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INSIDE

Insights

Enhancing Diversity and Inclusion in Rare Disease Clinical Trials: The Role of Sri Lanka

The need for diverse participation in clinical trials cannot be overstated, especially when it comes to rare diseases. Historically, racial and ethnic minorities have been underrepresented in clinical trials, which has resulted in significant health disparities among underrepresented populations. In fact, the Federal Drug Administration (FDA) issued draft guidance (April 2022) outlining the need for the development of race and ethnicity diversity plans for products under the FDA's remit, recommending that all products include a diversity plan. This guidance is a result of 30 years of policy priority and heroic efforts by healthcare advocates to improve clinical trial diversity.

South Asia, a melting pot of genetic diversity, is home to thousands of ethnically and culturally diverse populations (Tätte et al., 2019). While consanguineous marriages are nearly uncommon or prohibited by societal pressure in Western societies, in many parts of Africa and Asia, including South Asia, approximately 20–50% of marriages are consanguineous (Mobarak et al., 2019). In Sri Lanka

a study by Premawardhena et al., 2020 reveals that the overall national consanguinity rate is 7.4%. This contributes to an increased risk of rare diseases by facilitating the inheritance of recessive genetic variants within families.

A survey analyzing gene therapy clinical trials listed on ClinicalTrials.gov found that the majority of these trials were conducted in high-income countries and upper middle-income countries, with very limited representation from lower-middle-income and low-income countries (Cornetta et al., 2022). Specifically, when examining trials for diseases like Duchenne muscular dystrophy (DMD), spinal muscular atrophy (SMA), and Huntington's disease (HD), the overwhelming majority (99%) of trials were concentrated in HICs and UMICs, excluding South Asian countries (Wijekoon et al., 2023). This exclusion is particularly striking, considering that South Asians constitute a significant portion (40%) of the Asian population and 25% of the global population.

Including Sri Lanka in rare disease clinical trials can contribute to addressing issues of underrepresentation and improve the generalizability of the trial results.

Advantages of Sri Lanka for Rare Disease Clinical Trials:

1. Diverse Patient Population: Sri Lanka's diverse patient population ensures a broader representation of ethnic and genetic backgrounds. By including patients from different racial and ethnic groups, the trials can better understand the impact of treatments on diverse populations.

2. Disease Registries: Clinician researchers in Sri Lanka have established disease registries for rare diseases such as lupus nephritis, chronic obstructive pulmonary disease (COPD), and IgA nephropathy. These registries enable trial sponsors to identify suitable patients, track their outcomes, and gather valuable data on disease progression and potential treatments.

3. Healthcare Infrastructure: Sri Lanka possesses a robust healthcare infrastructure, including universal state-funded health coverage, dedicated specialty hospitals, and investigators with clinical trial experience. This infrastructure supports the execution of rare disease projects in line with international standards.

4. Regulatory Framework: Sri Lanka has a well-defined regulatory framework for clinical trials, ensuring compliance with ethical and safety standards. This regulatory support

facilitates efficient and streamlined trial initiation and execution.

5. Advanced Facilities: Sri Lanka offers CAP-accredited central laboratories, long-term document archival and retrieval facilities, drug destruction facilities for used and unused investigational medical products (IMPs), accredited calibration services, and temperature-controlled specimen and drug transport facilities. These advanced facilities contribute to reliable data collection, storage, and transportation throughout the clinical trial process.

Sri Lanka's potential as a location for rare disease clinical trials lies in its diverse patient population, disease registries, robust healthcare infrastructure, supportive regulatory framework, and advanced facilities. By conducting inclusive and equitable trials in Sri Lanka, sponsors can enhance diversity, improve the generalizability of trial results, and address historical underrepresentation.

To discover how RemediumOne can optimize participant engagement and enrollment in rare disease clinical trials in Sri Lanka, we invite you to connect with us.

