JMSCR Vol||06||Issue||05||Page 1128-1132||May 2018

www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v6i5.182

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Blood and Blood Products Regulation in Bhutan: Progress and Challenges

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Abstract
Bhutan is a small Himalayan Kingdom situated between the two giants of the world, India and China. The road to modern healthcare system in Bhutan began in 1961 coinciding with the first Five Year Plan. Healthcare service in Bhutan is provided free by the government. The existing 27 blood banks in the country are located within the hospital setting under the laboratory sections. The Blood and Blood Products Regulation (BBP Regulation) of Bhutan was launched on 14 June 2016. Blood and Blood Products (BBPs) are regulated by the Drug Regulatory Authority (DRA).
Safe blood, safe donor and safe transfusion are the three elements of blood safety. BBPs are potential source of infections and other adverse events although millions of lives are saved each year through blood transfusions. The BBP Regulation of Bhutan, 2016 is the guiding regulatory tool to ensure the quality and safety of BBPs in the country. The regulatory provisions includes requirement for premise, personnel, equipment and quality assurance system for blood centers (BC) and blood storage centers (BSC) among others.
The DRA is faced with several challenges while implementing the BBP Regulation due to lack of expertise in regulating BBPs. Similarly, the existing blood banks in the country are not able to meet the requirements of BBP Regulation. Ministry of Health and relevant agencies should collaborate to comply with the BBP Regulation and ensure quality BBPs for safer transfusions. This article attempts to describe the key components of BBP Regulation, 2016 and highlights the progresses and challenges of the BBP Regulation in Bhutan.
Keywords: *Drug Regulatory Authority, Regulation, Transfusions, Blood and Blood Products, Bhutan.*

Introduction

Bhutan is a small Himalayan Kingdom situated between the two giants of the world, India to the south and China to the north. The total population projected in 2017 was 779,666 (Statistical Yearbook of Bhutan, 2017) and the gross national income per capita was USD 2640.17 in 2016 (National Accounts Statistics, 2017). According to the Asian Development Bank, Bhutan is the fastest growing economies in the developing Asia region (Dorji, T, 2018).

Modern healthcare system in Bhutan began in 1961 with two hospitals, two doctors and two nurses (Tobgay, T et al., 2011) coinciding with the first Five Year Plan, 1961-1966 (Yangchen, S et al., 2017). Bhutanese people enjoy free healthcare

services provided by the government as enshrined in the Constitution (The Constitution of The Kingdom of Bhutan, 2008). Healthcare services in Bhutan is delivered through a three-tiered healthcare system from Out Reach Clinics to Basic Health Units (BHUs) at the primary level and District Hospitals at secondary level and the Regional Referral Hospitals to National Referral Hospitals at the tertiary level (National Health Policy, 2011).

District Hospitals and few BHUs in the country function as blood banks providing blood services for the people of the country. Currently, there are 27 blood banks spread across the country. These blood banks are located within the hospital setting under the laboratory sections with varying infrastructures, resources and capacities. Blood banks are involved in donor recruitment and screening, blood collection, processing, testing, storage and release of BBPs for transfusion.

The need to ensure the quality and safety of BBPs is crucial while making it available is also equally important. BBP Regulation of Bhutan came into force on 14 June 2016 coinciding with the World Blood Donor Day. Since BBPs are considered as medicinal products in Bhutan, the DRA is responsible to regulate and implement the BBP Regulation.

Importance of Regulation of Blood and Blood Products

Quality and safety of BBPs must be accorded the highest priority while instituting a culture of safe transfusion practices is mandatory. Safe blood, safe donor and safe transfusion are the three elements of blood safety (Chandrashekar and Kantharaj, 2014). Blood transfusions save millions of lives each year but BBPs are also potential source of infections and other adverse events (Smit Sibinga, 2017). Lack of coordination of blood transfusion services, poor donor selection practices and unnecessary clinical use of BBPs are important factors leading to unsafe transfusion. It is important to have legislative procedures in place to prevent all these factors leading to unsafe transfusions. Therefore, regulatory frameworks are required to protect and promote the health of the blood donors and recipients of BBPs.

Regulation of BBPs is regarded highly crucial gaining its place at the global stage as evidenced by many international meetings deliberating on the need to establish and strengthen regulatory control systems for BBPs. The Member States of the World Health Organization (WHO) during the 63rd World Health Assembly (WHA) held in 2010 passed the resolution on **s**trengthening regulatory systems control for BBPs to ensure the availability, safety and quality of BBPs (Resolutions of 63rd WHA, 2010). Subsequently in 2014, the 14th International Conference for Drug Regulatory Authorities (ICDRA) held in Singapore recommended the member states to build the technical capacity of national regulatory authorities for effective control of BBPs (Recommendations of 14th ICDRA, 2014).

The WHO is also willing to support resource-limited countries to develop an adequate legislative framework for control of BBPs (Aide Mémoire for Ministries of Health: Developing a National Blood System) and developed the WHO Assessment Criteria for development and/or strengthening of national blood regulatory systems (Assessment Criteria for National Blood Regulatory Systems).

