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# Comparative Health Policy Analysis: National Blood Policy of India, 2007 and National Blood Policy of Bhutan, 2007

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# **Review Article**

# Comparative Health Policy Analysis: National Blood Policy of India, 2007 and National Blood Policy of Bhutan, 2007

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# Abstract

In 2001, blood safety was identified by the World Health Organization (WHO) as one of its key priority areas. In the same year, member countries of the South-East Asia Region (SEAR) formulated a Global blood safety strategy at a regional consultation. India and Bhutan, two developing nations in the SEAR formulated their National Blood Policies in the coming years to promote blood safety by improving the availability and quality of blood. This article uses the health policy triangle given by Walt and Gibson and the question four of the 'What's the problem represented to be?' approach given by Carol Bacchi (2009) to analyze and compare the formation and implementation of these policies and to identify the silences in both of them. With both countries addressing the same problem in different contexts, these tools gave us a comprehensive picture of the interests and power distribution of the various stakeholders and their role in various steps of the policy process.

Key words: Bacchi approach, blood transfusion system, health policy analysis, health policy triangle

### Introduction

The WHO in 2001 identified blood safety as one of its key priority areas. A Global Blood Safety Strategy was formulated at the regional consultation of member countries of the SEAR, held at Myanmar in 2001 to promote blood safety by improving the availability and quality of blood. As per the report of this meet, India and Bhutan had no National Blood Transfusion Services (BTS) or National Blood Policy at that time.<sup>1</sup>India made its first National Blood Policy in 2002, which was reprinted in 2007 and Bhutan brought about its first National Blood Policy in 2007 based on guidelines given by WHO. This paper aims to analyze and compare the formation and implementation of National Blood Policy of India, 2007<sup>2</sup> with National Blood Policy of Bhutan, 2007.3

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#### Frameworks for analysis

This paper used the health policy triangle<sup>4</sup> as the main framework to analyze the two policies. At the end, question four of the 'What's the problem represented to be?' approach given by Carol Bacchi (2009)<sup>5</sup> was applied to identify the silences in both the policies. With both countries being developing nations addressing the same problem in different political contexts, these tools give a comprehensive picture of the interests and power distribution of the various stakeholders and their role in various steps of the policy process.

#### **Contextual factors**

Leichter (1979)<sup>6</sup> broadly classified factors that can affect policy making into situational, structural, cultural and international. Various structural components were seen affecting the policy formation in the Indian context. As stated in the policy, decentralization of BTS, lack of trained health care professionals and other manpower, poor infrastructure and funding, fragmented management of blood banks and shortage of blood components necessitated a need to formulate a National Blood Policy and initiate a National Blood Program. It

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1

was also expected to be in line with the directives of Supreme Court of India, 1996.

Bhutan also looked at ensuring blood safety and adequacy through a National policy for similar structural reasons as India. In addition, as seen in the policy document, there was a situational increase seen in infection transmission through transfusions like HIV and also seasonal shortages due to emergence of complex disease patterns which required large transfusions for management. Thus, a National Blood Policy was incorporated as an integral part of Bhutan's health policy in 2007. This was possible with international aid from WHO and the advocacy of the use of Global Blood Safety Strategy.

# Actors in the policies

National Blood Policy of India comes under the Ministry of Health and Family Welfare (MoHFW) in the National AIDS Control Organization (NACO) division. NACO allocates budget to the apex body for policy formulation-the National Blood Transfusion Council (NBTC). The Drugs and Cosmetics Law regulates the standards of blood and blood products and to maintain them is the responsibility of Drug Controller General of India. The State and Union Territory Blood Transfusion Councils (SBTC/ UTBTC) come into play at the implementation level. Along with NBTC, they try to involve trained and experienced clinicians, blood transfusion specialists, pathologists, NGOs of repute, the Red Cross Society of India, Federation of Indian Thalassemics (FIT), and Haemophilia Federation of India (HFI) and various donor organizations.7

In Bhutan, the responsibility for blood safety is solely of the Ministry of Health and it executes it through National Blood Transfusion Service (NBTS). The WHO SEARO was involved in the formulation of the policy and the funding and technical support was provided by the World Bank and the HIV/STD prevention and control project. The policy suggests introduction of NBTS under 'Health care and diagnostics services' division of the Department of medical services. The National/Regional and District blood banks would act as focal centres for collaborations and communication. In both the policies, very limited/no role is seen of pressure/interest groups or any private sector companies or community. Voluntary donors constitute important actors for the success of both the policies. Also, both policies mention prohibition of trading (sales and purchase) of blood, so the individuals/organizations involved in this would eventually become important stakeholders.

