The influence and impact of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) on blood transfusion services in Africa

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Namibia’s transition from whole blood-derived pooled platelets to single-donor apheresis platelet collections

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5.1 Abstract

Background
Few African countries separate blood donations into components, however, demand for platelets is increasing as regional capacity to treat causes of thrombocytopenia, including chemotherapy, increases. Namibia introduced single-donor apheresis platelet collections in 2007 to increase platelets availability while reducing exposure to multiple donors via pooling. This study describes the impact this transition had on platelet availability and safety in Namibia.

Study Design and Methods
Annual national blood collections and platelet units issued data were extracted from a database maintained by the Blood Transfusion Service of Namibia (NAMBTS). Production costs and unit prices were analyzed.

Results
In 2006, NAMBTS issued 771 single and pooled platelet doses from 3,054 whole blood (WB) donations (drawn from 18,422 WB donations). In 2007, NAMBTS issued 486 single and pooled platelet doses from 1,477 WB donations (drawn from 18,309 WB donations) and 131 single-donor platelet doses. By 2011, NAMBTS issued 837 single-donor platelet doses per year; 99.1% of all platelet units. Of 5,761 WB donations from which platelets were made in 2006-2011, 20 (0.35%) were from donors with confirmed test results for HIV or other transfusion-transmissible infections (TTI). Of 2,315 single-donor apheresis donations between 2007-11, none of the 663 donors had a confirmed positive result for any pathogen. As apheresis replaced WB-derived platelets, apheresis production costs dropped by an average of 8.2% per year, while pooled platelet costs rose by an annual average of 21.5%. Unit prices paid for apheresis and WB-derived platelets increased by 9% and 7.4% per year on average, respectively.

Conclusion
Namibia’s platelet transition shows that collections from repeat apheresis donors can reduce TTI risk and production costs.

5.2 Background

In sub-Saharan Africa, most blood transfusions are performed with whole blood, and fewer than half of countries report separating any collected blood units into components. [1] Reasons for reliance on whole blood transfusions include transportation, inventory management and cold chain challenges, inadequate storage capacity, clinicians’ inexperience in the appro-
appropriate use of blood components, and limited financial resources to support blood component production facilities. [2-7] In developed countries, platelet transfusions are most frequently indicated for hematologic and oncologic conditions complicated by thrombocytopenia. [8-10] While obstetric hemorrhage, malaria-related anemia, and trauma have historically accounted for most transfusions in sub-Saharan Africa, increased numbers of patients with hematologic conditions and other malignancies are expected due to improved diagnostic and clinical capacity. [11-15] As blood banking capabilities in the region continue to develop, there has been growing emphasis on the preparation of blood components, including platelets, to effectively manage thrombocytopenia due to malignancy or chemotherapy-related complications. [16,17]

In Namibia, a medium human development index (HDI) country in southern Africa with a high HIV burden, the Blood Transfusion Service of Namibia (NAMBTS), a non-profit organization that funds the majority of its operations through a cost-recovery system, is the only entity authorized to collect, process and distribute blood and blood components, including platelets. Nearly all transfusions in the country occur with components rather than whole blood. NAMBTS only collects blood from voluntary, non-remunerated blood donors (VNRD) and prepares platelets from repeat VNRD who have made at least two previous donations, a group considered at lowest risk for HIV infection. [18,19]

The country has relatively small numbers of cancer diagnoses annually. Between 2006 and 2011, the Cancer Association of Namibia (CAN) documented 13,652 new cases of adult cancers (unpublished data, CAN). Patients have historically been referred to neighboring South Africa for treatment, [20-22] however, increasingly, therapy for hematologic and other malignancies is provided in Namibia. [20] To meet the national demand for platelets, NAMBTS initially prepared whole blood-derived (WB-derived) platelets using the buffy-coat method. [23] In 2007, however, NAMBTS procured apheresis equipment and began single donor apheresis platelet collections. The decision to transition from WB-derived platelets pooled from several donors to single-donor apheresis platelets was driven by concern about Namibia’s high HIV population prevalence, estimated at 13.1% (range: 11.1%-15.5%) during the study period, [24] and a desire to reduce the risk of transfusion-transmitted infections (TTI) associated with exposure to multiple donors. [25]

