How to Cite:
Dhinwa, M., Jha, N., Jyani, S., Chandra, R., Kumar, S., Lachyan, A., & Chauhan, A. (2022). The journey of tuberculosis control, conceptual changes and implications of the shift from NTP to RNTCP to NTEP: A review. *International Journal of Health Sciences*, *6*(S1), 12269–12281. https://doi.org/10.53730/ijhs.v6nS1.8072

The journey of tuberculosis control, conceptual changes and implications of the shift from NTP to RNTCP to NTEP: A review

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***Abstract*---**Tuberculosis (TB) has long afflicted communities and nations. People have suffered for generations as a result of tuberculosis, and even today, when newer methods of diagnosing and treating the disease have made it curable, people continue to suffer and dying from it and malnutrition, overcrowding, air pollution, poor living conditions, and other factors that contribute to the TB burden. Financial decentralisation, as well as increased community participation, are required to achieve TB control in India.

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.
Manuscript submitted: 27 March 2022, Manuscript revised: 9 April 2022, Accepted for publication: 18 May 2022

Furthermore, RNTCP should be effectively integrated with other related programmes i.e., the NACP to address co-infection (TB-HIV) and the National Rural Health Mission. Emerging problems such as childhood tuberculosis, multidrug-resistant tuberculosis, and multidrug-resistant tuberculosis should be addressed. Financial decentralisation, as well as increased community participation, are required to achieve TB control in India. Furthermore, RNTCP should be effectively integrated with other related programmes i.e., the NACP to address co-infection (TB-HIV) and the National Rural Health Mission. Emerging problems such as childhood tuberculosis, multidrug-resistant tuberculosis, and multidrug-resistant tuberculosis should be addressed.

***Keywords*---**tuberculosis, RNTCP, NTEP.

Introduction

Tuberculosis (TB) has long afflicted communities and nations. People have suffered for generations as a result of tuberculosis, and even today, when newer methods of diagnosing and treating the disease have made it curable, people continue to suffer and dying from it and malnutrition, overcrowding, air pollution, poor living conditions, and other factors that contribute to the TB burden [(1)]. TB not only causes human suffering, but it also has a significant socioeconomic impact in our country, India. Furthermore, tuberculosis has a global socioeconomic impact on our country's progress. In the case of tuberculosis, nearly 40% of people are infected with TB bacilli, and approximately 10% develop tuberculosis throughout their lives. In addition, if one sputum positive patient is not treated, it can infect 13-15 people in a year, and poorly treated patients develop drug-resistant and severe forms of tuberculosis. Because tuberculosis is more common between the ages of 20 and 50, which are the most productive years of a person's life, It places a significant financial strain on the country and has a significant impact on the lives of patients in terms of working days and money earned [(2)]. Since the early 20th century, India has long been a leader in tuberculosis control and research. Many efforts came under existence during the time to reduce the disease burden, despite many achievements by various strategies under TB programmes to date, we continue to face many challenges, so this article focusing on the conceptual changes and implications of the shift from NTP to RNTCP to NTEP and analyzing important components and program strategies of RNTCP.

Objectives

Discussing the conceptual changes and implications of the shift from NTP to RNTCP to NTEP.
To analyze important components and program strategies of RNTCP and NTEP.

Review

The Journey of tuberculosis control so far in India [3,4]

Tuberculosis control in India has a long history. India has been at the forefront of tuberculosis control and research since the early 20th century. In 1906, a Christian organisation established the first open-air sanatorium in Rajasthan's Ajmer district at Tilauniya and more sanatorias, dispensaries, and societies sprang up across the country over the next two decades after that In 1929, India became a member of the International Union Against Tuberculosis and the King George V Thanks giving Fund for Tuberculosis Control and the Tuberculosis Association of India (TAI) was founded in February, 1939 for tuberculosis treatment and model training Institutes as a registered society.

In 1943, Sir Joseph Bhore was the chairman of the Health Survey and Development Committee with the concept of primary health care, committee recommended re-modeling health services at all levels i.e., integrate curative, preventive medicine and in 1946, to manage the estimated 2.5 million TB patients, the committee proposed establishing tuberculosis clinics in each district, as well as mobile clinics in rural areas.

