

TRANS

POSE

Grant Agreement 738145

TRANSfusion and transplantation PrOtection and SElection of donors



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TRANSPOSE

*(TRANSfusion and transplantation: PrOtection
and SElection of donors)*

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The Netherlands

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Objectives

TRANSPOSE aims at a structured, alternative approach to construct risk-based Guidelines and a standard DHQ for the procedures used to collect SoHO, including the selection and protection of donors.

The objective of this action is:

- To collect and compare EU and national donor selection and protection criteria;
- To identify the information needed from donors or their families to allow the application of appropriate donor deferral or exclusion criteria for the protection of recipients; and
- To propose approaches to control and minimise these risks.

Work Packages

There are three horizontal work-packages (WPs);

- Coordinating,
- Disseminating, and
- Evaluating the project.

Four **technical** ones with specific deliverables and milestones to be regularly produced, according to the Grant Agreement.

Work Packages

WP Number	WP Title	Lead Beneficiary
WP1	Coordination of TRANSPOSE	Sanquin Blood Supply
WP2	Dissemination of the results of TRANSPOSE	Centro Nazionale Sangue
WP3	Evaluation of TRANSPOSE	Établissement Français du Sang
WP4	Inventory of Donor Selection & Protection Practices	University of Cambridge
WP5	Development of Donor Selection & Protection Guidelines	Region Hovedstaden Denmark
WP6	Development of a Standard Donor Health Questionnaire	University of Hamburg
WP7	Training Course/Workshop on the Use of the Guiding Principles	Établissement Français du Sang

WP4 (University of Cambridge)

Inventory of Donor Selection & Protection Practices

Leader: Emanuele di Angelantonio

- Questionnaires to experts about current practices donor selection and protection (all SoHO)
- In-depth inventory of current practices donor selection and protection
- Overview of similarities and differences

Completed

WP4 - Inventory of Donor Selection & Protection Practices

- In-depth semi-structured interviews with key stakeholders in blood, plasma, stem cell, ART, and tissue collection were conducted to identify main topics for improvement in the current DSC.
- A survey was sent to professionals from collection institutions of all SoHO to get feedback on current systems from as many EU-MS organizations as possible. Questionnaires were sent to a total of 163 experts
- (40 blood; 40 plasma; 27 tissues; 47 stem cells; 9 ART) and 39 (24%) completed questionnaires were received. Where information was lacking, additional experts were asked to recommend upon DSC.

WP4 – Interview Results

- DSC are perceived redundant on a substantial number of aspects
- Besides achieving the goal of save and sufficient SoHO for patients, many regulations could be improved to diminish deferrals and decrease donor risks.
- TRANSPOSE will add to reviewing, improving and harmonizing these regulations and criteria.
- Furthermore, TRANSPOSE will provide suggestions to improve directives and guidelines and a DHQ, focusing on both donor health protection and safety of donations, but also removing deferral criteria that are not relevant (anymore), and offer a future research agenda to make DSC more evidence-based.

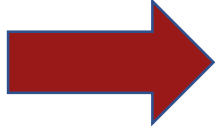
WP5 (Regio Hovedstaden Denmark)

Development of Donor Selection & Protection Guidelines

Leader: Henrik Ullum

- Critically reviewing risks both donors and recipients (scientific paper) (June 2018)
- Assess those risks in a workshop to produce guiding principles on eligibility criteria (October 2018)
- Finalise risk-based donor selection and protection criteria in a workshop (April 2019)
- Final guiding principles for critical evaluation of existing donor eligibility criteria and development and validation of emerging eligibility criteria (June 2019)

WP5 - Development of Donor Selection & Protection Guidelines

- During workshops, it became clear that there were diverging opinions across members on certain criteria and that there was a wide lack of evidence.
- The decision was then to re-assess all items in the current criteria in order to propose expert-based or evidence-based recommendations in the WP5 deliverables, namely the Donor Selection & Protection Guidelines.
-  Risk assessment method, used per risk for all SoHO
- This process has recently been completed and in the April TRANSPOSE meeting we will be beginning to write up the Guidelines which will be submitted also as a scientific paper.

WP6 (University of Hamburg)

Development of a standard Donor Health Questionnaire

Leader: Michel Clement

- Draft of first version of a standard donor health questionnaire (February 2019)
- Validated draft version of a standard DHQ (April 2019)
- Availability of standard DHQ and modules in principle languages

WP6 - Development of a standard Donor Health Questionnaire

Development of DHQ is defined by several steps:

- Ask experts what is currently lacking (done via WP4 questionnaire)
- Develop the standard DHQ:
 - Database of basic questions which must be asked:
 1. General module (common trunk)
 2. Country & SoHO specific questions (customization)
 - How different risks should be assessed through different types of questions?
 - Decide between paired vs. individual risk assessment?

WP7 - Training the use of the Donor Selection & Protection Guidelines

Leader: Sylvie Gross (EFS - Établissement Français du Sang)

- WP7 has recently commenced and started working on the draft version of the TRANSPOSE Educational Framework.
- Constructing the training content for teaching on the guiding principles, Guidelines, and DHQ. The first TRANSPOSE Educational Workshop has been planned as a pre-meeting for the final TRANSPOSE Meeting on 25 September 2019.

Focus on Donor Protection

- So far, much of the work has been on inventory, but we are now starting to apply what we have learned from the expert interviews into creating items which will focus on donor selection and protection:
 - Our take is that donor protection should begin from the start – thus we propose a more in-depth risk assessment method from the beginning and starting with new donors.
 - Inventory of yet unknown/ theoretical risks for donors and those risks that have not been properly investigated
 - Also a more harmonised risk based assessment method. To develop this, we are modifying and simplifying the ABO tool that is developed for risk assessment.

Next Steps

- The first draft of the WP6's Donor Health Questionnaire has been completed in February 2019 and will be validated during the TRANSPOSE April meeting in Amsterdam.
- WP5 will begin writing up their work in order to develop the Donor Selection & Protection Guidelines.
- WP3 has begun work on the TRANSPOSE interim evaluation report. This will be completed by the end of March.
- WP7 will be presenting the draft version of their Educational Plan at the April 3rd meeting in Amsterdam.

Thank you for your attention!

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Acknowledgement: Gaia Mori and Transpose team

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