While Namibia’s annual production of platelets is small compared to industrialized countries, the evolution of NAMBTS’s platelet collection and production practices may provide useful lessons for other countries in the region considering implementing or expanding platelet production. This assessment of Namibia’s transition to apheresis platelet collections confirms the increased safety of highly regular apheresis donors, a rare group of repeat blood donors in sub-Saharan Africa, and quantifies and describes the current demand for platelets in an African healthcare system. Finally, investments in apheresis platelet production in Namibia have had important cost and sustainability implications for Namibia which may be relevant to other countries in the region.
5.3 Materials and Methods

Approval was obtained from the Namibian Ministry of Health and Social Services (MOHSS) prior to data collection. Because data were collected as part of routine public health program activities, the project was exempted from review by an institutional review board by the U.S. Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, USA.

Study sites and data collection
Demographic, clinical and laboratory data are routinely collected on all NAMBTS blood donors, including the type of collection (whole blood or apheresis), infectious disease screening results, the number of previous donations, and the number and type of components produced from each collection. Some limited information on transfusion recipients, including diagnosis and patient demographics, is regularly recorded on blood request forms, which were last updated in 2007. Blood donor, laboratory screening, and platelet production data are stored in an electronic, NAMBTS-designed SQL database, which also captures information on blood requests from facilities.

To describe the transition of platelet production from whole blood collections to apheresis, and to calculate the prevalence of transfusion-transmissible infections (TTI) among the two groups of platelet donors, a dataset containing information on donor demographics, donation type (whole blood or apheresis), and TTI results was extracted from the database for all donations between January 1, 2006 and December 31, 2011.

A pooled adult platelet dose is prepared by combining five WB-derived platelet units resulting in a product with an average volume of 275-300 ml and expected platelet count of >240 x 10^9/L. A pediatric dose is a single, un-pooled, WB-derived platelet unit with an average volume of 50-60 ml and a platelet count of >55 x 10^9/L. An adult apheresis dose is collected from a single donor in 200-300 ml bags using Haemonetics MCS+9000 apheresis equipment (Haemonetics Corporation, Braintree, MA, USA) and has an expected platelet count of >300 x 10^9/L. All platelets are collected and produced at the NAMBTS blood center in Windhoek.

All TTI screening was performed by the South African National Blood Service (SANBS), which uses an algorithm combining immunoassays and individual-donation nucleic acid tests (ID-NAT) for HIV, HBV and HCV screening and confirmatory testing, and Treponema pallidum Hemaglutination Assay (TPHA) for syphilis screening. [26] An infected donor was defined as a platelet donor with a confirmed laboratory result for at least one of the four pathogens.

Blood request data, including underlying patient diagnoses, are captured by blood banks nationally and returned on a routine basis to NAMBTS headquarters. For this study, the total number of all platelet units requested and issued to healthcare facilities nationally were extracted for all years (2006-2011). To describe national demand for platelets, four years (2007-2011) of electronic platelet request records that included patient diagnosis information were reviewed. The standardized national blood request form requires physicians to enter a di-
agnosis for each patient, but physicians are not required to use a standard set of diagnostic codes or terms. For this analysis, >200 individual diagnoses entered by physicians were reviewed by one of the co-investigators (S. Basavaraju) and grouped into 20 broad diagnostic categories defined by the WHO International Classification of Disease system (ICD-10). [27]

To evaluate the impact of introducing apheresis collections on unit prices charged to public sector hospitals via the NAMBTS cost-recovery system, invoice data were extracted from an electronic accounting system used by NAMBTS. The analysis was limited to the public sector since MOHSS-operated facilities accounted for an average of 77% of all platelet units issued each year. Prices are set annually by NAMBTS in consultation with the MOHSS and are derived from a costing algorithm that divides the sum of all production costs (including waste) minus any non-cost-recovery revenue (e.g., external grants) by the total number of platelet units produced each year. [28] Pooled platelet costs and prices were analyzed for 2006-2011. Because the accounting database does not match the calendar year, 2008 was the first full year for which apheresis unit costs and prices were available for analysis. All analyses were conducted using unadjusted Namibian Dollars. Average annual US Dollar exchange rates are provided in Table 1.

