

## CERVICAL CANCER PREVENTION IN INDIA: EXAMINING THE CASE FOR LEGAL MANDATES ON VACCINATION

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**BEST CITATION** – PRANAV DEEPANKAR KETHINENI, CERVICAL CANCER PREVENTION IN INDIA: EXAMINING THE CASE FOR LEGAL MANDATES ON VACCINATION, INDIAN JOURNAL OF LEGAL REVIEW (IJLR), 4 (1) OF 2024, PG. 1470-1487, APIS – 3920 – 0001 & ISSN – 2583-2344.

### 1. SYNOPSIS

#### 1.1) Introduction–

Cervical cancer is one of the growing medical concerns in for women in India. It is the cancer that develops in the cervix of the women which is the entrance to the uterus from the vagina. Various strains of the human papillomavirus, (hereinafter referred as HPV), play a role in causing most cervical cancers. HPV is a common infection that's passed through sexual contact. When exposed to HPV, the body's immune system typically prevents the virus from doing harm. In a small percentage of people, however, the virus survives for years. This contributes to the process that causes some cervical cells to become cancer cells.

Cervical cancer is the fourth most common cancer in women. In 2018, an estimated 570 000 women were diagnosed with cervical cancer worldwide and about 311 000 women died from the disease. When diagnosed, cervical cancer is one of the most successfully treatable forms of cancer, as long as it is detected early and managed effectively. Cancers diagnosed in late stages can also be controlled with appropriate treatment and palliative care.<sup>2305</sup>

GRASP - EDUCATE - EVOLVE

<sup>2305</sup> [https://www.who.int/health-topics/cervical-cancer#tab=tab\\_2](https://www.who.int/health-topics/cervical-cancer#tab=tab_2)

## Ways to tackle cervical cancer-

There are few ways in which the possibility of a women getting cervical cancer be prevented at an early stage –

### 1. Screening tests –

Two screening tests can help find changes that could become precancer or cervical cancer—

- The Pap test (or Pap smear) looks for *precancers*, cell changes on the cervix that might become cervical cancer if they are not treated appropriately.
- The HPV test looks for the virus (human papillomavirus) that can cause these cell changes.

Both tests can be done in a doctor's office or clinic.

### 2. Human Papillomavirus (HPV) Vaccine –

The HPV vaccine protects against the types of HPV that most often cause cervical, vaginal, and vulvar cancers.

- HPV vaccination is recommended for pre- teens aged 11 to 12 years, but the dosage of vaccinations can be started at age 9.
- HPV vaccine also is recommended for everyone through age 26 years.
- HPV vaccination is not recommended for any women who is older than the age 26 years. However, some adults who are aged between 27 and 45 years and are not already vaccinated may decide to get the HPV vaccine after speaking with their doctor about their risk for new HPV infections and the possible benefits of vaccination. HPV vaccination in this age range provides less benefit, as more people have already been exposed to HPV.

If vaccination is started before age 15, then in that case a two-dose schedule is recommended, with the doses given 6 to 12 months apart.

For people who start the series after their 15th birthday, the vaccine is given in a series of three shots.

HPV vaccination prevents new HPV infections, but does not treat existing infections or

diseases. This is the reason HPV vaccine should be given at an early stage, so as to prevent the cervix towards the exposure of HPV infections.

### 3. Use of contraceptives

Contraceptives, which prevent some sexually transmitted diseases, can decrease the risk of HPV transmission. However, they do not completely prevent it. Therefore, exposure to HPV is still possible in areas that are not covered by the contraceptives.<sup>2306</sup>

#### 1.2) Literature Review: –

The following Books and Articles are reviewed as the basis for this particular research study:

1. *“Cervical Cancer Prevention Efforts in India”* by Neerja Bhatia, Jyoti Meena, Sarita Kumari, Dipanwita Banerjee, Prerana Singh, and Jayashree Natarajan: This article provides the proper steps that have been taken by the Indian Government so far in order to prevent the spread of Cervical Cancer India and the researcher shall use it to understand it as well as to see whether the efforts made are enough or not.<sup>2307</sup>
2. *“Comprehensive Cervical Cancer Control: A Guide to Essential Practice”* – This article gives the researcher a broad vision of what a comprehensive approach to cervical cancer prevention and control means. In particular, it outlines the complementary strategies for comprehensive cervical cancer prevention and control, and highlights the need for collaboration across programmes, organizations and partners.<sup>2308</sup>
3. *“Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries”* – Hyuna Sung, Jacques Ferlay, Rebecca L Siegel, Mathieu Laversanne, Isabelle Soerjomataram, Ahmedin Jemal, Freddie Bray. This article provides an update on the global cancer burden using the GLOBOCAN 2020

