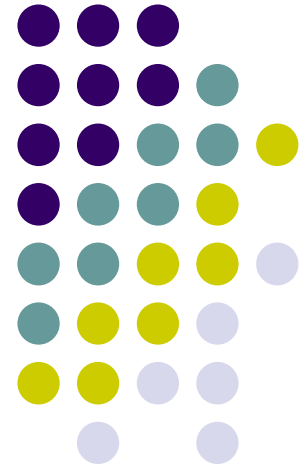


# Blood Bank Accreditation Program in India

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# DEVELOPMENT OF BLOOD TRANSFUSION PROGRAMME IN VARIOUS STATES



- Satisfactory
- Fair
- Poor



प्रथमा

# Basic about Indian BTS



- Governed by Drug & Cosmetics Act (1945), notified through multiple Gazette Notifications.
- Constrains of blood banking sector in India
  - Accessibility and affordability of safe blood
  - Highly fragmented BTS
  - Absence of a nation-wide network of blood banks.
  - Different levels of Quality standards.
  - Absence of a system for the continuous monitoring and evaluation of the service



# Introduction: Status



- Indian BTS is highly fragmented.
- There are >2700 blood banks at present.
- Blood banks are in four sectors (approx):
  - # 40% are in government sector
  - # 35% from Corporate sector
  - # 20% are from NGO sector
  - # 5% from corporate sector



# Introduction: Management

- Govt. sector:
  - # BTO manages under MS/ Director of a hospital
  - # Usually HOD Path/ Lab Service manages
- Red Cross Society: Administrative committee manages through BTO
- NGO: Charitable; mostly VRNBD; quality conscious
- Corporate: try to make profit; quality conscious; competition forces for accreditation

# Introduction: Regulations



- Indian BTS regulated by Drugs & Cosmetics (D&C) Act through federal & provincial Govt agencies
- Quality management system (QMS) varied in between cities even BB in same city.
- Utmost important to implement uniform QMS
- Efforts were made to bring uniform QMS through common Accreditation Program under federal Govt.





# Types of blood banks

As per service offered

- Storage centers
- Service units: stand alone/ hospital base
- Regional Blood Transfusion Centers
- (Model/ Central Blood Bank)



# Need for Accreditation

- Wide variance in quality standards among blood banks
- To achieve a benchmark for quality standards
- Limited Information / Knowledge
- Inadequate:
  - # Resources: Personnel/ equipment/ consumable
  - # Monitoring system
- Need to Improve services to donor & patients
- To ensure safety of blood

# Accreditation Agencies (1)



## International

- # Joint Commission for Accreditation of Healthcare Organizations (JCAHO) USA.
- # These cover accreditation of biological laboratories keeping linkage with ILAC.

# Accreditation Agencies (2)



In India,

- NABL : only Government organization:  
traceability with APLAC (Asia Pacific  
Laboratory Accreditation Council)→  
traceable with ILAC (International  
Laboratory Accreditation Council)

# Accreditation Agencies (3)



## **NABL:**

- Previously: ISO 17025
- Presently: ISO 15189
- Accreditation for testing & calibrating lab
- Blood Centre: does not cover donation & component sections

# In private sector: ICRA



An independent & Professional Investment Information & Credit Rating Agency

- Started 1991
- Covers > 40 industry sectors
- 2002: Launched grading scheme for health care institutes in India
- Grading: H1 to H4: depends on quality of service provided & consistency



# In private sector: CRISIL



Credit Rating Information services of India Ltd

- Incorporated in 1987
- Grading : A to D
- First blood bank (Prathama, Ahmedabad) accredited in 2003
- Withdrawn from BB grading:2006

# Benefits of accreditation (1)



- Accreditation results in high quality of care and safety of donor / patient
- Donor/ patient gets services by credible medical staff.
- Donor/patient safety regularly evaluated
- Confidence of donor/patient increases

# Benefits of accreditation (2)



- Blood bank is stimulated for continuous & demonstrates commitment to quality care
- Improved credibility of blood centre
- Unbiased assessment by an external agency

# Benefits of accreditation (3)



- Staff:
  - # more satisfied
  - # continuous learning/ good working environment
- Promotes intra and inter-institutional interactions.
- Achieve a benchmark in blood banking

