



(REVIEW ARTICLE)



## Recent advancement in regulatory requirements on hypertension in India as per CDSCO in comparison with south Africa

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World Journal of Advanced Research and Reviews, 2023, 20(01), 447–450

Publication history: Received on 30 August 2023; revised on 09 October 2023; accepted on 11 October 2023

Article DOI: <https://doi.org/10.30574/wjarr.2023.20.1.2058>

### Abstract

Hypertension is a significant health issue in India and KwaZulu-Natal, South Africa, and it is associated with a considerable reduction in adverse cardiovascular disease outcomes. The India Hypertension Control Initiative (IHCI) was launched to accelerate access to treatment services and reduce hypertension prevalence by 25% by 2025. The IHCI project was designed to improve hypertension control in public sector clinics, and it was launched in the 2018–2019 in 26 districts across five states of India: Punjab, Madhya Pradesh, Kerala, Maharashtra, and Telangana.

Both India and KwaZulu-Natal, South Africa, face significant public health issues related to hypertension, with 29.8% of adults suffering from the condition. India has made significant progress in addressing hypertension and refining regulatory measures. The overall occurrence of hypertension in India is 29.8%. There was a vital difference in the prevalence between urban and rural areas and among certain demographic groups in both countries. In rural areas, awareness, treatment, and control were significantly lower among men compared to women. Hypertension prevalence was higher in urban than rural areas in all studies that covered both types of area in the country. Awareness and treatment are especially important in the rural areas. It appears that hypertension is a significant issue in both countries, with higher prevalence rates in urban areas and among certain demographic groups. In this paper, we review and focus on the comparison on regulatory requirements on hypertension in both the countries.

**Keywords:** Regulatory requirements; Lifestyle modification; IHCI; Hypertension management; Healthcare initiative; KwaZulu-Natal.

### 1. Introduction

Hypertension (high blood pressure) is when the pressure in your blood vessels is too high (140/90 mmHg or higher). It is common but it can be serious if not treated.

People with high blood pressure may not feel the symptoms. The only way to know is to get your blood pressure checked. Today, as per the World Health Organization (WHO), Hypertension is the number one cause of deaths globally - accounting for 7.5 million deaths per annum. Hypertension is a significant risk factor for cardiovascular diseases, secretarial for approximately 30 percent of deaths globally, thus it is a pervasive health issue impacting millions of human beings. Revising the hypertension prevalence in India and KwaZulu-Natal, South Africa. The Indian government has set a target of a 25% relative reduction in the prevalence of hypertension (increased blood pressure) by 2025. To achieve this, the Indian Hypertension Control Initiative (IHCI) was launched to fast-track access to treatment services for over 220 million people in India who have hypertension.

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Only about 12% of people with the hypertension in India have their blood pressure under control. KwaZulu-Natal, a coastal South African province. Hypertension is a significant health issue in KwaZulu-Natal, South Africa, and is linked with a substantial reduction in adverse cardiovascular disease outcomes. A study was conducted in 2023 aimed to investigate the individual and area-level socioeconomic correlates of hypertension prevalence, awareness, treatment, and control in uMgungundlovu, KwaZulu-Natal, South Africa. It was found from the study that the hypertension prevalence was higher among individuals with lower education levels, lower income, and those living in rural areas. The study emphasizes the status of addressing socioeconomic inequalities to improve hypertension control in the region. The studies suggest that refining adherence to treatment plans and addressing socioeconomic inequalities are crucial for achieving improved blood pressure control and decreasing hypertension prevalence in the region.

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## **2. Comparative Analysis of Hypertension Prevalence and Management Strategies in India and South Africa, KwaZulu-Natal.**

Firstly, the prevalence of hypertension differs significantly between the two countries, India and South Africa. According to a study, the hypertension prevalence in India is around 33 percent, while in South Africa, it is as high as 78 percent. These rates are equivalent to those reported in high-income countries (source). Additionally, it was found from the South African Hypertension Guidelines that men are expressively more likely to be hypertensive compared to women, and Indian ethnicity is associated with lower hypertension prevalence in South Africa (source).