<sup>2306</sup> [Division of Cancer Prevention and Control, Centers for Disease Control and Prevention](#), What Can I Do to Reduce My Risk of Cervical Cancer? (August 21, 2023)

<sup>2307</sup> Neerja Bhatla, Cervical Cancer Prevention Efforts in India, *Indian J Gynecol Oncol*, Vol 19(3): 41, 2021

<sup>2308</sup> *Comprehensive Cervical Cancer Control: A Guide to Essential Practice* 2nd edition. Geneva: World Health Organization; 2014.

estimates of cancer incidence and mortality produced by the International Agency for Research on Cancer. Worldwide, an estimated 19.3 million new cancer cases which would help the researcher in understanding the statistics of this disease as well.<sup>2309</sup>

4. *Effect of visual screening on cervical cancer incidence and mortality in Tamil Nadu, India: a cluster-randomised trial.* Authors Rengaswamy Sankaranarayanan, Pulikkottil Okkuru Esmey, Rajamanickam Rajkumar, Richard Muwonge, Rajaraman Swaminathan, Sivanandam Shanthakumari, Jean-Marie Fayette, Jacob Cherian - The article assessed the effect of screening using visual inspection with 4% acetic acid (VIA) on cervical cancer incidence and mortality in a cluster randomised controlled trial in India and this would give the researcher the idea about the seriousness about the disease in its rate of spreading in India.<sup>2310</sup>

5. *Survival of Patients with Cervical Cancer in Rural India*—by Jissa Vinoda Thulaseedharana, Nea Malilab, Rajaraman Swaminathan, Pulikkottil Okkuru Esmey, Matti Hakamab, Richard Muwongef, Rengaswamy Sankaranarayanan the article was the resultant of assessing 165 women diagnosed with cervical cancer from the routine care control arm of a randomized screening trial conducted in rural south India. Kaplan-Meier curves were plotted to illustrate the observed survival of cancer patients. The effect of socio-economic factors was assessed using Cox proportional hazards regression analysis. This helped the researcher in understanding how prevalent this disease is among women living in rural areas.<sup>2311</sup>

### 1.3) Statement of Problem—

Cervical cancer is the cancer that ranks second among women's cancers in India which had over 1,23,000 new cases and also 77,000 deaths

were reported in year of 2020. The awareness with respect to this disease is still less in India which leads to late diagnoses as well as poor outcomes. The aim of this paper is to analyze the current situation of India with respect to cervical cancer. whether mandating the vaccines can be considered approach which is necessary or not for mandating vaccinations for the prevention of cervical cancer. And if India can reach the targets set by the World Health Organization with respect to elimination of Cervical Cancer.

### 1.4) Scope and limitation of the Study

To study about the disease of cervical cancer as well as to focus on the ways to taking a legal approach to curb the spread of this disease. The limitation of this paper shall be with respect to studying about the vaccines that are available in India and whether there is a need of them being mandated

### 1.5) Objectives

- To assess if there is a need to mandate cervical cancer vaccines in India.
- To analyse the initiatives taken by international health organizations to curb the spread of this disease.

### 1.6) Research Question

- Whether there is a need to mandate the vaccines of Cervical Cancer.
- To analyse and interpret, If India can reach the targets set out by WHO for the elimination of cervical cancer.

### 1.7) Hypothesis

The hypothesis that the researcher is assuming for this research is that there is a need for a better vaccination program and also a requirement for mandating Cervical Cancer vaccines.

### 1.8) Methodology of the Study

The research will follow the doctrinal method as it is mostly influx of data from various places. The sources are mostly secondary. We have consulted as many sources of books and Journals and also different articles and lectures of leading legal thinkers from India and around the world. Original articles and books by leading

<sup>2309</sup>Rebecca L. Siegel, Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, A Cancer Journal for Clinicians, Vol 71 Issue III, 2021

<sup>2310</sup> Rengaswamy Sankaranarayanan, Effect of visual screening on cervical cancer incidence and mortality in Tamil Nadu, India: a cluster-randomised trial, THE LANCET, Vol 370 Issue 9585 pg (398-406), 2007

<sup>2311</sup>Jissa Vinoda Thulaseedharana, Survival of Patients With Cervical Cancer in Rural India, Journal of Clinical Gynecology and Obstetrics, ISSN 1927-1271 Vol 4, December 2015

thinkers on the respective ideologies are the most important all the sources. The following methods will be relied upon to fulfill the objectives of the study and collection of necessary data. In addition, various case laws both Indian and Foreign are referred which involves this construction.