# The Policies' processes

# Problem identification

The Ministry of Health and Family Welfare (MoHFW) recognized the need of an organized BTS with a blood safety initiative to minimize transmission of infections through transfusion and to provide safe and adequate transfusion services. The policy, in its introduction states that the existing system of BTS was a defragmented one, with inadequate manpower, infrastructure and funds. States to state, city to city and centre to centre in the same city variations were present in the service delivery, with no blood banks in many clinics, hospitals and nursing facilities. This had caused privatization of blood bank services. Thus, it identified the limited blood component production and availability, shortage of health care professionals and quality assessment as the problem area, necessitating the need for blood centres which were well equipped and managed by trained professionals. This, if present under one central body, could make the process of blood transfusion more uniform.

Bhutan recognized safe blood transfusion as a lifesaving intervention forming an essential part of modern health care. Also, the number of HIV infections and the risk of procuring a transfusion transmitted infection (TTI) through sero-negative transmission were on a gradual increase in the country. Also, despite an adequate donor base and nationwide collection of blood showing no shortage, blood banks often still faced a shortage of blood. This called for a well-developed voluntary blood donor program and a check on the unnecessary use of blood and blood components. BTS had started to be seen as a pharmaceutical industry requiring 'Good Manufacturing Practices (GMP),' where blood was labeled as 'drug'. Also resources like

#### Malik P: Comparative Health Policy Analysis: National Blood Policy of India, 2007...

trained professionals, proper infrastructure and finances had become limited. This necessitated the need of framing a National Blood Policy that defined organizational, financial and legal structures through a 'comprehensive, efficient and a total quality management approach' as stated in the introduction of the policy document.

# Policy formulation

With establishment of NACO in 1992 for policy development and scrutiny of prevention and control programs of HIV and AIDS, a common cause petition was filed about non-licensed blood banks in unhygienic environments with no trained personnel or storage facilitates and against blood from paid donors, some of whom had no medical check or screening test for transfusion transmissible diseases (TTDs) like HIV etc.<sup>8</sup> It was further stated that by 1996, NBTC was constituted as per the Supreme Court mandate to promote voluntary and safe blood donation and transfusion and provide infrastructure and manpower to blood centres. For various activities related to BTS, this now acted as the apex policy making body, as well as the coordinator of the State Blood Transfusion Councils (SBTCs), other Ministries and some health programs. In 2002, India adopted the National Blood Policy. An action plan on blood safety was formulated by the governing body of NBTC to address all the objectives of the National Blood Policy.

In case of Bhutan, not many supporting documents were available about the formulation of the policy. The policy document itself gives an idea though, that the WHO was advocating the use of Global Blood Safety Strategy in the SEAR countries, with an emphasis on role of formulating and implementing a Blood Policy at the National level. With funds and support coming from the WHO and World Bank, Department of Medical Services, Ministry of Health Bhutan recognized the importance of safe blood transfusion and with technical assistance from WHO, Jigme Dorji Wangchuk, National Referral Hospital published the National Blood Policy.

# Policy implementation

In the implementation of both the policies, a Top Down approach $^9$  can be seen. The description

of the actors shows the power distribution in the implementation. In order to improve the standards of blood banks and the BTS in the country, NACO via the Technical Resource Group on Blood Safety, formulated and called for dissemination at various levels, a set of comprehensive standards to have a better quality control at all stages, i.e. collection, storage, testing, distribution of blood and blood components. For effective clinical use of blood, clinical staff was trained. To attain maximum safety, good laboratory practices (GLP) were established. Penalties for unauthorized and illegal practices in blood banking system were also established.

For Bhutan as well, the description of actors above shows the implementation plan. Five objectives with various strategies under them are operated through the NBTS via the Regional, District and Basic Health Units.