The National Blood Policy (2007) of Bhutan emphasizes the need to develop effective legislation and a national regulatory body to oversee the operation of blood services in the country. In line with this, drafting of the BBPs Regulation in Bhutan began way back in 2012. Series of consultative meetings and workshops were conducted until the finalization of BBPs Regulation in 2015. The Blood Technical Advisory Committee (BTAC) in its first meeting reviewed the draft BBPs Regulation before it was endorsed by the Bhutan Medicines Board (BMB) in 2015 (Minutes of 14th BMB Meeting).

Requirements for Blood Centers and Blood Storage Centers

The BBPs Regulation of Bhutan (2016) outlines the regulatory requirements for BC and BSC including the enforcement measures for non-compliances. The BBP Regulation was adopted to ensure universal access to safe BBPs through the strategy of self-sufficiency based on voluntary, non-remunerated blood donation as the sole source of blood in the country through proper control of premises, facilities, equipment, reagents and processes as per the national standards. Key components of BBPs Regulation (2016) are briefly discussed below.

Quality Management System is a basic requirement for any organization aspiring to achieve efficiency in public service delivery. BC and BSC are required to have a documented Quality Manual with defined scope of services and procedures spelling out the requirements in terms of organization structure and hierarchies of management, personnel, premises, equipment, reagents and quality assurance system among many others. Procedures for reporting product defects, complaint handling and internal audit system are essential for continual improvement of BC and BSC to ensure the quality and safety of the BBPs.

BC and BSC should operate with adequate human resources and infrastructure. Updated job descriptions with defined tasks and responsibilities of professionals are essential. Periodical training and competency assessments are critical to verify and ensure the proficiency and competency of the personnel working in the BC and BSC. The minimum qualification for personnel to work in the BC and BSC is Certificate in Medical Laboratory Technology having a minimum of six months on-the-job training.

Blood donor recruitment, screening and selection, blood collection, component preparation, testing, storage and release of BBP should be carried out by qualified personnel in accordance with the National Standards (NSBTS, 2013). Standard Operating Procedures must be developed for all these activities to ensure uniformity and consistency in the operation. While encouraging voluntary, non-remunerated blood donation, safety of the donor and recipient are of paramount importance.

BC and BSC intending to operate in Bhutanese market should obtain technical clearances from the DRA which will be issued only after satisfying the adequacy and suitability of the premises and other requirements as per the BBPs Regulation. BC and BSC differs in their scope of activities as shown in the Table 1.The BC as a Haemovigialance Center need to collect, assess and report adverse transfusion reactions to the National Haemovigilance Center i.e. DRA.

Table 1. Differences in the Activities of Blood Centers and Blood Storage Centers

Blood Centers	Blood Storage Centers
Blood donor recruitment	No Blood donor recruitment
Donor selection	No Donor selection
Blood collection	No Blood collection
Blood component preparation	No blood components preparation
Testing of blood and blood products including blood grouping and cross matching	Only blood grouping and cross matching allowed
Storage, Issue, Transport and Distribute blood and blood products to Blood Centers	Store and issues blood for transfusion
Conduct mobile blood donation	Cannot conduct mobile blood donation
Report adverse transfusion reactions to National Hemovigilance Center	Report adverse transfusion reactions to Hemovigilance Centers

Progress and Challenges

It has been about two years since the BBP Regulation of Bhutan, 2016 was launched. Notable directives for implementation of BBP Regulation were made by the last five BTAC meetings. Several blood banks have been inspected by DRA and inspection findings are disseminated for improvement and compliance. Blood banks re-inspected are found to have improved their compliance. There is an improvement in terms of procedures and documentations related to BBPs. Personnel involved in handling of BBPs were sensitized and trained on the BBP Regulation including the nurses involved in blood transfusions. Numbers of guidelines and standards to supplement the implementation of the BBP Regulation are being developed and sensitized.

However, DRA is faced with challenges as regulation of BBPs is different from regulation of pharmaceutical products. Most of the existing blood banks do not comply with the premise, infrastructure and other requirements of the BBP Regulation as they are located in the hospitals built long before. DRA do not have officials trained in regulating BBPs and therefore, capacity of the existing officials must be enhanced and recruit officials trained in blood transfusions and related professions. National Drug Testing Laboratory must be strengthened for testing blood and blood products. Moreover, as the BBP Regulation is new, more healthcare professionals must be sensitized on importance of quality BBPs and importance of reporting adverse transfusion reactions.

The existing hospital-based blood banks must be consolidated as BC and BSC to enable prioritization and optimization of resource allocation and utilization. Parameters like easy road accessibility between the proposed BC and BSC and population size of the local community should be studied for consolidation. Consolidation would reduce duplication of activities, improve efficient management and ensure specialization of activities in the BC and BSC.

Conclusion

The BBPs Regulation of Bhutan, 2016 is the guiding document for regulation of BBPs in the country. All the BC and BSC are supposed to comply with the regulatory provisions although compliance rate is found low as revealed by the inspection findings. However, considering the limitations in our own context, gradual enforcement of the BBP Regulation is critical. Concerted efforts must be put in by all relevant agencies to collaborate in complying with the BBPs Regulation to ensure quality and safe BBPs for the public.

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