After Independence of the India in 1949, the Central Government of India created a TB Division within the Ministry of Health's Directorate General of Health Services to oversee the plan and new tuberculosis drugs became available over the next twenty years i.e., starting from (streptomycin was in 1944, para-amino salicylic acid in 1946, thioacetazone in 1950, isoniazid came in 1952, and rifampicin was in 1966). And while hospitals for tuberculosis were being built across the country and other services were becoming more widely available i.e., X-rays and chemotherapy but coverage and accessibility to the hospitals remained limited.

In 1951, approximately 65 million children were immunised in a mass Bacillus Calmette-Guerin (BCG) vaccination campaign, but infection rates in both areas (rural and urban) were higher than expected. A national survey conducted by the Indian Council of Medical Research (ICMR) from 1955 to 1958 discovered a prevalence of TB of around 8 million people, with 80 percent of cases living in rural areas.

The Tuberculosis Chemotherapy Centre, later renamed the TB Research Centre (TRC), was established under the ICMR in Chennai in 1956 (with the assistance of the British Medical Research Council, World Health Organization, and the Government of India), and a series of studies on the feasibility and effectiveness of mass ambulatory chemotherapy were conducted, and home-based tuberculosis treatment was found to be more effective than hospital treatment in terms of co-morbidity. In 1959, the Government of India established the National Tuberculosis Institute (NTI) to develop a national tuberculosis control programme in Bangalore with the goal of establishing prompt diagnosis and ambulatory treatment (NTP). Since then, the longest battle against the disease has begun.

National Tuberculosis Programme [5] (NTP); 1961- 1986

India developed a "nationally applicable, socially acceptable, and epidemiologically effective National Tuberculosis Program (NTP)", serving as a model for many other countries. NTP was based on the principle of domiciliary treatment, and sharing of the cost between the centre and the state was 50:50 in NTP. A standard anti-TB treatment regimen lasted 12 to 18 months.

Symptomatic diagnosis and a passive case detection approach were used in NTP, and all of this was done through general health services. It offered home-based care rather than institutional care. Sputum examination was used by the NTP to diagnose tuberculosis cases in rural institutions, and chemotherapy was used to treat them. District TB centres (DTC) were established to monitor the TB control programme and provide feedback to the centre and states, DTC at district headquarters was in charge of training health workers who keep track of all tuberculosis cases and refer them. Between 1983-1984, this programme had been implemented in 353 districts, and 1,308,880 cases were treated under it.

NTP implementation was hampered by some issues includes-

- Health officials prioritise child immunisation over malaria treatment and family planning, resulting in thousands of infectious patients going untreated.
- Scarcity of resources as well as default cases due to poverty and necessitated significant resource consumption.
- India was dealing with a high population load at the time, other programmes, such as family planning, were prioritised.
- BCG does not protect adults against tuberculosis, according to long-term surveys and epidemiological studies.
- Thousands of tuberculosis deaths are being blamed on bureaucracy and indifference on the part of public health leaders.

Need for Revised National Tuberculosis Control Program (RNTCP) [6]; Challenges in NTP

The Indian Government reviewed the national tuberculosis programme, in collaboration with the World Health Organization (WHO) and the Swedish International Development Agency (SIDA), in 1992 and concluded that the National Tuberculosis Programme had failed to control the spread of Tuberculosis and reported that-

- The detection of cases was prioritised over the treatment of TB cases, only 30% patients with tuberculosis were diagnosed and out of these, only 30% were completed their treatment.
- Inadequate health infrastructure, funding and budget allocation
- Positions were filled with lack competent individuals
- Flaws in management
- Resistance to MDR-TB cases
- Excessive reliance on roentgenogram
- Unusual treatment protocols

- Poor completion rates of treatment to multiplicity of the treatment regimen, irregular drug supplies, shortage of drugs and non-compliance of medicines
- A scarcity of systematic data on treatment outcomes
- Poor quality of sputum microscopy

Different studies reported that there is no need for active case finding, individuals who have infected with tuberculosis infection. One study reported about sufficiency of sputum examination for TB diagnosis, with no need of x-ray for it and another finding was on a daily regimen for treating tuberculosis is just as effective. So, experts were found that need to be strengthen the health services, diagnostic services and facilities i.e., drug bank need to be improved for regular supply. Two drugs (Pyrazinamide and Rifampicin) were introduced in Short Course Chemotherapy (1986-1993), with reduced duration time period (6-8 months)

Revised National Tuberculosis Control Programme [7]; 1997-

As a result, a pilot project was started in 1993 at five states (Delhi, Gujarat, Kerala, Maharashtra and West Bengal) with financial support from World Bank. The Revised National Tuberculosis Control Program (RNTCP) was introduced in 1997 and gradually expanded throughout the country. It was based on the widely accepted Directly Observed Treatment Short-course (DOTS) strategy, and expanded gradually until it reached nationwide coverage in March 2006. This programme now serves over 1 billion (1164 million) people in 632 districts across 35 states and union territories. DOTS has begun treatment for over 12.8 million tuberculosis patients and 2.3 million additional lives saved.

