Blood Safety Overview in Iran

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Iran Country Profile

Demographic & Socioeconomic Indicators

Population Estimated: 77,800,000 (2014)

Population growth rate: 1.2% (2014)

Total area: 1,648,000 sq. km

Language: Farsi (official)

Human Development Index: 0.742
Ranks 76 out of 187 (2012)

HIV/ AIDS Prevalence: 0.038%

HBV Prevalence: 2-3%

HCV Prevalence: <1%
The Iranian Blood Transfusion Organization (IBTO)

- A nationally coordinated blood transfusion organization

- Established on the 31st of July, 1974

- In 1984 a new statute was passed by the Iranian parliament in which IBTO was assigned the sole responsible body for ensuring the supply of adequate and safe blood.
Iranian Blood Transfusion Organization (IBTO)

- IBTO is an integral part of the national health system.
- IBTO is a centralized system. All blood centers throughout the country are under supervision of IBTO headquarters.
- All soft goods including blood bags, test kits and anti-sera, equipment and devices, software, documentation including policy, SOPs, forms, records, labels, and training are the same and follow a similar standard in all blood centers.
Institute of Transfusion Medicine is supervised by Managing Director
Blood Collection Facilities

**Blood Collection Centers:**
Responsible for donor recruitment and recall, for blood collection, and donor care.

**Blood Collection & Preparation Centers:**
Responsible for recruitment, blood collection, processing into blood components, storage & distribution.

**Blood Transfusion centers:**
Responsible for recruitment, blood collection (apheresis in some cases), processing, testing for blood groups with or without transfusion-transmissible infections, storage, distribution to hospital blood banks as well as other blood centers, overlooking the clinical use of blood, and surveillance of adverse transfusion events.
IBTO Network

- 138 Blood collection centers
- 23 Blood Collection & Preparation Centers
- 68 Blood Transfusion centers
- 229 in Total (in 31 provinces)
Blood Donation Index (Year: 1974 - 2012)
Whole blood donations per 1000 population, 2011*
Blood safety and availability (WHO)
Fact sheet N°279
Reviewed June 2015

• Blood donation rate in high-income countries is 36.8 donations per 1000 population;
• 11.7 donations in middle-income
• 3.9 donations in low-income countries.
Donor selection & Blood Safety

- Exclusion of donor groups/donors sits with high risk factors
- 100% Voluntary blood donors from 2007
- Self-deferral procedure which is implemented nationwide since 1997, during which donors are asked not to donate blood if they had acquired immunodeficiency syndrome (AIDS)-related symptoms, HIV-related risk behaviors and history of jaundice or viral hepatitis.
ID card and full identification and link to donor to current and previous records
Before consultation with medical doctor

Before Registration

Before phlebotomy
Acquiring a computerized software and data registry of blood donors across the country
- ☑ A uniform and more efficient donor selection and deferral procedure which is carried out by trained medical doctors.
- ☑ Uniform donor deferral criteria, which is implemented and mandated nationwide since 1997.
Network in provinces and country

• All of centers software in every province connected to each other and the data of donations share between them.
• All of provinces connected to server in head quarter
• Especially rejected data is shared between all provinces
Since 2002 the confidential unit exclusion (CUE) became mandatory and implemented in all blood centers.
The impact of donor selection on blood safety in Iran

• Material and method: A blood sample was collected from participants (rejected blood donors) and tested for three viral markers: HBsAg, anti-HCV, and anti-HIV.

• Results: The prevalence of HIV, Hepatitis B, and Hepatitis C was 120 (CI 95%; 90-150), 1280 (CI 95%; 1170-1390), and 580 (CI 95%; 510-650) in 100,000 deferred donors respectively. A significant increase exists in the prevalence of HBV (1.7 times), HIV (24 times) and HCV (15 times) in deferred donors as compared to accepted blood donors.

• Conclusion: The effectiveness of donor selection in identifying high risk individuals is obvious upon comparing the prevalence of selected viral infections in deferred donors with those accepted for blood donation.

