Selecting a low risk donor: Getting the right balance between safety & sufficiency

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Talk will dwell upon

- What does low risk mean?
  - Recipient (TTI safety)
  - Donor (Safety during/after blood donation)

- What is sufficiency?
  - National requirement
  - Hospital (PHC/CHC/GH/MC/Referral)
  - Audit of previous years
The initial concept of low risk donor (safe) 1921

- Mobile donor service: Mr. Percy Lane Oliver
- British Red Cross Blood Transfusion Service
- Blood grouping & Syphilis testing

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Concept of safety of volunteer donor

- Transfusion associated hepatitis (TAH): Grady and Chalmers (1964)
  - VD  ~~ 0.6 cases/1000 units
  - VD & Commercial donors  ~~ 2.8 cases/1000 units
  - VBD & HBsAg  ~~ 70% reduction of TAH & 85% reduction in hepatitis B.


- “The prevalence of all TTI markers was significantly less in VD”
- “Among the voluntary donors, transfusion transmissible disease markers were significantly less in student donors as compared to other donors.”

“Voluntary blood source is safer by the observation of a statistically significant (p < 0.05) higher percentage of TTI reactivity in replacement donors when compared with voluntary donors.”

Scenario changes with demography
2010 –Ghana (West Africa)

- HIV: FT-VD group ~ RD (1.1% vs. 1.03%)
  
  Age < 20 yrs FT-VD ~ RD (p = 0.31)
  Age > 20 yrs FT-VD > RD (2.1% vs. 1.1%, p < 0.05)

- HBsAg: FT-VD ~ RD (13.8 vs. 14.9%)
  
  Age > 20 FT-VD > RD (20.3 vs. 15.1%, p < 0.0001)

- Viral safety of RD & FT-VD was similar, constituting a single population of donors

The healthy donor effect (HDE) is an important methodologic pitfall in health research among blood donors. The HDE is a term applied to the phenomenon of decreased morbidity rates and a healthier lifestyle in donors when compared to the general population, but also in the comparison between donors and non-donors and between active donors and lapsed donors. As a result, effect estimations obtained from studies using such comparisons may be biased. The HDE may act as selection bias or confounding bias. When designing a study, one should carefully think through the type of bias that may be present and how the bias operates in that particular study. In case of confounding, the HDE can be taking into account in advance by restricting the study to specific groups (e.g., one sex category or a particular age class) or matching study subjects on important confounding factors (e.g., age and sex matching).

Read between the lines* terms/conditions apply

2014- Egypt

- The prevalence of HBV and HCV were much higher in family donors than in voluntary donors, with the differences being highly statistically significant.

- Prevalence of transfusion-transmissible infections is much higher among family replacement donors than among voluntary donors, and that voluntary donors are the best way of achieving safer blood.

- However!!! A comparison of the demographic data of the donors in the two groups revealed highly significant differences for both age and sex (p<0.001), with the voluntary donors being younger and including a higher percentage of women.

Concept of safety of repeat donor

2015 (N=8,68,095)

- TTIs: 972 new donors and 381 repeat donors.
- New donors had higher rates of TTIs compared to repeat donors.

**Experience over time!!! 2001 (868,403 RD)**

- **REDS**: The incidence rates (IR) for HIV, HCV, and HBV infection did not appear to differ among donors with lower or higher numbers of donation per year.
- The findings do not provide evidence of a for lower IR transfusion-transmissible viral infections among repeat WB donors who give more frequently.
- Little or no benefit in selectively targeting retention programs toward the most frequent donors, especially considering the limited number of additional donations even very frequent donors can give.
- Increasing the return of infrequent repeat donors would help ensure an adequate blood supply without jeopardizing safety.
- The lack of a decrease in the IR with increasing frequency of donation fails to support the assumption that frequent donors have lower behavioural risks than less frequent repeat donors and hence could be screened with abbreviated donor intake questionnaires.

Experience over time!!! (2012)

- Apparent increase of HIV and HCV among repeat donors

  (Incidence /100 000 person-years)

- HIV from 1.55 to 2.16 (2000/2001 to 2007/2008)

- HCV from 1.89 to 2.98 (2000/2001 to 2007/2008)

- Prevalence rates:
  - FTD > Rpt donor
  - Male (first time or repeat) > female (HIV & HBsAg)

- These observed fluctuations confirm the need for continuous monitoring and evaluation.