RNTCP is divided into two phases-
RNTCP Phase 1 (1997 to 2006)
RNTCP Phase 1 came in existence from 1997, with focus to expand DOTS services to whole country. In this phase the population coverage was estimated 18 million.

Components:

Political and administrative commitment
Tuberculosis is the leading cause of death in the world. Mortality due to disease in women high rather than men. However, because tuberculosis can be cured, as well as the epidemic can be reversed, the government should make it a priority. Priority should be given to the state, district, and local levels by a respective form of government, and efforts should be made to obtain funds through international assistance.

Good quality diagnosis
To identify all infected patients, high-quality microscopy binocular microscopes were provided to all parts for this purpose, and sputum microscopy quality assurance is performed on a regular basis.

Good quality drugs and an uninterrupted supply of good quality anti-TB drugs
One separate box is provided for each registered patient to ensure that the full course of medications is administered and that there is no interruption due to drug shortages. Blister packs and color-coded boxes are also available.

Supervised treatment to ensure the right treatment
Despite the availability of the best anti-TB drugs, there is a risk of treatment failure if it is not administered correctly. Directly Observed Treatment is provided by any trained individual who is not related to the patient. DOTS provider ensures that the patient takes the medication while they are present. Community members such as teachers, postmen, shopkeepers, and cured patients are also involved in providing DOTS. They are also rewarded for every cured patient treated under their supervision.

Systematic monitoring and accountability
This component is carried out using a standard reporting system. With the concept of supportive supervision, all key indicators and cure rates are monitored, and performance analysis is performed at every level. Following the establishment of the TB unit, there is also the establishment of sub-district level mobile supervisory staff. In RNTCP, responsibility for cure is transferred from the patient to the health system.

The Government of India and WHO reviewed RNTCP jointly in 2000, and some significant issues were identified. Expansion of RNTCP on a rapid scale will reduce quality and may result in increased drug resistance; if it is slowed, momentum gained to date will be lost, potentially leading to HIV-associated TB epidemics and multidrug-resistant TB in un-covered areas. In addition, our country's primary health care infrastructure is deficient. The State Government's commitment is far below the desired level, and TB is given very little priority.The private sector is less-equipped to treat tuberculosis, and there is a greater need for collaboration between NGOs and the private sector. In addition, due consideration is given to the quality sputum microscopy network under RNTCP, drug quality management and regular drug supply, enhancements to the state TB Centre, and financial management should be more decentralised.

RNTCP Phase 2[6,7,8] (2006 to 2011)

First phase goal was to bring DOTS service to the entire country. However, the focus in the second phase was on increasing accessibility and service activities, consolidating gains to date, and countrywide maintaining achievements for TB control. The second phase of RNTCP incorporates the entire new Stop TB Strategy. They are as follows:

- **Strive for quality DOTS expansion and improvement**
  By improving case detection and cure through a patient-centered approach that reaches all patients, particularly the poor.
- **Address TB-HIV, MDR-TB and other issues**
  By expanding TB-HIV collaboration activities, DOTS Plus, and other pertinent approaches**.**
- **Contribute to the strengthening of the health-care system**

Collaboration with other health-care programmes and providers of general services.

- **Involve all medical professionals (public, nongovernmental and private)**
  By scaling up approaches based on a public-private mix (PPM) to ensure compliance with International Tuberculosis Care Standards.
- **Involve people with tuberculosis and affected communities**
  To increase the demand for and contribute to effective care. This will entail expanding community TB care while also creating demand through context-specific advocacy, communication, and social mobilisation.
- **Encourage and facilitate research**
  In order to develop new drugs, diagnostics, and vaccines, Increase rural people's access to equitable, affordable, accountable, and effective primary health care, especially for low-income women and children.