References:

Cornetta K., Bonamino M., Mahlangu J., Mingozzi F., Rangarajan S., Rao J. Gene therapy access: global challenges, opportunities and views from Brazil, South africa, and India. Mol. Ther. 2022

Mobarak A.M., Chaudhry T., Brown J., Zelenska T., Khan M.N., Chaudry S., et al. Estimating the health and socioeconomic effects of cousin marriage in South Asia. J. Biosoc. Sci. 2019;51(3):418–435.

Tätte K., Pagani L., Pathak A.K., Kõks S., Ho Duy B., Ho X.D., et al. The genetic legacy of continental scale admixture in Indian Austroasiatic speakers. Sci. Rep. 2019;9(1):1–9.

Wijekoon N, Gonawala L, Ratnayake P, et al. Gene therapy for selected neuromuscular and trinucleotide repeat disorders - An insight to subsume South Asia for multicenter clinical trials. IBRO Neurosci Rep. 2023;14:146-153.

Information

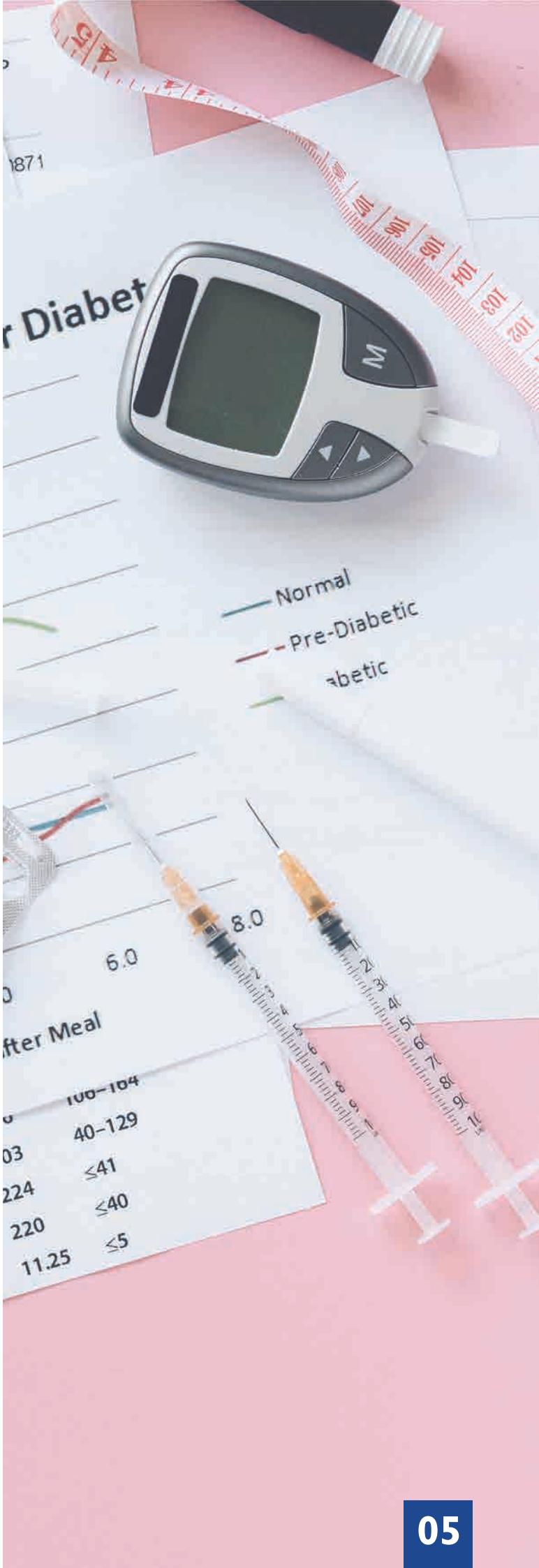
Non-Communicable Disease Burden in Sri Lanka

Non-communicable diseases (NCDs) have emerged as a significant global health challenge, accounting for the majority of morbidity and mortality worldwide. Sri Lanka, a country located in South Asia, is no exception to this trend. This article aims to provide an overview of the burden of non-communicable diseases in Sri Lanka, highlighting key facts and factors contributing to this growing public health issue.