Higher TTI reactivity was observed in repeat donors (1.4%) as compared to first time donors (0.63%), statistically significant (P <0.05).

Safe?? VD/RD/Repeat/Young/Female
2015 (252,202 volunteers and 2771 replacement donors)

- TTIs higher in replacement group which were related to donor's sex, age and donation time
- Male RD > female RD (< 30 years)
- Repeated RD < FT replacement donors
- Appropriate pre-donor screening and other donor selection policy replacement donors and voluntary donors provide a similar level of viral safety.
- Focus on retaining both young replacement and young voluntary donors as repeat donors and
- promoting the donation proportion of females, which will improve blood safety

<table>
<thead>
<tr>
<th></th>
<th>83865</th>
<th>HIV</th>
<th>HBV</th>
<th>HCV</th>
<th>SYPHILIS</th>
<th>TTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>75773</td>
<td>66</td>
<td>263</td>
<td>433</td>
<td>2</td>
<td>764</td>
</tr>
<tr>
<td></td>
<td>(90.35%)</td>
<td>(0.08%)</td>
<td>(0.34%)</td>
<td>(0.57%)</td>
<td>(0.002%)</td>
<td>(1.01%)</td>
</tr>
<tr>
<td>Female</td>
<td>8092</td>
<td>2</td>
<td>5</td>
<td>16</td>
<td>00</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>(9.64%)</td>
<td>(0.02%)</td>
<td>(0.06%)</td>
<td>(0.19%)</td>
<td></td>
<td>(0.28%)</td>
</tr>
</tbody>
</table>

Table 1. Estimated Frequency of HBV, HCV, HIV, and HTLV I Infectious Donations Issued Per Million Donations Tested, UK, 2007 to 2009

<table>
<thead>
<tr>
<th>Risk due to:</th>
<th>HBV</th>
<th>HCV</th>
<th>HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Window period donation</td>
<td>1.39</td>
<td>0.01</td>
<td>0.19</td>
</tr>
<tr>
<td>per million</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All causes</td>
<td>1.50</td>
<td>0.01</td>
<td>0.20</td>
</tr>
<tr>
<td>All donations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donations from new donors</td>
<td>5.23</td>
<td>0.06</td>
<td>0.27</td>
</tr>
<tr>
<td>Donations from repeat donors</td>
<td>1.10</td>
<td>0.01</td>
<td>0.19</td>
</tr>
</tbody>
</table>

Blood donor selection

Aim

- good health
- will not harm them (donor safety)
- prevent transmission of infections or the effects of drugs

Steps

- Education phase
- Confidential pre donation interview
- Medical screening
- General health assessment

UDHQ......checklist......ensures compliance.

Blood donor selection

- Prospective blood donor
  - Self–administered form
    - Initially determine if he/she complies with all criteria for blood donation. (5 Minutes)
  - Confidential interview
    - Ascertain that the prospective donors understand the process of blood donation, the questions in the self–administered form, and that his/her responses are adequate. (12 Minutes) – Art of screening a blood donor!!!!

UDHQ (Blood donor history questionnaire)

Recipient Safety
- HIV/AIDS
- Hepatitis B or C
- Sexually transmitted diseases
- Tattooing/Ear Piercing/Dental...
- Malaria
- Typhoid
- Tuberculosis
- Dengue/Influenza/Mumps/Measles/Chickenpox.....
- Drug/Medication (teratogenic / bacteremia / vireamia..subclinical)

Donor Safety
- Heart /Lung/Kidney Disease
- Epilepsy/ Fainting spells
- Hypertension
- Diabetes
- Slept well last night
- Eaten within 4 hours
- Menses/Pregnancy/Feeding Child...
- Discomfort during/after last donation
Donor risk assessment (First crucial step)

- Diagnostic window period & incubation period

- Donors who donate during the window period generally pose the greatest threat to blood safety and the selection process needs to be able to identify and defer such individuals.

- Individual donor risk may be impossible to ascertain; the application of the precautionary principle may require that a donor is deferred on the basis of knowledge of the risks to which the donor may be exposed.