1. Study of the existing books.
2. Primary and secondary source of books and journals.
3. Internet sourcing.
5. Listening to the lectures of leading jurists

## **Chapter 2 – Study of Cervical Cancer in India**

### **Risk Factors which may cause Cervical Cancer**

There have been a numerous risk factors that have been seen for acquiring an HPV infection and its subsequent progression to cervical cancer.

The co-factors most likely to affect the risk of HPV and progressing from cervical HPV infection to:

- High-grade cervical precancers
- Long-term use of oral contraceptive pills
- Tobacco use
- Co-infection with other sexually transmitted agents is one of the common risk factors.
- Lifestyle factors may influence such as multiple sexual partners, younger age at first sexual encounter, and immunosuppression.
- Improper diet

### **Causes for Cervical Cancer –**

- **Human papillomavirus (HPV):** Individuals with HPV (high-risk strains) are at high risk of cervical cancer. It is the major cause of cervical cancer in girls and women.
- **Smoking:** Women who have the habit of smoking are at risk of cervical cancer than non-smokers. Smoking makes immunity less effective against HPV, which leads to cervical cancer. However, the risk of cancer can also be

increased if you are a passive smoker (second-hand smoke).

- **Weakened immune system:** Individuals with weak immune systems, such as individuals living with AIDS/HIV or those taking immunosuppressive medications, are more susceptible to developing cervical cancer. Those are more prone to HPV infection, which causes cervical cancer.
- **Multiple sex:** Having multiple sex partners may lead to HPV infection (sexual transmission), which increases the risk of cervical cancer in women.
- **Family history:** Women who have a family history of cervical cancer have an increased chance of getting it. However, most cervical cancers are not inherited genetically, but some rare types can be passed down through genetic transmission.<sup>2312</sup>

Around the world, cervical cancer is caused due to a significant amount of morbidity and mortality. High-risk HPV strains are a well-known primary cause of cervical cancer

### **Current Situation of Cervical Cancer in India –**

Cervical cancer is the most common cause of cancer mortality among women, with nations that are developing contributing to more than a quarter of the global burden. Despite alarmingly high figures, India has no nationwide government-sponsored screening program. The purpose of this study is to assess the burden of cervical cancer in India and review the performance characteristics of available cervical cancer screening tools in order - to provide evidence-based recommendations for the most practical screening test to be used in resource-poor field settings.

**As per the reports of Globocan 2020**, 604,100 fresh new cases of cervical cancer were

<sup>2312</sup> <https://www.mrmed.in/health-library/cancer-care/cervical-cancer-awareness-month-2023-january>



detected globally in year 2020 and 341,831 deaths were caused due to this.<sup>2313</sup>

In the country of India, cervical cancer had accounted for 9.4% of all the cancers and 18.3% which is an approximate of 123,907 of new cases in year of 2020. It still is amongst the commoner cancers in India and a leading cause of cancer-related deaths in women in low- and middle-income countries.<sup>2314</sup>

During the year of 2022, about 365.71 million women in India over the age of 15 are at risk of developing cervical cancer. India accounts for 132,000 newly diagnosed cases and 74,000 fatalities yearly. It is estimated that 6.6 per cent of women in the general population currently have **cervical HPV infection**. Nearly 76.7% of cervical cancer in India is caused due HPV serotypes 16 and 18.<sup>2315</sup>

The issue in India with respect to spreading of Cervical Cancer can also be due to the below stated reasons –

1. Lack of Knowledge
2. Limited access to medical care women
3. Hesitations

### **Screening of Cervical Cancer in India –**

Cervical cancer is the second most common cancer among women. But the peak age of a women developing cervical cancer in is 50 – 59 years compared to the age of 35 – 44 years in countries that are more developed.<sup>2316</sup>

But the screening of cervical cancer cannot be more stressed upon, as the diagnosis of this disease at an early stage is ideal to achieve a complete cure.

In India, the prevalence of cervical cancer screening was reported as 29.8% among

women aged 30–49 years and 22.3% among women aged 15–49 years, as per the fourth round of the National Family Health Survey (NFHS-4) conducted during the year 2015–16.