The Revised National Tuberculosis Control Programme now seeks to broaden the scope of providing standardised, high-quality treatment and diagnostic services to all tuberculosis diagnosed individuals in a patient-friendly environment, regardless of the health care facility where they seek treatment. Recognizing the importance of reaching every TB patient in the country, the programme has made special provisions to reach out to marginalised groups, such as creating demand for services through targeted advocacy, communication, and social mobilisation activities.

Issues faced by RNTCP:

- Insufficient man power available for programme implementation.
- In both the public and private sectors, there is inefficiency and delay in the diagnosis of tuberculosis.
- There are numerous flaws in RNTCP supervision, monitoring, and evaluation.
- The private sector is insufficiently linked to RNTCP
- Inadequate airborne infection control measures in health care facilities.
- There is no enforcement mechanism in place to regulate the prescription and sale of anti-TB drugs in order to prevent MDR and XDR tuberculosis cases.

However, overall RNTCP has been successful in reducing tuberculosis load and mortality in half when compared to 1990 as the baseline year.
The following changes were made as a result of RNTCP: -

- Because of quality sputum microscopy and laboratory diagnosis quality control, sputum examination is accepted as a primary diagnosis method, and case finding is passive.
- The decentralisation of diagnosis and treatment services is complete, and budgetary allocation has been increased. The TB unit, a district-level supervisory unit, has been established, with dedicated TB supervisors assigned to it.
- The treatment categorization and standardisation processes were completed.

- By providing patients with wise boxes, a consistent and uninterrupted supply of drugs was ensured, and health professionals were able to assess treatment outcomes.
- Sputum examination was used on a regular basis to monitor the patient.
- Drugs are administered under the RNTCP's supervision. Anti-TB services are provided to patients as near to their residences as possible, patient education has been prioritised, as have staff training, IEC activities, and operational research.

Conceptual changes and implications of the shift from NTP to RNTCP [8]:

NTP was developed in an Indian context in response to various studies conducted by the National Tuberculosis Institute, and it was based on the natural history of tuberculosis and was an epidemiologically sound programme; whereas RNTCP was developed in a Western context and has a more techno-centric approach. NTP made no mention of tuberculosis control, whereas RNTCP does for the first time in India.

NTP was based on the following assumptions:

The patient receives relief from symptoms at the nearest health facility, and if these facilities function properly, they can diagnose a large number of cases in that area. Workload due to tuberculosis will not interfere with other activities at the health institute; referral x-rays will be used in addition to sputum examinations.

RNTCP was based on following assumptions-

Individuals infected with tuberculosis will seek treatment in hospitals. As a result, active case finding is not required. Furthermore, it was discovered that sputum examination is sufficient for TB diagnosis, with no need for additional emphasis on x-ray. Another finding was that an intermittent regimen for treating tuberculosis is just as effective as a daily regimen. Ambulatory care, treatment supervision, and the efficacy of intermittent therapy were also introduced.

With these conceptual changes, RNTCP launched in India
Financial and technical assistance

- The Indian government funded NTP, whereas WHO and SIDA funded RNTCP as well as provide programme strategies and technical assistance (Swedish International Development Agency). It was simply a loss of autonomy over the programme by the government, and at each stage, there was interference from such external agencies.
- From NTP to RNTCP, the central government's role expanded, as did the center's financial support for the TB programme. The cost-sharing arrangement between the federal government and the states in NTP was 50:50, whereas RNTCP was implemented as complete centrally sponsored programme.

Monitoring, Supervision and Feedback of the programme

In NTP, the District Tuberculosis Centre was a functional unit and there was a lack of monitoring and supervision whereas in RNTCP increased peripheral supervision by creating a subdistrict level unit called TU (TB Unit). Two STS and STLS positions were also created at the TU level to ensure the program's successful implementation and RNTCP achieves greater programme decentralisation as a result.

General Health System

NTP was founded on general health services to provide diagnostic, curative, and preventive services to a community near their homes, whereas RNTCP was founded on the system and infrastructure that NTP had already established. Or, to put it another way, NTP was integrated and implemented through the general health system, and it was assumed that the general health system could do TB work in addition to other routine work, whereas RNTCP was the vertical programme, and separate staff and funding were made available for programme implementation.