# Journey for Blood Bank Accreditation



- Blood bank accreditation: N/A 10 years back
- Grading available from Crisil & ICRA
- NABL accreditation for Lab. (part of Blood Bank)
- ISBTI thought to start accreditation via blood banks: not materialized
- NACO: Accreditation/ grading task to ICRA & CRISIL
- NABH: Complete blood bank accreditation

# Future benefits of accreditation



- Accreditation is the higher benchmark for quality achievement in blood banks
- It is always voluntary.
- Commitment from management & staff
- Helpful for Medical Tourism
- May be used as scale for providing Govt. (NACO) support to blood banks
- Medical insurance firms may ask (future) for accreditation for repayment.



# Road map for NABH accreditation



- Release of accreditation Standard
- Put relevant info in the website
- Sensitization program among blood bankers in major locations
- Lead assessor training program
- Application & fee submission
- Accreditation process starts

# What is Accreditation?



- Accreditation is a public recognition of the achievement of accreditation standards by an organization, demonstrated through an independent external peer assessment organization.



# How to go ahead? Clauses...

1. Organization and management
2. Accommodation and environment
3. Personnel
4. Equipment
5. External Services: Supplies & Reagents
6. Process Control
7. Identification of deviations and Adverse Effects
8. Performance Improvement
9. Document Control
10. Records
11. Internal Audit and Management review

# Aims of Accreditation Program



- To study the BB accreditation pattern in India.
- To study factors influencing success of the program.

# Methods: Initiation



- Quality Council of India (QCI) was created by Federal Govt. & Industry Associations
- NABH is constituent part of QCI
- NABH has accreditation prog. including BB
- BB program initiated in 2006 & technical committee constituted.

# Methods: Preparing Standard



- NABH BB Standard prepared by 5 members Technical Committee (TC) on following platform:
  - # ISO-15189
  - # D&C Act-1940 (Govt. regulation)
  - # Technical Manual (NACO- Govt. of India)
  - # Technical Manual DGHS (MoH, Govt. of India)
  - # Technical Manual-AABB; Standard- NATA.
- NABH BB Standard released : January 2008
- Accreditation Prog. rolled out in same year.



# Methods: Process



- Application in website; submit with fees/ doc.
- Application scrutinized by secretariat; appoint Principal Assessor & send QM
- QM-NC closure followed by pre assessment
- Pre assessment NC closure
- Final assessment by team as per man day (1 P. assessor + 1 Tech assessor + 1 observer) .
- Final NC closure; approval by Accreditation Committee

# Methods: How process started?



- Started with 4 principal assessors
- Four assessors courses (5 days) in a year: 92 successful assessors
- Three days implementation program (preparatory) across India= 16 no.
- One day sensitization prog. for prospective BB province wise across India= 30 no.

# Methods: Monitoring program



- Regular evaluation of assessment processes:  
NABH secretariat
- Assessors performance feed back= 360°
- Assessors meeting (3 days) = self appraisal & homogenization of accreditation
- NABH BB audit by ISQUA



# Results: Accreditation

- First blood bank accredited in 2008
- 92 BB applied and 85 were accredited
- Surveillance every 1.5 years
- 183 assessment processes completed
- 59 surveillance & 29 renewal assessment
- **NO BB DROPED OUT IN 7 YEARS**

# Results: Sensitization Program



- Out of 32 provinces, 64 sensitization programs
- Program is known to Indian blood banking community
- Process is also known to blood bankers
- Competition felt among NGO & corporate BB

# Results: Implementation Program



- About 30 participants in each program
- Sixteen prog for blood banks personnel from all sectors (NABH)
- NABH program started with pre & post feedback; follow-up by TC members
- No results from Govt. from prog; 5 applications from NABH prog.

# Aims



- To find out effectiveness of implementation program (IP) among participants to initiate BBAP in respective blood banks.
- To find out difference in knowledge level among participants before and after attending IP.

# Methods (1)



- This program was organized in a class room interactive setting for three full days and two resource persons conducted the course.
- About 26-30 applicants were selected on the basis of their details in application.
- Before starting IP, one structured questionnaire (with identifier) was given to applicants and the same questionnaire was given at end of IP to find out the effectiveness of the program
- Fifteen multiple choice questions were added in post course questionnaire to understand their leaning on quality management system.