Secondly, both India and South Africa have implemented interventions to increase medication access for hypertensive patients. The Indian government has taken steps to rise medication access, and the South African government has also implemented interventions in this respect (source).

Furthermore, both countries have advanced guidelines for hypertension diagnosis, treatment, and treatment targets. These guidelines states to provide healthcare professionals with evidence-based sanctions for the hypertension management.

In terms of lifestyle changes, both India and South Africa recommend that all hypertensive patients must undergo necessary lifestyle modifications. This includes changes to diet, regular exercise, and stress management techniques. However, there are certain difference in hypertension switch rates between the two countries. While the exact control rates are not provided in the given information, and it is mentioned that South Africa has minor levels of awareness and blood pressure control compared to India.

A study from 2015-2021 found that 58% of present hypertension cases in India are undiagnosed people are unaware, with higher burdens in males, middle-aged, lower education levels, poorer wealth quintiles, STs, and rural inhabitants. The India Hypertension Control Initiative (IHCI) was launched to accelerate access to treatment services and reduce hypertension prevalence by 25% by 2025. Uncontrolled blood pressure is a major risk factor for cardiovascular diseases, and a nationally representative study found that at least one in four adults in India has hypertension, but only 12% of the people have their blood pressure under control. In South Africa, a 2014 study found poor adherence to treatment strategies led to inadequate blood pressure control and high morbidity among patients with hypertension. A 2023 study found hypertension prevalence was higher among individuals with lower education levels, lower income, and those living in rural areas. Both India and KwaZulu-Natal, South Africa, face significant public health matters related to hypertension, with 29.8% of adults suffering from the condition.

In recent years, there have been significant advancements in regulatory requirements for hypertension in both India and South Africa. According to the Central Drugs Standard Control Organization, India has made prominent progress in addressing hypertension and improving regulatory actions. One of the primary advancements in India's regulatory requirements is the recognition of the high prevalence of hypertension in the country. According to a study conducted by the CDSCO, it is reported that the overall prevalence of hypertension in India is around 33%.

As per the study, the prevalence rates reported in South Africa, where hypertension affects approximately 78% of the adult population. One possible reason for this difference in prevalence rates could be the variable socioeconomic factors and the lifestyle that the people have adopted in both the countries. Furthermore, the CDSCO has introduced guidelines and regulations aimed at educating the diagnosis and management of hypertension in India.

These guidelines highlights the importance of the regular blood pressure screenings, lifestyle modifications, and appropriate pharmacological interventions for individuals with hypertension. In comparison, regulatory requirements for hypertension in South Africa, particularly in the province of KwaZulu-Natal, have also undergone advancements.

The prevalence of hypertension in South Africa, specifically in KwaZulu-Natal, has been documented as the highest ever reported by a nationally demonstrative study for any country in the world.

The high prevalence of hypertension in South Africa has driven the government to implement stricter regulations and guidelines to address this public health concern. These regulations mainly focus on improving primary healthcare services, ensuring access to reasonable medications, and promoting a healthy lifestyle among the population. In conclusion, it can be said that both India and South Africa have made significant advancements in their regulatory requirements for hypertension.

As of the recent studies in Kwazulu-Natal, South Africa, have highlighted the need for improved hypertension management strategies. A 2014 study found poor adherence to treatment plans, leading to inadequate blood pressure control and high morbidity among hypertension patients. A 2023 study found higher prevalence among individuals with lower education, income, and rural areas. Despite no recent amendment specifically related to hypertension in KwaZulu-Natal, these findings review the importance of addressing socioeconomic inequalities for better blood pressure control.