Drug compliance and supervisory support

- In NTP, the patient was held responsible for his own cure, and it was assumed that if the patient became ill or displayed symptoms of tuberculosis, he would go to the nearest health facility for treatment, and that after receiving treatment, he would also take his medications on a regular basis. While in RNTCP, the responsibility for cure is transferred to the health system, and in that case, detection is performed, and the patient is given supervisory drugs, with the goal of curing tuberculosis as a social responsibility.
- Many patients in NTP have left treatment or are not receiving drugs because drugs are not always available. However, in the RNTCP, patient-specific individual drug boxes were provided for the duration of treatment, ensuring that each patient has their own drug boxes and that no patient has to deal with additional administrative or logistical issues.

Changes in treatment guidelines and diagnosis

In NTP, X-ray is overused, and more emphasis is placed on X-ray for TB diagnosis and, patients are referred for X-ray to a higher centre, whereas in RNTCP, the emphasis is on sputum microscopy for TB diagnosis, with no unnecessary referrals.

- There was no standardised treatment in NTP, whereas there was a standardised treatment protocol in RNTCP. The NTP used daily drug dosage, whereas the RNTCP uses an intermittent drug regimen, though the efficacy of the intermittent drug regimen is still being debated, and it is thought to be one of the probable causes of drug-resistant tuberculosis.
- In addition, no supervisory drugs were administered in NTP, whereas drugs are administered in RNTCP under the direct supervision of DOTS providers. Also, the NTP treatment duration was 12-18 months, whereas the RNTCP

treatment duration was much shorter, resulting in better patient compliance in RNTCP.

Operational feasibility of the DOTS strategy

In NTP, three out of every ten patients treated are cured, whereas in RNTCP, eight out of every ten patients treated are cured, demonstrating the operational feasibility of the DOTS strategy. Patients who had recently been diagnosed were given priority over those who had previously been treated. Drug treatment was standard anti-TB treatment that lasted 12-18 months, and it was a major issue in NTP.

Involvement of other agencies

There was no provision in the NTP for the involvement of private practitioners or non-governmental organisations, whereas the RNTCP felt the need to include them. in addition, unlike NTP, RNTCP encourages greater community involvement. Postmen, school teachers, shopkeepers, and cured patients are considered significant under RNTCP for providing DOTS, and various incentives are given to them for delivering DOTs to the patient.

Efforts towards social stigma

Many efforts in the NTP were not directed toward reducing the social stigma associated with it, whereas many efforts in the RNTCP are directed toward reducing the social stigma associated with tuberculosis disease i.e., a frequent IEC campaign and awareness campaign are promoted.

Battle still continues

The longest fight against tuberculosis in India began in 1962 with the National Tuberculosis Control Programme (NTCP), which was followed by two stages of RNTCP from 1997 to 2019. In 2019, tuberculosis was expected to affect 199 individuals per lakh in India in 2019. One-quarter of all tuberculosis cases occur in India. In India, the world's most TB-endemic country, 26.9 lakh cases are projected in 2019. (WHO). The year 2019 will be remembered as a watershed moment in India's TB surveillance effort, with a new high of 24 lakh cases reported, up more than 12% from 2018. 21.6 lakh of the 24 lakh TB cases were incident TB (new and relapsed/recurrent). This translates to a notification rate of about 159 cases per lakh versus an estimated incidence rate of 199 cases per lakh population, closing the difference between estimated and notified incident cases to only 40 instances per lakh population, or an estimated 5.4 lakh missing cases across India. India's tuberculosis (TB) control program, previously known as the Revised National Tuberculosis Control Programme, was renamed the National Tuberculosis Elimination Programme (NTEP) on January 1, 2020. (RNTCP).

However, challenges remain

According to the Joint Monitoring Mission of the Government of India, the NSP implementation from 2012 to 2017 did not result in the RNTCP's expected rise in case detection. Furthermore, the ambitious resource growth envisaged under the NSP, 2012–2017, will have trebled the previous plan's expenditure but has not been matched by allocations. While RNTCP spending has increased by 27% during 2012, the gap between allocated funds and the minimum investment required to achieve the plan's goals is widening.

The RNTCP's treatment outcomes were already pretty strong in 1994, and they continued to improve until 2006, when the aim of 85 percent treatment success was met in 2001. Unfavorable outcomes have continuously dropped below 15% since 2001. From their start on the administrative front, TB program management units have been incorporated into national health ministries and directorates of health services. The TB program has been a component of the National Health Mission since 2005.

Over 0.7 million TB patients have been notified in the United States since TB became a reportable condition in 2012. Furthermore, in 2012, the national program deployed an innovative and forward-thinking electronic recording and reporting system (Nikshay) across the country, with 98 percent of reporting units transmitting case-based TB patient reporting, including alerts from private clinics.Since 2014, all informed tuberculosis patients (public and private) have been offered universal drug sensitivity testing to determine the presence of rifampicin resistance at the time of diagnosis.

