unavailable, DD = Donor Deferred

**Donor availability not significantly affected in Germany.** Similar situation in Poland and UK, with a more pronounced impact in the week after lockdown.

- Increased not *interested/temporally unavailable* rates in week 13 („Lockdown“ in Germany)
- Moderate effect only; compared to Easter
- No significant increase in *medical temporarily unavailable or donor deferred*
- One (1) donor tested positive on day 3 G-CSF (no symptoms, tested after South Tyrol (Austria) was announced as risk area), donation aborted (back-up donation within days)



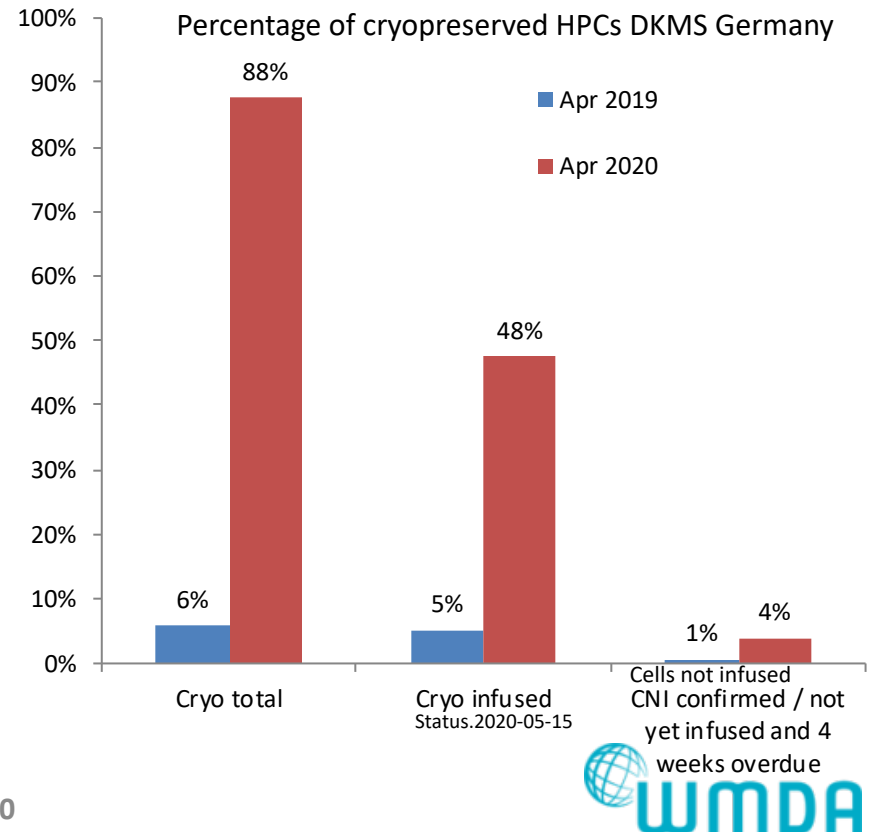
Few work-ups entirely cancelled, many postponements the week after border closings



# Cryopreservation – benefits and potential risks

**Pre-planned cryopreservation will allow patient conditioning to be withheld until successful donation and delivery are confirmed.** Cryopreservation at the collection centre may have additional advantages in relation to transport delays and travel restrictions. „Cryo-quarantine“ of blood products is *not* generally recommended by transfusion / transplant societies and competent authorities, such as FDA or RKI.

Benefit	Disadvantage / Risk
Arrival ensured before conditioning	Delayed transplantation
Cell count / viability determined before conditioning	Cell count determination after thawing difficult, especially Total Nucleated Cell Count
	<b>Cell count / viability losses, especially for Bone Marrow, after long shipping times, less experienced centres</b>
	Collection before final assessment, if recipient can proceed to transplantation
	Reactions to DMSO during transfusion
	Bone Marrow and PBSC products are intended for <i>immediate</i> use by EU legislation, and if not they require a SEC
	Unnecessary donation (next slide)



## Cryopreservation – ethical dimension

Hematopoietic stem cell donations are not a commercial, pharmaceutical product, but an altruistic gift. Willingness for volunteer donation is based on the general consensus a product will be used for transplantation into a patient unless something *unexpected* and *unavoidable* occurs.

Every donation, unrelated or related, means burdens such as pain, uncertainty, and organizational efforts for the donor.

**Every unnecessary donation, unrelated or related, means unnecessary burdens such as pain, uncertainty, and organisational efforts for the donor.**



“Unnecessary Donor Burden” is classified as *Harm to a Donor* by WMDA’s S(P)EAR Committee.

## Cells not infused – reasons provided

- Product will not be used due to cell count as low as *anticipated* after thawing

⇒ **WMDA alert:** Assess the feasibility of the request of the transplant centre before collecting the product.

- Product will not be used due to cell count substantially lower than expected after thawing

⇒ **WMDA alert:** Repeat testing, check if it is feasible that the donor donates for a second time

- Product will not be used due recipient condition deteriorated

⇒ Prolonged interval from donation to scheduled transfusion, recipient only administered and examined *after* collection

- Product will not be used due to donor being tested positive for SARS-CoV-2 after donation / suspected COVID-19

⇒ No scientific evidence for transmission via blood products!

# Mitigation, and potential actions on EU level

## ➤ **Re-assess recommendations on cryopreservation**

- ⇒ Should reflect actual situation, not worst case scenarios
- ⇒ If transport and donor availability is reasonably safe, 'fresh' products could be considered as standard procedure again

## ➤ **Cryo-quarantine of hematopoietic stem cell products**

- ⇒ Not recommended by professional societies
- ⇒ Especially since / if other blood products are not to be quarantined / donors tested
- ⇒ No scientific evidence of Corona virus transmission via blood
- ⇒ First data suggests that transplant recipients are *not* a specific risk group

D'Antiga L. Coronaviruses and Immunosuppressed Patients: The Facts During the Third Epidemic [published online ahead of print, 2020 Mar 20]. Liver Transpl. 2020;10.1002/lt.25756. doi:10.1002/lt.25756

## **Working towards an updated ECDC/EU recommendation?**

Cf. Directive 2014/110/EU on WNV

- More flight connections will mitigate shipping times
- Easier access to personal protection equipment



Thank you for your attention.

Questions:  
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