In the present, attempts are being made to identify the different barriers which are highly crucial to rural cervical cancer screening, various factors influencing the awareness and increasing ways of awareness of the disease among rural women.

Different strategies are being implemented to control cervical cancer at rural level such as rural cancer registries and camp approach have been discussed, and different diagnostic methods applicable to low resource settings are compared to find out the which is the most suitable model that could be considered feasible for mass screening cervical cancer among women in rural areas.<sup>2317</sup>

Types of Cervical Cancer Screening Tests –

#### 1. Cytology –

Cytology is the most widely used cervical screening test around the world, especially in countries that have a strong medical infrastructure. This is a common method in developed countries. In many countries, it has been integrated in medical and public health services, and also has been achieving high coverage.

However, Cytology programs have been largely ineffective in reducing cervical cancer burden due to poor coverage with screening, treatment and follow-up care and lack of quality assurance. Countries that have low or middle income did not initiate nor the have the capacity to initiate and maintain assured cytology screening programs as these tests require high number of resources and trained manpower as well.

Cytology tests require quality laboratory infrastructure, monitoring and highly skilled technicians or pathologists. These requirements

<sup>2313</sup> Asthana S, Satyanarayana L. Cervical cancer screening from the perspective of a rural population of northern India. *Ganga Ram J.* 2013; 3: 128–131

<sup>2314</sup> International Agency for Research on Cancer. *Globocan*; 2020. <https://gco.iarc.fr/>. Accessed 13 April 2024

<sup>2315</sup> Guidelines for cervical cancer screening. Government of India and WHO Collaborative Program. Available from: [http://www.whoindia.org/LinkFiles/Cancer\\_resource\\_Guidelines\\_for\\_CCSP.pdf](http://www.whoindia.org/LinkFiles/Cancer_resource_Guidelines_for_CCSP.pdf)

<sup>2316</sup> Bobdey S, Sathwara J, Jain A, Balasubramaniam G. Burden of cervical cancer and role of screening in India. *Indian J Med Paediatr Oncol.* 2016;37(4):278–285. doi: 10.4103/0971-5851.195751

<sup>2317</sup> Rakhi Kunkule, Ruchita Pakale, Swati Jadhav, Review on Cervical Cancer, SDNCRES's Mahalaxmi Institute of Pharmacy, Raigaon, Satara 415020, M.S., India. <http://e-currentscience.com/journal/e/CTPPC>

are highly challenging due to which the implementation in countries that have less resources.

## 2. LBC

This test offers an improved test specimen collection with lower possibilities of unsatisfactory smears, lesser debris, and lesser time needed for the interpretation of the results when compared to conventional cytology. This is considered as an advancement in cervical cytology. However, LBC test has more or less equivalent sensitivity and specificity as compared to cytology for the detection of CIN 2 or worse lesions.<sup>2318</sup>

## 3. HPV Testing

This type of testing involves the detecting HPV DNA or mRNA of two oncoproteins (E6 and E7) in cervical cell samples collected by pelvic examination or by self-sampling. HPV testing is the most accurate, reproducible and provider independent cervical screening test.

This type of testing is highly suited for those women who are aged above 30. These tests are widely evaluated in comparison to cytology.

This type of testing promises better results. Many European countries introduced HPV Testing as the primary mode of testing.

## 4. Visual Screening Tests

This type of test involves the naked eye visualization of the cervix 1 min after the application of 3–5% dilute acetic acid under bright light. Test results are reported as negative, positive or suspicious of invasive cancer.

VIA screening was followed by a 31% reduction in cervical cancer mortality in a randomized trial in Mumbai<sup>2319</sup>

This test is considered to be a simple and affordable in terms of providing immediate results that enable either diagnosis or treatment that has to be carried out in the same visit for screen positive women.

Diagnosis of this disease in its the initial stages is the best way to prevent mortality due to cervical cancer. This disease is considered to be amendable if attended to at early stages. That is the main reason that countries like India should increase the rate of screening of this disease.