- Relevant questions to assess their general health

  - any history, signs or symptoms indicative of current or past infections
  - specific high-risk behaviours or activities
  - travel history, contact with infectious diseases and possible exposure to infection

Kinetics of viraemia - TTIs
Role of donor counselling

- **Confidential dialogue** between a blood donor and a trained counsellor about issues related to the donor’s health and the donation process.

  - minimizes unnecessary loss of suitable donors
  - maximizes the retention of donors, including temporarily deferred
  - assists donors to provide informed consent for blood donation and to defer unsafe donors
  - aids donors to self-defer
    - if they are aware of having been exposed to any risk of a transfusion-transmissible infection
    - known health condition or have had a treatment that could influence their suitability to donate blood

*Blood Donor Counselling. Implementation Guidelines. World health Organization 2014*
Stages of blood donor counselling

Stage 1: Pre-donation information

Self-deferral

Stage 2: Pre-donation counselling (donor questionnaire, donor interview, donor health and risk assessment, and informed consent)

Deferral/Self-deferral

Stage 3: Counselling during blood donation

Post-donation confidential unit exclusion

Stage 4 (a): Post-donation counselling (notification, counselling and/or referral for positive and inconclusive test results)

Treatment, care and support

Stage 4 (b): Post-donation counselling (for negative test results)

Retain as regular donor and reinforce healthy lifestyle
Post-test notification and counselling

- Sexual risk factors for TTIs & 28% admitted to risk factors of permanent donor exclusion if revealed during the donor selection


- 85% repeat reactive donors had risk factors TTIs
  - Injectable treatment without knowledge of sterility status (22%)
  - Continuing sensitization of blood donation camp organisers to the need of privacy during blood donor selection

  ✓ Need to strengthen the pre-donation counselling
  ✓ Raise awareness amongst blood donors about the importance of post-donation counselling and follow up

Post-test notification and counselling

- Need for post interview follow-up to investigate underlying risk factors including high-risk behaviour in donors who subsequently confirm positive for TTD markers

- Assessment and analysis of prevalence and incidence data along with understanding of the characteristics of those donors could help in policy decisions, recruitment strategies, and screening practices to strengthen donor selection and maintain the safety of the blood supply

- Understanding of independent associations with demographic characteristics such as age, sex, high-risk behaviour, geographic location, and medical procedures can help to improve donor selection and screening

<table>
<thead>
<tr>
<th><strong>Total Donors = 83865</strong></th>
<th><strong>HIV (N=9)</strong></th>
<th><strong>HCV (N=56)</strong></th>
<th><strong>HBV (N=101)</strong></th>
<th><strong>Syphilis (N=1)</strong></th>
<th><strong>Total (N=167)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H/o injectable treatment without knowledge of sterilization status</strong></td>
<td>0</td>
<td>15 (26.78%)</td>
<td>22 (21.78%)</td>
<td>0</td>
<td>37 (22.15%)</td>
</tr>
<tr>
<td><strong>H/o high risk behaviour</strong></td>
<td>7*** (77.77%)</td>
<td>11 (19.64%)</td>
<td>15 (14.85%)</td>
<td>1 (100%)</td>
<td>34 (20.35%)</td>
</tr>
<tr>
<td><strong>H/o jaundice in themselves, family / close contacts</strong></td>
<td>-</td>
<td>3 (5.35%)</td>
<td>24*** (23.76%)</td>
<td>0</td>
<td>27 (16.16%)</td>
</tr>
<tr>
<td><strong>H/o tattooing or ear piercing</strong></td>
<td>0</td>
<td>7 (12.50%)</td>
<td>15 (14.85%)</td>
<td>0</td>
<td>22 (13.77%)</td>
</tr>
<tr>
<td><strong>H/o blood transfusion</strong></td>
<td>0</td>
<td>3 (5.35%)</td>
<td>1 (0.99%)</td>
<td>0</td>
<td>4 (2.39%)</td>
</tr>
<tr>
<td><strong>No significant history elicited</strong></td>
<td>2 (22.22%)</td>
<td>17 (30.36%)</td>
<td>24 (27.76%)</td>
<td>0</td>
<td>25 (14.97%)</td>
</tr>
</tbody>
</table>
Sufficiency

- In relation to total population. WHO estimate for national requirements is 1 – 3% of population.
  - India 1.2 Billion ~≈ 12 Million (with 1% estimate)