The focus of the worldwide public health and tuberculosis (TB) communities is changing from TB control to TB elimination. The success of India will determine worldwide progress toward tuberculosis eradication. The National Strategic Plan (NSP) 2017–2025 was prepared under the Revised National Tuberculosis Control Program (RNTCP). The declared goal is to eradicate the disease altogether by 2025. The four strategic pillars of "Detect, Treat, Prevent, and Build" (DTPB) have been added to the list of things that need to be done to get rid of tuberculosis.

Following greater political commitment and increasing community awareness about public health and cleanliness, as well as the threat of communicable illness in the aftermath of the COVID-19 epidemic, India has pledged to END TB and is at a critical juncture. As a result, the National Strategy to End Tuberculosis (2020-2025) makes use of this opportunity to collaborate closely with multiple ministries in order to encourage a multi-sectoral approach to END TB while continuing to implement and deliver effect. The global incidence rate must be reduced by 4-5 percent each year to meet the first milestone of the End TB initiative, a 20 percent reduction by 2020 (compared with 2015).

Only Central Europe, Latin America, and the Caribbean have had annual declines of more than 5%, and these are largely island nations with high average incomes. India's TB incidence has reduced by only 1.7 percent every year since 2016. Health spending by the government has been among the lowest in the world for decades, at 1.4 percent of GDP. The 2017 Union Budget includes additional

health financing, although it will fall well short of the 2.5 percent of GDP goal set out in the National Health Policy 2015. RNTCP has also struggled to secure funding that is commensurate with the magnitude of the pandemic in India. The budget was supposed to go up between 2012 and 2017, but this did not happen.
In India, the private sector presently handles about 28% of the country's 2.4 million new tuberculosis cases each year, as well as 42% of all pediatric TB cases reported. In Indian cities, the bulk of patients seek treatment at private clinics. According to WHO standards, bedaquiline was designed as a "last option" treatment for drug-resistant tuberculosis patients. Despite extensive medication resistance, only 27% of TB patients in India are candidates for this treatment. After decades of research, this is the only novel anti-tubercular medication discovered. This means that research needs to be focused on creating and/or testing new technologies, like rapid point-of-care diagnostics, new tuberculosis treatments, and vaccines.

Conclusion

Tuberculosis (TB) has long been a scourge of communities and nations. People have suffered and died from tuberculosis for generations, and even today, when newer methods of diagnosing and treating the disease have made it curable, people are continuing with suffering and dying because of this disease. IEC activities should be strengthened, and collaboration with all health providers, such as the private sector, NGOs, medical colleges, ESIS and Railway hospitals, TB hospitals, and so on, should be established.

Financial decentralisation, as well as increased community participation, are required to achieve TB control in India. Furthermore, RNTCP should be effectively integrated with other related programmes i.e., the NACP to address co-infection (TB-HIV) and the National Rural Health Mission. Emerging problems such as childhood tuberculosis, multidrug-resistant tuberculosis, and multidrug-resistant tuberculosis should be addressed.

Human resource management is an important issue. There are insufficiently skilled human resources on hand, as well as a disgruntled workforce. Motivational incentives or recognition of work done in difficult areas and conditions should be provided.

There is no social protection mechanism in place to address the issues of income loss and non-medical costs associated with tuberculosis patients. In addition, the problem of tuberculosis must be viewed in the context of the larger socioeconomic system.

This study was not supported by any other sources
The authors have declared no conflicts of interest
Consent to participate and ethics approval

This evaluation does not require ethical approval because no patient data will be collected. Plagiarism, confidentiality, malfeasance, data falsification and/or falsification, double publishing and/or submission, and duplication are all ethical issues that the author has thoroughly examined in this work.

Acknowledgements

Firstly, I would like to give all thanks to God for granting me the grace to complete this research. I would like to extend my greatest gratitude to my supervisors for their guidance and inspiration in completing this research. I would like to extend a special thanks to all my friends their endless support and assistance in the development of this research.

Last but not the least, this acknowledgement is incomplete if I fail in my duty to thank all my study subjects who have whole-heartedly participated in the study and have made the study complete. Lastly, I would like to thank my family for their love, patience and support during the development of this research.

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