Data were stratified by sex, age, type of donation, and year. Descriptive and statistical analyses were calculated with computer software (Microsoft Excel, Microsoft Corp., Seattle, WA; Stata 13.1, StataCorp., College Station, TX) National population estimates were drawn from the Namibian Central Bureau of Statistics. [29]

5.4 Results

Donor demographics
Between 2006 and 2011, NAMBTS produced WB-derived PLT units from 4173 WB donors. Of these, 2473 (59%) were males; the mean age was 40.1 years (range, 16-73 years). From 2007 to 2011, a total of 663 donors made apheresis PLT donations. Of these, 399 (60.2%) were males; the mean age was 43.2 years (range, 19-66 years). From 2006 to 2011, a total of 5761 WB donations from 4173 donors were converted into PLT units. Among this donor pool, the mean number of donations per donor per year was 1.2 (range, 1.5 in 2006 to 1 in 2011). By contrast, among apheresis PLT donors, a mean of 5.0 donations were made per year between 2007 and 2011 (range, 2.9 in 2007 to 6.7 in 2010). From 2006 to 2011, of 5761 WB donations from which PLT units were derived, 20 (0.3%) were from donors with laboratory confirmed results for one or more TTIs (Table 1). Of these, 12 donations (60%) were from male donors. No confirmed TTIs were detected among 663 apheresis PLT donors between 2007 and 2011 (Table 1).

Incidence rate and residual risk
Between February 1, 2012, and June 30, 2013, the alternative period for which person-years of
Table 1: Change in platelet production costs and unit prices, Namibia, 2006-2011

<table>
<thead>
<tr>
<th>Type of platelet unit (type of donation)</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>Average annual change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult WB-derived (5 pooled WB donations)</td>
<td>Production cost (N$ per unit)*</td>
<td>1,933.40</td>
<td>2,677.54</td>
<td>1,986.10</td>
<td>2,786.30</td>
<td>3,213.96</td>
<td>4,475.78</td>
</tr>
<tr>
<td>Sales price (N$ per unit)</td>
<td>2,433.00</td>
<td>2,433.00</td>
<td>2,676.80</td>
<td>2,945.00</td>
<td>3,181.00</td>
<td>3,467.30</td>
<td>7.4%</td>
</tr>
<tr>
<td>Pediatric WB-derived (1 WB donation)</td>
<td>Production cost (N$ per unit)</td>
<td>385.35</td>
<td>536.56</td>
<td>397.93</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sales price (N$ per unit)</td>
<td>404.00</td>
<td>404.00</td>
<td>444.80</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5.0%</td>
</tr>
<tr>
<td>Adult apheresis (single donor donation)</td>
<td>Production cost (N$ per unit)</td>
<td>-</td>
<td>-</td>
<td>3,034.83</td>
<td>2,738.58</td>
<td>1,822.47</td>
<td>2,159.73</td>
</tr>
<tr>
<td>Sales price (N$ per unit)</td>
<td>-</td>
<td>-</td>
<td>2,676.80</td>
<td>2,945.00</td>
<td>3,181.00</td>
<td>3,467.30</td>
<td>9.0%</td>
</tr>
<tr>
<td>Pediatric apheresis (single donor donation)</td>
<td>Production cost (N$ per unit)</td>
<td>-</td>
<td>-</td>
<td>349.46</td>
<td>453.32</td>
<td>358.96</td>
<td>614.86</td>
</tr>
<tr>
<td>Sales price (N$ per unit)</td>
<td>-</td>
<td>-</td>
<td>444.80</td>
<td>489.40</td>
<td>529.00</td>
<td>576.70</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