- Hospital bed based (could vary as per the level of Medical facility available and regions demography related disease prevalence)
  - 3-15 units/bed/year or 7-20 units/acute beds/year
  - PHC/CHC ~≈ 3 – 5 units/bed/year
  - Referral Institute ~≈ 25 - 30 units/bed/year

(Source Maharashtra SACS website)

WHO & IFRCRCS (1986)

- General ~≈ 10 units/bed/year
- Speciality ~≈ 20 units/bed/year
- Super-speciality ~≈ 30 units/beds/year
Sufficiency

- **In relation to past blood usage**: Audit of blood usage of last few years may also guide to plan the next year wise blood collection targets.

- **Variables affecting demand and supply**
  - Geography, population, epidemiology & genetic (Thalassemia & Haemophilia)
  - Level and rate of development of health care system
  - Preventive Health Services: e.g. anaemia, malaria
  - Diagnostic & Treatment: Modern Medical management, Organ transplantation
  - Location and accessibility of health care facilities
  - Disasters (natural or man-made)
  - Epidemics
Challenges........

- Seasonal shortage.
- Fixed date camps.
- Holiday culture.
- Festive mood.
- Decline in donor base...age/disease catch up.
- Anemia in potential female blood donors.
- Recognition & Acknowledgement.
- Reciprocation during need.
- Finance.
- Disaster
- Epidemics
Structured Blood donation Calendar

- Fixed Camps
- Sunday / Holiday Camps
- Saturday Camps-PTM
- Fluid Camps- used for spacing/buffering

Partners in voluntary blood donation
- Voluntary blood donor organizations.
- Voluntary organisations (NGOs).
- Government organisations.
- Religious organisations.
- Political organisations.
- Schools/Colleges/Universities (PTM/NSS/NCC/Red Cross).
- Industries/Corporate/IT companies and other private organisations (CSR activity).
- Resident/Market welfare associations.

As you sow so shall you reap… PTM camps, NSS / NCC/Red Cross units of Colleges…foster a culture of VNRRBD.

Mass coverage via media, radio, television, internet/social media sites etc.

Modern blood collection facility “Blood Mobile”
Scenario during lean months -2009-2010
Monthly trend of camps - Summer months

2010: 13
2011: 17
2012: 27
2013: 30
2014: 29
Monthly Blood collection - Summer months

- 2010: 3066
- 2011: 3771
- 2012: 4220
- 2013: 4398
- 2014: 4351
Monthly trend of camps – Winter months
Monthly Blood collection – Winter months

- 2010: 3265
- 2011: 3909
- 2012: 3850
- 2013: 4554
- 2014: 5043
Way Forward!!!

✓ Recommendation is to use UDHQ to identify and defer potential blood donors with clinical histories or behaviours associated with TTIs

❖ Capacity building of TM specialists – Art of screening
❖ Capacity building of Counsellors – Art of screening
❖ UDHQ – adapted to local risk factor questioning
❖ Creating a base of blood donors that understand both

➢ The need of blood donation – volunteer/repeat/regular
➢ Blood safety (umbrella safety) – target Schools/Colleges with focus on how TTIs spread (Unsafe injection practice/ Shared blades/Tattoo etc)
➢ Promote PTM (School Camps) and NSS/NCC/Red Cross (College Camps), Club 25 …
➢ Promote female blood donation (Target Hb of 11/12 by age of 11/12 etc)

✓ Balance between demand and supply is needed
  • Minimize wastage
  • Avoid blood shortages
  • Ensure adequate inventory at all times
Do we really need to worry about deferral for blood safety to ensure sufficiency?

- Predictions are that India is set to become the youngest country in the world by 2020
  - 50% of our population is below 25 and
  - 65% below 35.
- The average age of an Indian will be 29 years by 2020
- Sensitising school going children to blood donation at PTM camps in schools and college students (NSS/NCC/Red Cross) could lay a strong and safe foundation and foster a culture of blood donation in the future population of blood donors (Umbrella safety)

We need to focus on increasing collection

- Selecting low risk donors “as low as reasonably achievable” (ALARA)
- UDHQ, Capacity building of MO’s
- Using modern technology platforms for donor TTI screening with QA.