Currently in the country of India, cervical cancer contributes approximately 6–29% of different types of cancers in women. The age-adjusted incidence rate of cervical cancer varies widely among registries; highest is 23.07/100,000 in Mizoram state and the lowest is 4.91/100,000 in Dibrugarh district. The pooled estimates of sensitivity and specificity of visual inspection with acetic acid (VIA), magnified VIA, visual inspection with Lugol's iodine (VILI), cytology (Pap smear), and human papillomavirus DNA were found to be 67.65% and 84.32%, 65.36% and 85.76%, 78.27% and 87.10%, 62.11% and 93.51%, and 77.81% and 91.54%, respectively.<sup>2320</sup>

Few states in India have implemented their own state-level cancer controlling programmes. One of the Southern State of India Tamil Nadu has implemented the World Bank-supported NCD control program from the year 2008 using the VIA testing method in facility-based opportunistic mode, and later switched to the NPCDCS program. The early implementation of such a scheme can be considered as one of the main reasons for the relatively higher prevalence of cervical cancer screening in Tamil Nadu, which is coming into light so can be diagnosed early.

In a country like India screening can be still be prevailing less because of reasons such as lack of knowledge, regional issues, caste issues. These social, economic and demographic

<sup>2318</sup> Whitlock EP, Vesco KK, Eder M, Lin JS, Senger CA, Burda BU. Liquid-based cytology and human papillomavirus testing to screen for cervical cancer: A systematic review for the U.S. preventive services task force. *Ann Intern Med.* 2011;155:687-97. W214-5. doi: 10.7326/0003-4819-155-10-201111150-00376.

<sup>2319</sup> McCredie MR, Sharples KJ, Paul C, Baranyai J, Medley G, Jones RW, et al. Natural history of cervical neoplasia and risk of invasive cancer in women with cervical intraepithelial neoplasia 3: A retrospective cohort study. *Lancet Oncol.* 2008;9:425–34. doi: 10.1016/S1470-2045(08)70103-7

<sup>2320</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5234166/>

patterns can be considered as reasons as to why screening is still less in India.

### **CHAPTER 3 – World Health Organization Guidelines on Elimination of Cervical Cancer**

The World Health Organization (hereinafter referred to as WHO) has developed a strategy to guide the elimination of cervical cancer as a public health program.

WHO aims to initiate action against this as Cervical cancer is a disease that is preventable if detected at the early stages.

In the year of 2018, the WHO director announced a global call to eliminate cervical cancer. It was instilled that it be part of a public health program to make the elimination of this disease achievable.

In the year of 2020, the World Health Assembly had adopted a Global Strategy for Cervical Cancer Elimination.<sup>2321</sup>

#### **NEED FOR GLOBAL STRATEGY-**

Cervical cancer is a disease that can be easily prevented. It is also curable if it is detected at the early stages. Despite being preventable or treatable at early stages, it is one of the most common cancers among women across the globe.

The number of cases with respect to cervical cancer has been projected to increase from 570000 from the year of 2018 to 700000 till the year 2030. The annual number of deaths are projected to increase from 311 000 to 400 000. More than 85% of those women who are affected are young, undereducated women who live in the world's poorest countries. Many are also mothers of young children whose survival is subsequently truncated by the premature death of their mothers<sup>2322</sup>

The projections indicate that all the governments of various countries should make

attempts to add a program which would help in the elimination of this disease. This is one of the few diseases that could be prevented or treated if detected at an early stage.

The requirements of the program should be as per the population of women in the country.

#### **Targets of the Global Strategy-**

- Cervical Cancer is eliminated all around the world as a part of the Public Health Program
- A threshold of 4 per 100,000 women – years for the elimination as the public health program
- Implementation of 90 (90 % of girls fully vaccinated with the HPV vaccine by the age of 15 year) – 70 (70 % of women are screen by the age of 35 years and again by the age of 45 years) – 90 (90% of women identified with cervical cancer receive treatment) target which has to be met by countries by the year of 2030 who want to take initiatives towards the elimination of cervical cancer.

#### **STRATEGIC ACTION TO ACHIEVE THE TARGETS**

WHO calls for the targets being pursued within the framework of the National Policy of each country with the goal to eliminate cervical cancer. These targets require scaling up of the national health plans of citizens in order to meet their goals.