* During the study period, the annual Namibian Dollar - US Dollar exchange rate averaged N$7.5 to the US Dollar.
exposure were available for all donor records, 903 apheresis and 17,330 eligible WB donations were made in Windhoek. Among the 17,330 WB donations that met the eligibility criteria to be selected for buffy coat pooled PLT production, HIV, HBV, and HCV infections were confirmed by ID-NAT in 10 (0.06%), two (0.01%), and zero (0.0%) donations, respectively. None of the 903 single-donor apheresis donations had an ID-NAT confirmed-positive result for any of the three viral markers (Table 2). Incidence rates per 10,000 donations and residual risk estimates for each marker and the two donation groups are shown in Table 3.

Table 2: Disease prevalence among whole blood (pooled) and single-donor apheresis platelet donations, Namibia, 2007-2011

<table>
<thead>
<tr>
<th>Donation type</th>
<th>Number of Donations (N)</th>
<th>Confirmed HIV</th>
<th>Confirmed HBV</th>
<th>Confirmed HCV</th>
<th>Confirmed TPHA</th>
<th>Total confirmed TTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>5,761</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Single donor apheresis*</td>
<td>663</td>
<td>0</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0</td>
</tr>
</tbody>
</table>


In 2006, NAMBTS produced and issued 771 WB-derived platelet doses (341 pooled adult doses, 430 pediatric doses). Apheresis platelet collections were introduced in 2007. During that year, NAMBTS produced and issued 241 WB-derived platelet doses (218 pooled adult doses, 23 pediatric doses) and 245 apheresis platelet doses (130 adult, 115 pediatric). WB-derived pooled units were almost eliminated by 2011, when only eight pooled platelet units were issued nationally. By 2011, NAMBTS produced and issued 837 apheresis platelet doses (324 pediatric units, 513 adult units). As a proportion of all platelet units issued per year, single donor apheresis doses accounted for 37% (245/662) of all platelet doses issued in 2007, but 99.1% (837/845) of all platelet doses issued in 2011. (Figure 1)

Although 39 healthcare facilities (including 29 public hospitals) requested platelets between 2006 and 2011 (annual range: 20-25 facilities per year), 64.2% of all requests were from two large public, tertiary referral hospitals in the capital, Windhoek.

Patient diagnosis data from blood request forms were routinely captured by the NAMBTS information system starting in 2007. Between 2007-2011, 4,015 platelet doses were issued to hospitals nationally. (Figure 1) Of these, 1,199 (30%) were given to patients with ICD-10 diagnoses associated with “malignant neoplasms” (C00-C97) and “aplastic anemia” (D50-D64) which collectively accounted for the highest proportion of all diagnoses.
Table 3: Estimated incidence rate and residual risk of HIV, HCV and HBV transmission through transfusion of whole blood derived pooled platelet units and single-donor apheresis platelet units.

