



Policy Matters!

(verb; 3rd person present tense)

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Scope of discussion

- The existing regulatory/policy framework in India
 - A few examples from other countries
 - Progress
 - Why policy matters
 - Opportunities to collaborate
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- No conflict of interest to declare

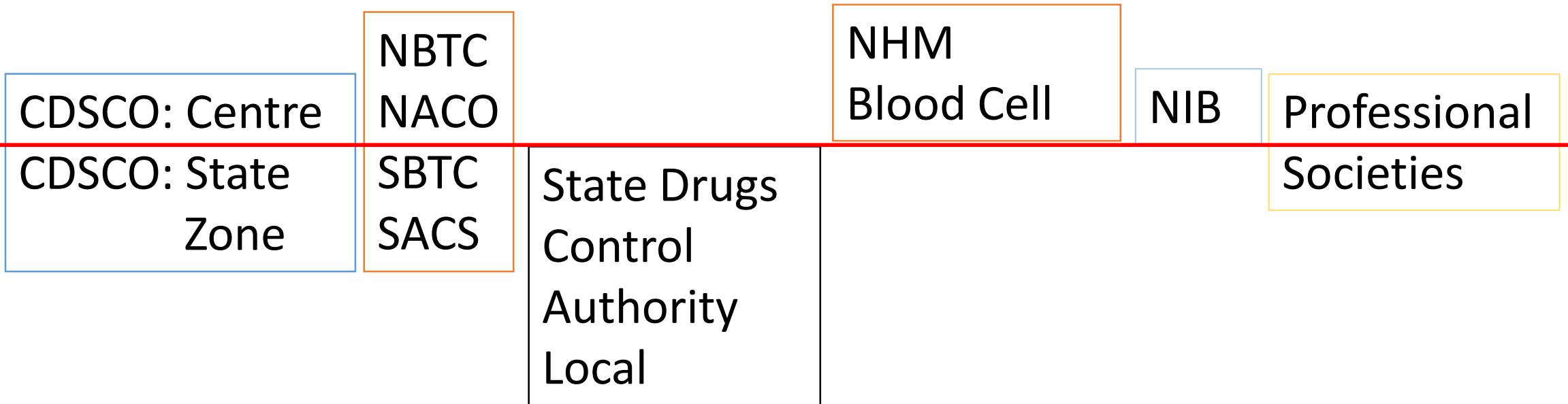


The Indian framework

- The Drugs & Cosmetics Act (1940) & Rules (1945)
 - Subsequent amendments
- Supreme court judgement 1996 (Common cause vs Union of India)
- National Blood Policy (2003) Plasma Policy (*addendum* 2014)
- Action Plan (2007)
- Various notifications and guidance notes published by NBTC/NACO
- *Draft National Health Policy (2015)*
- Blood Safety via the prism of HIV-AIDS



The Indian framework: Organizations that deal with Transfusion





Other countries

- **France**
 - Specific Law (2000)
 - EFS: French Blood Establishment
 - Regulated by French National Government
 - 153 permanent collection locations/4000 mobile units
 - 17 regional establishments
 - Haemovigilance system
- **Australia**
 - Therapeutic Goods Act 1989
 - Latest update :2013
 - National Blood Authority (2003)
 - Australian Red Cross Blood Service (ARCBS)
 - 4 Processing centres



Other countries - USA

- US – Federal FDA
- Basic Law for establishments: 21 CFR Part 1270
 - human cells, tissues, and cellular and tissue-based products (HCT/Ps)
- Section 361 (Sec. 361) of the Public Health Service
 - 1997 >2001; 2004
- CBER: Center for Biologics, Evaluation and Research
 - Center within FDA that regulates biological products for human use under applicable federal laws
- Professional Society - AABB
 - Professional guidance
 - Proficiency testing
 - Accreditation
 - Advocacy
 - Research
 - Haemovigilance
- CDC: one of the federal agencies responsible for assuring the safety of the U.S. blood supply by protecting health through investigations and surveillance.



Progress: Where have we reached?