## Methods (2)

- During the course, participants were trained on all clauses of NABH Standard; gap analysis; preparation of quality manual; organogram; quality policy (QP); calibration and validation of equipment; SOP writing; internal audit (IA) and management review; adverse incident reporting (AIR); nonconformity/ deviation; EQAS; QC/QA; document control; hospital transfusion committee; application process for BBAP; fees involved and future assistance channels.
- Both questionnaires were analyzed participant wise and results were evaluated.

# Results (1)



- **Participants observed great values in IP for BBAP. There was significant knowledge enhancement in post assessment.**
- **In preparing biomedical waste management policy and SOP, knowledge increased from 20% to 96%. Knowledge of preparation of QP and developing identification no. for equipment increased from 72% to 96%.**
- **Only 56% knew about IA and 32% knew how to implement.**
- **Knowledge in IA improved to 83%. About 28% had knowledge about AIR and it increased to 96%.**
- **Initially 32% participants knew structure of HTC but it was improved to 83% after the IP.**



## Results (2)

- Implementation of record retrieval was known to 28% and 96% become confident after IP. About 50% participants knew about all BB SOPs and it improved to 76% afterwards.
- Nine participants came from accredited blood banks, therefore their knowledge was better.
- About 84% knew how to prepare organogram; 96% knew about equipment maintenance; 88% thought that documentation was in place; 68% already participated in EQAS program.



# Summary/ Conclusions:

- Knowledge about BBAP has greatly enhanced after the IP among participants. It is due to intense exposure to all clauses NABH Standard.
- There is significant difference on level of knowledge among participants before and after the IP.
- The feedback identified hand on approach, individual & group exercises, interactive sessions, presentations by participants and success story discussion made this program most successful and effective.

# Results: Assessors Program



- Hugely successful & high demand for BB doctors
- Assessors meet regularly for harmonization of assessment process.
- All assessors are rotated under two senior TC members
- New assessment prog not done: deployment an issue (surveillance increased to 1.5 years)

# Results: Look Back



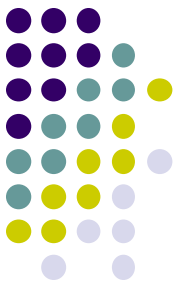
- Why only 92/2700 BB coming forward?
- Quality standard of BB not at accreditation level
- Blood bankers not familiar with non technical clauses (e.g. personnel, external services, internal audit, MRM, accommodation etc.)
- Apprehension (Q Manual, internal audit etc.)
- Not mandatory by regulation (voluntary)
- Fees to be paid (~US\$2000 for 20K collection)

# AABB Accreditation Program (1)



- AATM & AABB signed MoU for development of BTS in Asian countries
- Agreement for accreditation and distant learning program in cell & tissue therapy
- International coordinator committee constituted in Oct'15.
- Field trial started in February, 2016
- Program roll out by July, 2016

# AABB Accreditation Program (2)



- AATM starts with stepwise Accreditation Prog
- AATM starts with training of assessors during AABB-AATM regional meeting in Dec, 2016
- Individual BB starts from AABB Accreditation
- Initially starting in India, Sri Lanka, Iran= 3<sup>rd</sup> Q
- Stepwise Prog starting in Asian countries from 1<sup>st</sup> Q, 2017
- Hope to start AABB prog in all Asian countries



# Conclusions: Program



- First BB accreditation program in South Asia based on a defined Standard
- Sense of competition started among BB; indirectly elevating QMS in BB
- Sensitization excellent in blood bankers mind
- Fear factors are in mind; more implementation program & follow up needed to remove fear.



# Conclusions (1)

- It is a successful accreditation program in highly fragmented BTS.
- Success because of consistent sensitization/ implementation program organized by NABH to enrol blood banks.
- Success contributed to perseverant efforts by NABH secretariat and TC members to involve new BBs.



## Conclusions (2)

- There was no drop out from accredited blood banks shows satisfaction of customers with the process.
- Brining QMS parity in a fragmented BTS has started in India and intervention needed for covering government sector BBs where enrolment is low.

*Thanks for Your Kind Attention*