Each preventive measure with respect to the disease has its own set of requirements for implementation of the strategy, and each of these pose a unique challenge. In order to implementation of plans that would help reach the global targets, each country should devise a plan as taking into consideration each of its deficiency which could be different from that of another country. Each country has its deficiency such as sociocultural or gender, and myths and misconceptions about the disease and its prevention and treatment that increase cervical cancer incidence, morbidity and mortality. The Approach to scale up interventions in an urban setting may be comparatively easier than rural areas. Other issues such as inequities of wealth

<sup>2321</sup> Cervical Cancer Elimination Initiative. (n.d.). <https://www.who.int/initiatives/cervical-cancer-elimination-initiative>

<sup>2322</sup> WHO Cervical Cancer Prevention and Control Costing (C4P) tool. Geneva: World Health Organization ([https://www.who.int/tools/who-cervical-cancer-prevention-and-control-costing-\(c4p\)-tool](https://www.who.int/tools/who-cervical-cancer-prevention-and-control-costing-(c4p)-tool)), accessed 6 October 2020).



or some population including women with HIV call for tailored approach.<sup>2323</sup>

These comprehensive preventive strategies must include factors such age-appropriate information sexual and reproductive habits, it should promote safer sexual practices and also cessation of tobacco use.

Concrete efforts to promote healthy lifestyles are to be included to promote steps against this disease.<sup>2324</sup>

### Preventive Measures as per the Strategic plan

#### Primary Measure of Prevention - HPV Vaccination

Vaccination at a young age is the most effective long term preventive measure that could help in the intervention for reducing risk of women developing cervical cancer at an early age. Initiation of HPV vaccination among all the countries can be a great step to promote the fight against this disease.

Evidence also suggest that coverage of high HPV Vaccination also leads to the protection of unvaccinated individuals through herd immunity. This enhances the protection of the community and plays a strong role in curbing the spread of this disease.<sup>2325</sup>

The current WHO guidelines recommend that adolescent girls who are aged between 9 years to 14 years receive two dosages of the vaccine and be protected.<sup>2326</sup>

The comprehensive strategy must include plans to distribute vaccines inequitable across geographical settings the vaccines should be available in countries with high income as well

<sup>2323</sup> Kuruvilla S, Sadana R, Villar Montesinos, Beard J, Vasdeki JF, Araujo de Carvalho I et al. A life-course approach to health: synergy with Sustainable Development Goals. Bulletin of the World Health Organization. 2018;96:42–50. doi:10.2471/BLT.17.198358.

<sup>2324</sup> Romanowski B: Long term protection against cervical infection with the human papillomavirus: review of currently available vaccines. Hum Vaccin 2011;7:161-169

<sup>2325</sup> Drolet M, Bénard E, Pérez N, Brisson M, on behalf of the HPV Vaccination Impact Study Group. Population-level impact and herd effects following the introduction of human papillomavirus vaccination programmes: updated systematic review and meta-analysis. Lancet. 2019;394(10197):497–509. doi:10.1016/S0140-6736(19)30298-3

<sup>2326</sup> Brotherton JM, Budd A, Rompotis C, Bartlett N, Malloy NJ, Andersen RL et al. Is one dose of human papillomavirus vaccine as effective as three? A national cohort analysis. Papillomavirus Research. 2019;8:100177. doi:10.1016/j.pvr.2019.100177.

low income. To ensure sustainability as well coverage of vaccines, governments should aim to involve this vaccine as a part of their national immunization programs. With these vaccination programs, there should be strategies which would be aiming to affirm the people about the safety of the vaccinations. There should also be ready made strategies to address the anti- vaccine movement as a contingency plan.

#### Strategic Actions to achieve 90 % coverage of vaccinations

Securing sufficient and Affordable vaccines – there should efforts between the governments and the manufacturers of these vaccines with the aim of the government being able to procure these HPV Vaccinations at an affordable price as well the availability of the vaccine should be as per the scheduled and planned.

Increase the Coverage of the Vaccination – there should be an increase in the coverage of these vaccination programs. This is possible if governments include HPV vaccinations as part of their National Vaccination Programs as well increase the coverage by campaigning about the same. There should be efforts by schools by educating as well taking efforts by hosting immunization programs.

Improve communication and social mobilization – There should be efforts to increase the vaccination programs. There should also be efforts taken by medical professional as well as the government in breaking societal barriers which may affect the acceptance and intake of the vaccines.

Innovate guidelines to improve the efficiency of the vaccine delivery – Natinal guidelines, policies and strategies should be devised which helps in increasing access to HPV vaccinations.

#### Secondary Measure of Prevention – Screening and treatment of precancerous lesions

The ultimate aim behind devising a strategy plan is to reduce and possibly eliminate cervical cancer incidence and mortality. Vaccinations



though helpful but comes with age criteria. To those women who cannot be eligible for vaccination due to age or any other issue should be given the equal chance to fight against the disease.