In both the countries, the Regional levels are usually not involved in the policy formulation but play a major role in the implementation and feedback of the services.

# Policy evaluation

The eighth objective of National Blood Policy of India states strategies to monitor and evaluate BTS. Each State sets its own action plan and evaluates. A Rapid Situation Assessment of Blood Transfusion Services in India<sup>10</sup> was carried out between 13th Feb to 5th March, 2014 by US Centers for Disease Control and Prevention-Division of Global HIV/ AIDS (CDC-DGHA), India and Christian Medical Association of India (CMAI), where desk review was done and site specific observations were made. The thematic reviews, presentations, documents and guidelines developed by multilateral and bilateral agencies, annual work-plans, country program documents, program review meeting reports, national surveys, national reviews, annual and quarterly reports, and published journal articles in peer-reviewed journals were reviewed. It served as a guide to explain the situation of BTSs, the gaps, and challenges and gave recommendations to improve. According to report, the availability of safe blood increased from 44 to 93 lakhs from 2007 to 2013 and the HIV sero-reactivity also declined from 1.2% to

### Malik P: Comparative Health Policy Analysis: National Blood Policy of India, 2007...

0.2%. Also, number of voluntary blood donations increased substantially.

The National Blood Policy of Bhutan aims to get the quality system established by it reviewed regularly and even accredited by an external agency. A comprehensive Assessment Study of BTS, Bhutan, conducted in 2011<sup>11</sup> listed its achievements in areas such as the mapping of various centres, the assessment by trained teams, defining targets, finalizing action plans, capacity building and the consolidation of blood services. It also highlighted the constraints and gaps in terms of inadequate organization coordination in certain areas, lack of secure funding, technical capacity at some blood bank and lack of infrastructure at some.

# Content of the policies

Based on the context in which it was made, the National Blood Policy of India focuses on eight objectives with different strategies under each objective. These objectives show the political commitment to ensure adequate supply and proper usage of safe and quality blood and blood components by a re-organization of the BTS. Capacity building is seen in the ways they plan to conduct awareness programs. Appropriate use of blood, after screening it for TTIs, blood in wellequipped premises by trained professionals, and its storage and transport under optimum conditions are health promotion activities in the policy. Provision of above services irrespective of socio-economic status through comprehensive, efficient and a total quality management approach are covered under the policy.

The National Blood Policy of Bhutan aims to ensure an adequate, timely and easy access to safe and quality blood and blood products through the establishment of a National Blood Transfusion Service, effective legislation, and a National Regulatory Body to oversee the operation of the blood service and a sustainable National Blood Program. It advises appropriate clinical use of blood and transfusions to be carried out under the supervision of a trained health care professional. It focuses on five objectives with different strategies under each.

# Identifying the silences

There are challenges in ensuring availability and accessibility of blood in some districts of India, which still do not have government supported blood centers. India collects only 9 million units against an annual demand of 12 million units; only around 70% is from voluntary blood donors.<sup>12</sup>Less attention is given to organizational and management issues hindering the effective service provision in the country, and to the inequity in the availability due to cultural, ethnic differences etc. in the National Blood Policy.<sup>13</sup>

The Blood Policy of Bhutan, compared to India has not laid much emphasis on making latest technology available for transfusion services or on development of a research and development. Though some steps to monitor and evaluate the policy have been decided to be put in place, there was very less element of having legislative and regulatory mechanisms to eliminate profiteering in Blood Banks.

# Conclusion

The National Blood Policies of both the countries have been formed based on WHO guidelines by their Ministries of Health. While India started with some existing National Guidelines and incorporated elements from WHO guide, Bhutan mainly followed the Global Blood Safety Strategy. Both the policies follow a Top-Down approach of implementation. For India, the complex involvement of various stakeholders requires a holistic and comprehensive approach in formulating the policy with coordination between the BTS, health services, educational institutes, religious, social and industrial organizations, mass media and other stakeholders. Bhutan, on the other hand, as the policy states faces the major problem of shortage due to inappropriate use of already available blood/blood products and thus, the policy lays emphasis on the same. The evaluations done in 2014 and 2011 showed improvement in the BTSs in India and Bhutan, respectively.

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