THERAPEUTIC PHLEBOTOMY AND BLOOD DONATION IN PATIENTS WITH HEREDITARY HAEMOCHROMATOSIS AND ERYTHROCYTOSIS: A 15 YEAR REVIEW IN THE WESTERN CAPE REGION OF SOUTH AFRICA

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Background

- WPBTS has accepted therapeutic donations for clinical use since the early 1990’s. Therapeutic donors are referred to donate blood to assist in the management of medical conditions such as Erythrocytosis and Hereditary Haemochromatosis (H/H).

- Phlebotomy is often the treatment of choice for these conditions and with an effective therapeutic phlebotomy programme we are able to assist these donors and contribute to the blood supply.

- Policies vary regarding the use of blood from therapeutic phlebotomies and are based either on legislation or are determined by individual blood services.
Background continued

• In the 1970’s, the higher prevalence of post transfusion hepatitis from paid donors resulted in a voluntary only system and a reduction in post transfusion hepatitis.

• The advent of HIV in the 1980’s again highlighted the importance of voluntary donations.

• Concern has been raised that therapeutic donations are not altruistic, voluntary donations as they are beneficial to the donor and therefore less safe than voluntary donations.
The objectives of this retrospective study were to:

• Summarise our experience of utilising blood collected via our therapeutic phlebotomy programme for the period 1st January 2000 - 31st December 2014.

• Confirm that therapeutic donations do not present a threat to the safety of the recipients of these units and are therefore as safe as the voluntary supply.
New therapeutic donors registered
Therapeutic phlebotomy criteria

• Donors must enrol on the therapeutic phlebotomy programme when blood donation is prescribed by a clinician as a form of treatment for a medical condition.

• The following question on the donor questionnaire alerts staff to therapeutic donors:

  “Has your doctor ever advised you to donate blood for medical reasons (high iron, “thick blood”, polycythaemia or haemochromatosis)”?

• Donors must meet the specific requirements of the programme.

• Must adhere to routine donor acceptance criteria.
Therapeutic phlebotomy criteria continued

• Therapeutic donors complete the donor questionnaire at each donation.

• Therapeutic staff individually interview donors at the first donation and emphasise blood safety.

• A file is kept for each therapeutic donor and individual, computerised instructions are in place.

• Specific work instructions and documentation is utilised.

• Donations are screened for transfusion transmitted infections (TTIS): HIV, HBV, HCV and Syphilis.
Therapeutic phlebotomy criteria continued

Defined criteria in The Standards of Practice for Blood Transfusion in South Africa are followed:

- Therapeutic phlebotomy is only performed when prescribed by the patient’s physician and with the consent of the Medical Director (MD)/Medical Officer (MO).

- Acceptance criteria for therapeutic donors may differ from those of allogeneic donors.

- Individuals with haemochromatosis/secondary polycythaemia may become allogeneic blood donors with the consent of the MD/MO.
• Units classified as therapeutic phlebotomies for Primary Erythrocytosis (polycythaemia vera) and High Affinity Haemoglobin are not used for allogeneic transfusion.

• The first unit of blood drawn is not used for transfusion.

• The attending physician or MD/MO determines the bleeding intervals for therapeutic donors.

Materials and Methods:

Referring clinician must provide the following referral information:

• Completed WPBTS therapeutic phlebotomy referral form.
• Supporting blood test results.
• Health conditions/medications.
• Medical reports.
• Phlebotomy intervals required.

Transfusion medical specialist (TMS) oversees the programme. Acceptance is based on:

• Presenting diagnosis.
• Health conditions/medications.
• WPBTS routine donor acceptance criteria.
Materials and Methods:

Haemochromatosis
- PCR for Haemochromatosis
- Ferritin + Iron Profile (and after every 6th donation)
- Liver functions if ferritin >1000ug/L

Secondary polycythaemia
- 2 full blood counts taken one month apart

Polycythaemia Vera
- JAK2 test
- 2 full blood count results

High affinity haemoglobin
- p50 result
- 2 full blood count results
### Data from 1\textsuperscript{st} January 2000 - 31\textsuperscript{st} December 2014

<table>
<thead>
<tr>
<th>Hereditary Haemochromatosis</th>
<th>Raised Ferritin - No PCR - PCR neg</th>
<th>Secondary Erythrocytosis</th>
<th>Polycythaemia Vera</th>
<th>High Affinity Haemoglobin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotyped</td>
<td>Liver biopsy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (1127)</strong></td>
<td>455 (40.4%)</td>
<td>36 (3.2%)</td>
<td>307 (27.3%)</td>
<td>264 (23.4%)</td>
</tr>
<tr>
<td><strong>Male (901)</strong></td>
<td>336</td>
<td>29</td>
<td>258</td>
<td>229</td>
</tr>
<tr>
<td><strong>Female (226)</strong></td>
<td>119</td>
<td>7</td>
<td>49</td>
<td>35</td>
</tr>
<tr>
<td><strong>Mean age at enrolment</strong></td>
<td>47.2</td>
<td>46.3</td>
<td>50.8</td>
<td>50.8</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>47.8</td>
<td>45.7</td>
<td>51.1</td>
<td>50.4</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>45.5</td>
<td>49.1</td>
<td>47.8</td>
<td>51.3</td>
</tr>
</tbody>
</table>
Haemochromatosis: Genotype breakdown

- H63D/S65C
- C282Y/S65C
- H63D/H63D
- C282Y/H63D
- C282Y/-
- H63D/-
- C282Y/C282Y

[Bar chart showing genotype breakdown]
Results

1127 therapeutic donors donated 17 699 units of whole blood.

12 030 units (68%) were accepted for clinical use.
Results continued

- In 2014, therapeutic donations were 1.5% of the total collections.

- Donor satisfaction has been noted at our clinic:
  - thorough investigation is required before enrolment
  - contributing to the blood supply
  - phlebotomy by trained staff
  - consistent follow up
TTD marker prevalence was lower than the general donor population.

<table>
<thead>
<tr>
<th></th>
<th>HIV</th>
<th>HBV</th>
<th>HCV</th>
<th>TPHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence in</td>
<td>0</td>
<td>0.02</td>
<td>0</td>
<td>0.005</td>
</tr>
<tr>
<td>therapeutic donors (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Prevalence in</td>
<td>0.037</td>
<td>0.129</td>
<td>0.008</td>
<td>0.065</td>
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<tr>
<td>general donor population (%)</td>
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</tbody>
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Since 2009 WPBTS has obtained > 1000 donations annually from a cohort of donors with a low prevalence of TTD markers.
Conclusion

• The study has shown that an effective therapeutic phlebotomy programme ensures that therapeutic donations do not compromise blood safety.

• The study has also confirmed that therapeutic donors do not present a higher risk than the general donor population for TTIS.

• The mean age at enrolment of therapeutic donors is 44.9-61.8 years which is a lower risk age group in terms of TTIS in the general donor population.
Conclusion

• The increasing enrolment of therapeutic donors is evidence that this service benefits the therapeutic donors and the transfusion service.

• The target blood results and health benefits achieved for therapeutic donors assists in maintaining healthy donors for the future.

• Despite therapeutic donors not falling within the strict definition of altruistic, volunteer donors they select to have their phlebotomy via a transfusion service in order to assist the blood supply and not only themselves.
Thank you

- Sr Cindy Sims, WPBTS
- Anna Van Zyl, WPBTS
- Dr Arthur Bird, WPBTS
- Dr Caroline Hilton, WPBTS
- Dr Greg Bellairs, WPBTS