<table>
<thead>
<tr>
<th>Test</th>
<th>Number of donors</th>
<th>Number of donations</th>
<th>ID-NAT&lt;sup&gt;a&lt;/sup&gt; confirmed cases</th>
<th>Prevalence</th>
<th>Incidence Rate per 10,000 donations</th>
<th>Person Years (PY)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Incidence Rate (IR) per PY</th>
<th>Residual Risk&lt;sup&gt;c,d&lt;/sup&gt;</th>
<th>Pooled Residual Risk&lt;sup&gt;e&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-donor apheresis</td>
<td>129</td>
<td>903</td>
<td>0</td>
<td>0.0%</td>
<td>0.0</td>
<td>100.8</td>
<td>0.0000</td>
<td>0.000%</td>
<td>–</td>
</tr>
<tr>
<td>Eligible whole blood donations</td>
<td>6,140</td>
<td>17,330</td>
<td>10</td>
<td>0.06%</td>
<td>5.8</td>
<td>3,929.5</td>
<td>0.0025</td>
<td>0.003%</td>
<td>0.016%</td>
</tr>
<tr>
<td>HCV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-donor apheresis</td>
<td>129</td>
<td>903</td>
<td>0</td>
<td>0.0%</td>
<td>0.0</td>
<td>100.8</td>
<td>0.0000</td>
<td>0.000%</td>
<td>–</td>
</tr>
<tr>
<td>Eligible whole blood donations</td>
<td>6,140</td>
<td>17,330</td>
<td>0</td>
<td>0.0%</td>
<td>0.0</td>
<td>3,930.9</td>
<td>0.0000</td>
<td>0.000%</td>
<td>0.000%</td>
</tr>
<tr>
<td>HBV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-donor apheresis</td>
<td>129</td>
<td>903</td>
<td>0</td>
<td>0.0%</td>
<td>0.0</td>
<td>100.8</td>
<td>0.0000</td>
<td>0.000%</td>
<td>–</td>
</tr>
<tr>
<td>Eligible whole blood donations</td>
<td>6,140</td>
<td>17,330</td>
<td>2</td>
<td>0.01%</td>
<td>1.2</td>
<td>3,930.4</td>
<td>0.0005</td>
<td>0.002%</td>
<td>0.010%</td>
</tr>
</tbody>
</table>
Notes

a) ID-NAT: Individual donor nucleic acid testing

b) Person-time was calculated as the difference between the date of the current donation and the date of the previous donation. This difference was then scaled to years by dividing it by 365.25. Each interval was defined based on the current donation type (i.e., single-donor apheresis or eligible whole blood donation). Intervals ending in ID-NAT confirmed cases were divided by two. If the previous donation date occurred prior to the start of the study period, the date of the previous donation was set to February 1, 2012.

c) Residual Risk = IR × (WP/365.25)


e) Pooled Residual Risk = 1 - (1-Residual Risk); pooled residual risk estimate was calculated because five whole blood-derived platelet units were pooled for each adult transfusion dose.

The cost to produce an adult WB-derived pooled platelet dose increased by an average of 21.5% per year between 2006-2011 (Table 1). As apheresis donations accounted for an increasing proportion of all platelet units produced by NAMBTS, production costs for adult apheresis doses declined by an average of 8.2% per year between 2008-2011. (Table 1). During the study period, unit prices for WB-derived doses and apheresis doses increased by an average of 7.4% and 9.0% per year. By 2011, as the production of WB-derived platelets fell to nearly zero, non-apheresis platelets cost more to produce than the cost-recovery price.

5.5 Discussion

Investments in apheresis technology allowed NAMBTS to improve the safety and availability of platelets in Namibia by collecting platelets from a core population of reliable, high frequency, repeat apheresis donors. This finding adds to an already solid evidence base supporting repeat VNRD as the safest blood donors in settings with high population burdens of HIV and other TTI. [30-32] Namibia’s experience also highlights the potential for blood services in resource limited settings in sub-Saharan Africa to support the broader healthcare sector to treat patients with hematologic and oncologic diseases, and match demand as population increases (Namibia’s population grew by an estimated 9.7% between 2006-2011 [29]). The investments made in Namibia allowed for incremental reductions in platelet unit production costs, but this experience raises important questions about consumers’ ability or willingness to pay, as well as the need for additional funding to sustain current apheresis platelet production capacity, and expand platelet availability beyond the capital.