• Razjou F. and et al. Transfus Aphers Sci; 2012
Donor selection & Blood Safety

• Donor notification of any abnormalities in post-donation laboratory tests

• Telephone call-back as a system established on beginning of 2010
Education efforts of IBTO and MOH to increase public’s knowledge on blood-borne infections and routes of transmission.
Screening tests by automated systems from 2006
Since foundation of Iranian Blood transfusion Organization (IBTO) in 1974, screening of blood donations for hepatitis B surface antigen (HBsAg) became obligatory. In Iran screening of blood donations has became mandatory for HIV from 1989 and for HCV from 1996.
<table>
<thead>
<tr>
<th></th>
<th>HIV</th>
<th>HBV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High-income countries</strong></td>
<td>0.002%</td>
<td>0.02%</td>
<td>0.02%</td>
</tr>
<tr>
<td></td>
<td>(0.004%-0.02%)</td>
<td>(0.008% - 0.24%)</td>
<td>(0.004% - 0.22%)</td>
</tr>
<tr>
<td><strong>Middle-income countries</strong></td>
<td>0.12%</td>
<td>0.64%</td>
<td>0.37%</td>
</tr>
<tr>
<td></td>
<td>(0.03% - 0.2%)</td>
<td>(0.19% - 2.33%)</td>
<td>(0.13% - 0.71%)</td>
</tr>
<tr>
<td><strong>Low-income countries</strong></td>
<td>0.85%</td>
<td>3.59%</td>
<td>1.07%</td>
</tr>
<tr>
<td></td>
<td>(0.48% - 2.0%)</td>
<td>(2.01% - 6.08%)</td>
<td>(0.63% - 1.96%)</td>
</tr>
</tbody>
</table>
• The lower prevalence of TTI in blood donations compared to the general population and trends of their prevalence suggest that most of the safety measures employed at IBTO in the recent years have been effective.
Prevalence of HBV in Blood Donations, Different Donation Status

<table>
<thead>
<tr>
<th>Donation Status</th>
<th>Prevalence/10^5 Donations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2006</td>
</tr>
<tr>
<td>First Time</td>
<td>898</td>
</tr>
<tr>
<td>Repeat</td>
<td>198</td>
</tr>
<tr>
<td>Regular</td>
<td>68</td>
</tr>
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</table>
Prevalence of HCV in Blood Donations, Different Donation Status

<table>
<thead>
<tr>
<th>Donation Status</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Time</td>
<td>231</td>
<td>241</td>
<td>227</td>
<td>249</td>
<td>222</td>
<td>224</td>
<td>211</td>
<td>216</td>
<td>205</td>
</tr>
<tr>
<td>Repeat Time</td>
<td>81</td>
<td>58</td>
<td>51</td>
<td>41</td>
<td>29</td>
<td>29</td>
<td>18</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Regular</td>
<td>28</td>
<td>25</td>
<td>14</td>
<td>12</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
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</table>
## Prevalence of HIV in Blood Donations, Different Donation Status

<table>
<thead>
<tr>
<th>Donation Status</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Time</td>
<td>6.7</td>
<td>9.1</td>
<td>8.3</td>
<td>10.3</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Repeat Time</td>
<td>2.1</td>
<td>1.2</td>
<td>1.6</td>
<td>1.6</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Regular</td>
<td>0.0</td>
<td>0.4</td>
<td>1.1</td>
<td>1.0</td>
<td>0</td>
<td>0.6</td>
<td>0.3</td>
<td>0.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>
• Evaluation of ELISA and confirmatory kits for tender and every transportation.
• Material vigilance for blood bags, kits, tube.
• Participation in proficiency testing four times every year.
Quality Assurance Establishment

Document and records control
Corrective and preventive action
Change control
Training program
ISO Quality Management Certificate
9001-2008

Blood Transfusion Centers: 68 certificate
Blood Collection and Processing Centers: 23 Certificate
Head Quarter: 1 certificate

Scope of HQ: Supervision of all blood transfusion centers across the Country
The backbone of these procedures is a validate and comprehensive software.
Cold Chain, Validation & Monitoring
Temperature monitoring Continuously
Validation of Transportation Blood Bags and Test Tubes

Data logger
Validation of Cold & Freezing Rooms

Every 18 months and after every repair
Internal and external inspections

• Certified quality assurance staffs did internal audit every blood transfusion center tow times every year according national standards, SOPs and GMP

• External audit were done by certified quality control, quality assurance, technical departments and recruitment office staffs from head quarter according national standards, SOPs and GMP

• External audit for ISO (9001:2008) certificate

• Audit by fractionators and authorized bodies from other countries.
Labeling according to ISBT 128 and Traceability
• **Appropriate clinical use of blood** and the use of alternatives, where possible, to minimize unnecessary transfusions

• Haemovigilance establishment as a system in hospitals started from 2008