This is possible through increase in screening. Screening helps in identifying the disease at an early stage. Screening based on Cytology has been successfully used to achieve the goal as a part of their national programs. Cytology Screening is expensive and is hard to implement in middle- and low-income countries.

Screening methods are generally expensive. They require high level of medical equipment and professionals. Market should shape initiatives to secure affordable, high in quality and supplies with respect to screening.

Cervical cancer screening will be requiring a matching increase in capacity for treatment of the detected lesions, as the screening of women without them receiving access to treatment is unethical.

WHO's treatment policies recently expanded to include thermal ablation as a therapeutic modality for women who have precancerous lesions eligible for ablation<sup>2327</sup>

### **Strategic Actions to achieve 70 % Coverage for Screening and 90 % treatment of precancerous lesions**

Creating an enabling environment – creating a robust mechanism to deal with structural barriers such as societal, cultural factors is high crucial. The strategies must be comprehensive to deal with educating women of local communities in the rural settings. Stigmas being broken should be a part of these ideal plans. Increasing health literacy, knowledge of rights and awareness of cervical cancer prevention and control helps to mobilizing and engaging the civil society.

Integration of Screening and Treatment services into the primary care package – the primary health care plan should be devised in such a way that services are being integrated with HIV care. There should be increase in gradual screening centers.

Ensuring an affordable Supply of Quality assured, high – performance screening tests and treatment devices – Market shaping for cervical cancer diagnostics and treatment devices will lead to an improved access and affordability.

Promotion of Screening and Treatment Approach – Countries have to expand the number of facilities where a single visit screen and treat approach can be implemented. The issue with this is that, this implementation is only possible for those countries who have a strong medical infrastructure. This approach is not feasible to be implemented everywhere.

Strengthening Laboratory capacities and Assurance Programs – efficient laboratory services will ensure the access of the treatment as well as results to taken the next steps ahead. Strong assurance programs are crucial to meet the requisite training standards. Training and supervision are an integral part of this step.

### **Invasive Treatment Plans**

Timely assessment of women with suspicion or confirmation of being infected with this disease is crucial for prevention for the loss of lives through this disease. Comprehensive management of cervical cancer requires availability of qualified medical professional as well access to required medical screening process such as pathology, medical imaging, radiotherapy and chemotherapy services.

The access to such services with respect to these diseases are important because, if this disease is treatable at early stages by surgery or radiotherapy. This would result in long term survival as well sure.<sup>2328</sup>

<sup>2327</sup> WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. Geneva: World Health Organization; 2019 (<https://apps.who.int/iris/handle/10665/329299>, accessed 29 April, 2024)

<sup>2328</sup> Cohen PA, Jhingran A, Oaknin A, Denny L. Cervical cancer. *Lancet*. 2019;393(10167):169–82. doi:10.1016/S0140-6736(18)32470-X.

Cost effective treatments should be a major part of the comprehensive strategic plans. As per the recommendations of WHO, Surgery and Radiotherapy, with or without chemotherapy are the most cost effective and viable treatment plans.<sup>2329</sup>

The treatment plans should comprise of Palliative Care. The plans for Palliative care should be integrated in the comprehensive treatment plans. The issue with palliative care is that middle- and low-income countries cannot afford to add in their strategic plans. Countries that have high income, especially who devise plans to increase health care should add palliative care with respect to treatment of this disease as well.

Strategic Actions to achieve treatment of 90 % cervical cancer cases

Implementation of cervical cancer management guideline – Nations are advised to develop and implement guidelines with respect to treatment as well as palliative care of this disease. The development of such guidelines ensures high quality care.<sup>2330</sup>

Strengthening of Pathology Services – Access to Pathological services is the most crucial step required for the management of invasive cancer. Countries that are a developing stage can increase access by increasing pathological centers. These centers help in treating not only cervical cancer but any type of cancer at the early stage.<sup>2331</sup>

Expanding Surgical Capacity – Cervical cancer can be treated by surgery itself, if it has been diagnosed at the early stages itself. However, the issue with surgery is that it cannot be construed under a cost-effective method of treatment. However, the expansion of surgical capacity in middle- and low-income countries

can only happen at a gradual rate.<sup>2332</sup> In countries that have high income, people have access to proper medical facilities.

Strengthening of Palliative Care Services – Palliative plans should be inclusive of those women who have suffered from Cervical cancer as well. For middle- and low-income countries, palliative care should be integrated as home-based models into their primary health care strategies.