The lessons learned in Namibia present several important points for consideration by
blood services operating elsewhere in the region, particularly those seeking to expand the availability of transfusion therapies to treat a broader range of clinical conditions, including hematologic and oncologic diseases. First, the findings of this study demonstrate that the size and safety of the platelet supply in a sub-Saharan African setting can be increased quickly and efficiently. However, decisions to develop platelet production capacity must be made in conjunction with an expansion of overall healthcare services beyond the traditional drivers of transfusion demand in sub-Saharan Africa (e.g., HIV, malaria, peri-partum hemorrhage). Planners must consider logistical challenges related to platelet storage requirements and the short shelf life of platelet units which may limit their utility in areas with limited distribution infrastructure. As demonstrated in this study, while the numbers of platelet units available nationally increased incrementally, most patients requiring platelet transfusions (e.g., oncology and hematology) continue to be referred to two large public hospitals in Windhoek, the same city where the platelets were manufactured. Expanding clinical services, including platelet availability, to population centers in the northern, more resource-constrained part of the country, will be an ongoing challenge for NAMBTS and healthcare planners in Namibia. Looking ahead, Namibia’s MOHSS has already indicated it will expand oncology services elsewhere in the country. In 2010, for example, radiotherapy services were expanded at the regional referral hospital in Oshakati, a city approximately 700 kilometers north of Windhoek. [33]

Second, planning for platelet production must include extensive training of clinicians (on appropriate component use), collection staff (on apheresis collection machines), laboratory workers (on apheresis unit handling and quality control), and donor mobilization teams (to educate donors on the difference between whole blood and apheresis donations). Finally, particularly in areas where apheresis platelet production is being considered, reliance on apheresis equipment will require investments in maintenance and contingency planning for periods when the equipment may be off-line. By 2011, platelet production in Namibia was highly dependent on two Haemonetics apheresis machines. Although apheresis donors could agree to return to whole blood donations in the event that the machines were unavailable, contingency plans must also consider on-going training for laboratory staff to ensure the quality of pooling procedures in facilities that no longer routinely produce pooled units.

Consideration should also be given to the long-term sustainability of platelet production systems, especially given the high per unit costs observed in this study. In Namibia, the investments that allowed NAMBTS to expand platelet production were substantially subsidized by grants from the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). However, despite these grants, platelet unit prices remained high in Namibia, a reflection of the blood service’s need to recover a growing proportion of costs as the PEPFAR subsidy declined. While Namibia’s upper middle income economy has been able to support this cost structure, similar costs would likely make platelet therapy prohibitive elsewhere in the region, despite substantial PEPFAR investments in strengthening blood services. [34,35] As PEPFAR funding for blood
safety scales down in Namibia and other parts of the region, mobilizing adequate domestic resources will become a greater challenge, as will the need to sustain the reduced apheresis production costs observed in this study. Domestic and international program and policy planners in Namibia and similar settings should continue to pay close attention to costs and pricing to ensure continued availability of blood and blood components, and to ensure that cost-recovery systems remain a viable option for financial sustainability. An increased focus on understanding costs and the impact of reductions in external funding on healthcare service delivery has also been included in proposed US legislation to re-authorize the PEPFAR initiative through 2018. [36] Supplemental revenue sources may also be required, particularly since a cost-recovery-only model may not be feasible in many sub-Saharan African countries. For example, to augment its non-cost-recovery revenue base, NAMBTS exports plasma to South Africa for fractionation. Other countries in the region may explore similar possibilities, but in countries that currently fund national blood transfusion services through government budgets and external donor support, expansion of platelet production may be precluded by the substantial resource mobilization requirements, as well as limited capacity to consume platelets in the healthcare system.

This study is subject to the following limitation. Because there is currently no system in Namibia to track the use of blood products within healthcare facilities, blood request and issuance data are considered a proxy for patient demand. While the figures presented here are likely reasonable estimates of actual platelet demand in public and private sector hospitals and clinics, they do not capture instances where platelets were not available to fill a request, or the needs of patients who cannot access a healthcare facility. As a result, these findings likely represent an incomplete estimate of platelet demand and clinical capacity to treat conditions requiring platelets.

In conclusion, Namibia’s experience with growing clinical capacity for platelets and reduced production costs following the introduction of apheresis technology are certainly positive signs. But in more resource-limited settings in the region, a longer term approach than observed in Namibia may be required before similar gains can be realized.

Acknowledgements
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5.6 References

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