Hypertension is a significant public health issue in both the countries India and KwaZulu-Natal, South Africa. In India, 29.8% of adults suffer from hypertension, with males being more prone than females. The prevalence increases with age, and 42.8% of rural and urban women in India are aware of hypertension. In KwaZulu-Natal, South Africa, the provinces of KwaZulu-Natal and Mpumalanga showed significantly higher hypertension prevalence in 2016. Hypertension was higher among males, from the coloured population group, and from urban areas. The prevalence of hypertension increases non-linearly with age, BMI, waist circumference, and blood cholesterol. Urban areas had higher hypertension prevalence in all studies. In India, 76.1% of individuals with hypertension had been screened, 44.7% were aware of their diagnosis, 13.3% were treated, and 7.9% had achieved control. However, there is no specific data provided on screening, awareness, treatment, and control in KwaZulu-Natal. Both India and KwaZulu-Natal face significant challenges in addressing hypertension.

## **2.1. General comparison on hypertension in India and KwaZulu-Natal**

Hypertension, or high blood pressure, is a significant health issue in both India and KwaZulu-Natal, South Africa.

Here is a comparison of the two regions:

### *2.1.1. Prevalence*

- The overall prevalence of hypertension in India is 29.8%.
- A substantial proportion (29.8%) of adults in India suffer from hypertension.
- The prevalence of prehypertension and hypertension is higher among untrained respondents in India.
- In KwaZulu-Natal, it is stated that uncontrolled hypertension is higher in low- and middle-income countries (LMICs) like South Africa.
- The prevalence of hypertension was higher among participants who were male, from the coloured inhabitants group, and from urban areas.
- The prevalence of hypertension increased non-linearly with age, BMI, waist border, and blood cholesterol.

### *2.1.2. Awareness, Screening, Treatment and Control*

- In India, among individuals with hypertension, 76.1% had been partitioned, 44.7% were aware of their diagnosis, 13.3% were treated, and 7.9% had achieved control.
- No specific data on screening, awareness, treatment, and control in KwaZulu-Natal.

### *2.1.3. Gender Differences*

- In India, hypertension is more prevalent in males in the age group of 35-50 years, but after 50 years of age, it becomes more prevalent in females. Hypertension occurrence in India increases with age.
- In young adults (20-39 years) in Kerala, South India, awareness, treatment, and control of hypertension were meaningfully lower among men compared to women.
- Hypertension was significantly higher among participants who were male, from the coloured population group, and from urban areas.

#### 2.1.4. Rural vs. Urban

The search results mention that improvements in access to hypertension diagnosis and treatment are specifically important in rural areas in India. A survey of 4608 rural and urban women in India found that 42.8% were aware of hypertension.

#### 2.1.5. Risk factors

Obesity is a major common risk factor for hypertension in both regions. Other risk factors such as age, gender, and education level may also leads to hypertension prevalence in India. In KwaZulu Natal, male gender, urban residence, and belonging to the coloured population group are allied with higher hypertension prevalence.

As of all studies that covered both types of area in KwaZulu-Natal, Hypertension prevalence was higher in urban than rural areas. The prevalence of hypertension was higher among members who were male, from the coloured population group, and from urban areas.

Over all, both India and KwaZulu-Natal face significant challenges in moralizing hypertension, it appears that hypertension is a significant issue in both India and KwaZulu-Natal, with higher prevalence rates in urban areas and among certain demographic groups.

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### 3. Conclusion

Hypertension is a significant health issue in KwaZulu-Natal, South Africa, associated with reduced cardiovascular disease outcomes. And the major reasons includes, lacking improved management strategies and regulatory improvement. The prevalence is higher in urban areas and specific demographic groups. The Indian Hypertension Control Initiative (IHCI) implements certain strategies such as standard treatment, consistent drug supply, team-based and patient-centered care, and an information system. This paper highpoints the importance of improved hypertension management, including screening, diagnosis, treatment, lifestyle modification, and patient education.

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### Compliance with ethical standards

#### *Acknowledgments*

The authors wish to thank the management and faculty of Sree Siddaganga College of Pharmacy, Tumkur, for providing facilities to carry out this research.

#### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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