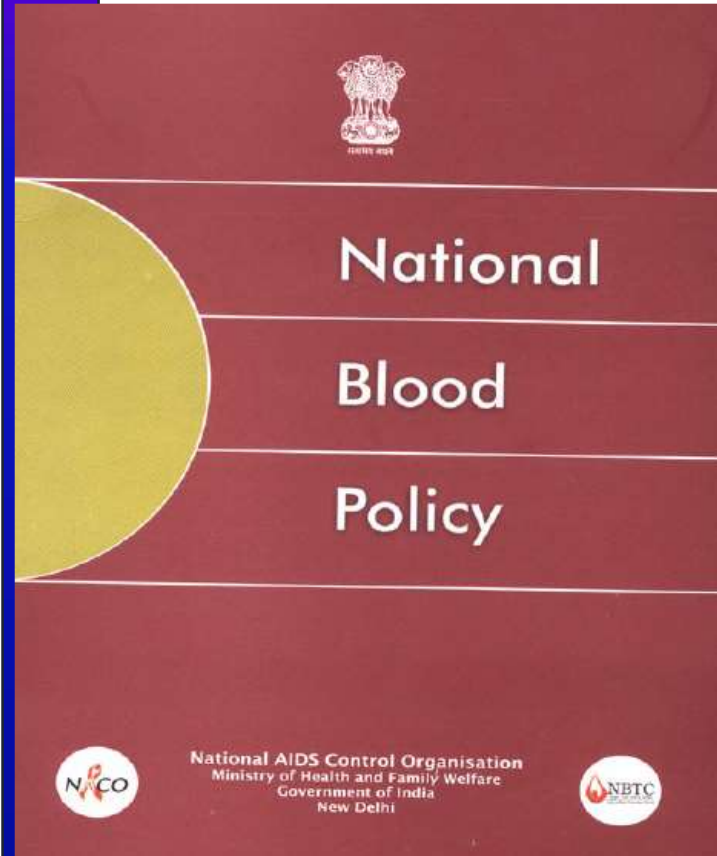
- Gradual progress : Legacy issues
- Legislation/Policy: live documents
 - Keeping up with change
 - Risk based framework
 - Guidelines
- Implementation
- Challenges:
 - Multiplicity of organizations
 - Communication
 - Coordination
 - Fragmented BTS system
 - Heterogeneity
 - States
 - Population
 - Geographical
- Role of Partners



OBJECTIVES OF THE POLICY:

To achieve the above aim, the following objectives are drawn:

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.
2. To make available adequate resources to develop and re-organise the blood transfusion services in the entire country.
3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.
4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.
5. To encourage appropriate clinical use of blood and blood products.
6. To strengthen the manpower through human resource development.





Why Policy Matters:

- Policy as statement of intent
- The intent of the state: **to provide safe blood to its citizens**
- **Patient care**
- This community is the most aware
 - Scientific basis
 - Evidence informed
- Positive influence
- Systems approach
- Making an impact

HOW?

- Become involved
- Research
- Generate evidence
- Publish



CDC-CMAI Project (PEPFAR Funded)

- Capacity building
 - Domain specific
 - Revision of training content/methods/standardization
 - Trainers standardization
 - Regional Training Centres
- Quality Management Systems
 - Concept: phased; progressive
 - Content/methods/standardization
 - Training of Trainers
- Evidence generation
 - Rapid Situation Analysis (2014)
 - Baseline assessment (on going)
 - Blood requirements (on going)
- Technology
 - Donor kiosk
 - Vein-Vein safety
 - GIS mapping

*Facilitating implementation
Bridging the gap*



Upcoming opportunities to collaborate

- Review of the Drugs and Cosmetics Act
- Review of the DGHS Technical Manual
- Send an email with Sub: “**Volunteer DACA**” or “**Volunteer DGHS Manual**”
- **Name**
- **Designation**
- **Department/Institution**
- **Contact phone number**
- **Specify which one of the above you are interested in**

volunteerbts@gmail.com



Thank you



Acknowledgements

NACO/NBTC

Drugs Control Authority

Partners: CMAI, CDC, CHAI

The Transfusion Medicine Community

My own Colleagues at CMC