Prevalence and Risk Factors

NCDs encompass a range of chronic conditions, including cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes. In Sri Lanka, NCDs account for approximately 80% of all deaths, making them the leading cause of mortality in the country [1]. Moreover, around 35% of the population aged 15 years and above have at least one NCD, with hypertension being the most prevalent condition [2].

Several factors contribute to the high prevalence of NCDs in Sri Lanka. The country has undergone a rapid demographic transition, with an aging population. It is estimated that by 2030, the proportion of Sri Lanka's population aged 60 years and above will reach 21% [3]. This aging population, coupled with changes in lifestyle patterns, has resulted in a higher NCD burden.



Urbanization and globalization have led to shifts in dietary habits. Sri Lanka has witnessed an increased consumption of processed foods high in salt, sugar, and unhealthy fats. According to a national survey, over 10% of adults consume fast food at least once a week [4]. Additionally, sedentary lifestyles have become more prevalent, with less physical activity and increased reliance on motorized transportation.

Tobacco use is another significant risk factor for NCDs in Sri Lanka. The prevalence of smoking among adults is estimated to be around 20%, with higher rates among males [5]. Harmful alcohol consumption is also a concern, with an estimated 26% of the population consuming alcohol regularly [6].

Impact on Health and Economy

The burden of NCDs in Sri Lanka extends beyond the realm of health. These diseases place a significant economic burden on the country, affecting productivity, healthcare expenditure, and overall development. It is estimated that NCDs cost the Sri Lankan economy approximately 1.5% of its gross domestic product (GDP) annually [7]. The cost of treating NCDs, coupled with the loss of productive years due to premature mortality and disability, exacerbates the strain on the healthcare system and hinders socioeconomic progress.

Healthcare Response

Recognizing the severity of the NCD burden, the Sri Lankan government has taken several steps to address the issue. The National NCD Prevention and Control Program, initiated in 2017, focuses on promoting healthy lifestyles, early detection, and optimal management of NCDs. Efforts have been made to strengthen primary healthcare services, improve health education, and implement policies to control risk factors such as tobacco and alcohol consumption.

Collaboration between the health sector and other relevant stakeholders, including civil society organizations, has been crucial in implementing preventive and control measures. The integration of NCD management into the existing healthcare system and the training of healthcare professionals to provide comprehensive care are essential components of the response.
In summary,

The burden of non-communicable diseases in Sri Lanka has reached alarming levels, adversely affecting the health and well-being of its population. The country's demographic transition, coupled with changing lifestyles and risk factors, has contributed to this growing public health challenge. Efforts to address the NCD burden have been made through policy interventions, health promotion, and improved healthcare services.

However, sustained, and concerted action is necessary to combat the rising tide of NCDs in Sri Lanka. Comprehensive strategies that target risk factors, improve access.

References

1. World Health Organization (WHO). Noncommunicable diseases country profiles 2018. Geneva: WHO; 2018. Available from: https://www.who.int/nmh/countries/lka_en.pdf

2. Ministry of Health, Sri Lanka. Non-Communicable Diseases Risk Factor Survey, Sri Lanka 2015. Available from: http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/2015/Risk%20Factor%20Survey%202015.pdf

3. United Nations Population Fund (UNFPA). Sri Lanka: Ageing Population. Available from: https://srilanka.unfpa.org/en/topics/ageing-population

4. Ministry of Health, Sri Lanka. National Nutrition Survey 2012. Available from: http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/nutrition/NNS%202012%20final%20report.pdf

5. Institute for Health Metrics and Evaluation (IHME). GBD Compare: Sri Lanka. Seattle, WA: IHME, University of Washington; 2019. Available from: http://vizhub.healthdata.org/gbd-compare

6. World Health Organization (WHO). Global status report on alcohol and health 2018. Geneva: WHO; 2018. Available from: https://www.who.int/publications/i/item/9789241565639

7. Nugawela P, Warnakulasuriya N, Peiris-John RJ, Weerasinghe MC. Estimating the economic cost of non-communicable diseases in Sri Lanka: a cost-of-illness study. BMC Public Health. 2020;20(1):1574. doi:10.1186/s12889-020-09553-7

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