Blood Bank Accreditation Program in India

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DEVELOPMENT OF BLOOD TRANSFUSION PROGRAMME IN VARIOUS STATES

- Satisfactory
- Fair
- Poor
Basic about Indian BTS

- Governed by Drug & Cosmetics Act (1945), notified through multiple Gazette Notifications.

- Constraints 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)
- ISBTDI 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 feedback = 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 stated in February, 2016
- Program roll out by July, 2016
AABB Accreditation Program (2)

- AATM starts with stepwise Accreditation Program
- AATM starts with training of assessors during AABB-AATM regional meeting in Dec, 2016
- Individual BB starts from AABB Accreditation
- Initially stating in India, Sri Lanka, Iran= 3rd Q
- Stepwise Prog starting in Asian countries from 1st 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