Reducing Cancer Stigmatization – Cancer Stigmatization is a crucial step to be taken towards the steps against this disease. This should include patients' awareness, access to initiatives as well as educating the people about the initiatives. This should specially be done through the survivor groups. It would be cost effective and the awareness has the possibility of the message being passed thoroughly.

It can be interpreted that even though WHO has taken initiatives and has given targets and strategies to implement. But these comprehensive plans are highly complex and there are too many barriers that are to be broken. Governments of various countries at the moment did not even prioritize to take initiatives.

In the opinion of the researcher, middle- and low-income countries, government should start taking initiatives by breaking the stigma and educating patients with respect to this disease. They should on a parallel road keep the availability of vaccines. The pricing of the vaccines could be dependent on the patient. The factors that could be taken into consideration is their health insurance plan, the income, their health history as well as the health history of the family and any other relevant factors.

The strategy devised by WHO does consider all the factors. But the implementation purely depends on the resources available in the

<sup>2329</sup> Supra

<sup>2330</sup> . Chuang LT, Feldman S, Nakisige C, Temin S, Berek JS. Management and care of women with invasive cervical cancer: ASCO Resource-Stratified Clinical Practice Guideline. *Journal of Clinical Oncology*. 2016;34(27):3354–5. doi:3310.1200/JCO.2016.3368.3789

<sup>2331</sup> Montgomery ND, Tomoka T, Krysiak R, Powers E, Mulenga M, Kampani C et al. Practical successes in telepathology experiences in Africa. *Clinics in Laboratory Medicine*. 2018;38(1):141–50. doi:10.1016/j.cll.2017.10.011

<sup>2332</sup> Sullivan R, Alatis O, Anderson B, Audicio R, Autier P. Delivering safe and affordable cancer surgery to all. *Lancet Oncology Commission on Global Cancer Surgery*. *Lancet Oncology*. 2015;16(11):1193–224.

country. The question of seriousness or the spread of it only can come into light if the citizens of the countries have access to screening and treatment facilities.

High Income countries, even though having resources or the financial capacity to avail the resources can only curb to deal with spread of the disease when they start making it a priority as well. This would include add cervical cancer vaccines to their national vaccination programs. When these countries have the financial capacity to avail resources, they should start making health plans revolving around this disease.

#### **CHAPTER 4 – Can legally mandate on Vaccines help in making India reach the WHO Guidelines**

##### **Is Vaccination the best preventive measure in India?**

It can be stated that India is still at a developing country. The medical infrastructure has a long way to go. Cervical Cancer Vaccines can be considered as a start to curb the spread of this disease. Women adhering to routine screenings as per the recommendations of the doctor can be considered a way ahead but the issue with that is India's Medical Infrastructure is still not completely equipped for routine screening among women, especially considering the scale of the population, routine screenings on a large scale is difficult to achieve because of reasons such as cost, lack of knowledge. And in India, it is believed that there are people who despite having the knowledge would still not take the required medical tests.

##### **Vaccines Available in India**

There are two vaccines that are licensed globally and available in India. These two vaccines are as below –

1. Gardasil (Marketed by Merck) – A quadrivalent Vaccine (stimulation of an immune response against four different types viruses). The clinical trials started with three doses at the time period of 0, 2 and 6 months in more than 16,000 women aged between 16 to 26 years from five different continents, which

included Asia. These clinical trials have shown 100% efficacy at a median follow-up of 1.9 years against types 16/18-related CIN-2/3 and AIS in the per-protocol analysis (the women who were vaccinated with all three doses of the vaccine and remained uninfected with vaccine HPV type at onset and for 1 month after completion of the vaccine schedule).<sup>2333</sup>

2. Cervarix (Marketed by Glaxo Smith Kline)– A bivalent Vaccine (stimulation of an immune response against two different type viruses). The Clinical trials with respect to this vaccine took place with three doses at the time intervals of 0, 1 and 6 months in more than 18,000 women globally. The vaccine has shown 90% efficacy against type 16/18-related CIN-2/3 and AIS at the 15-month follow-up in the modified intention to treat the analysis. (This included those women who were at the baseline negative for HPV DNA of vaccine type virus and those who received at least one dose of the vaccine). The follow up on the subset of participants over the period of up to 4 to 5 years displayed no evidence as of the immunity waning.<sup>2334</sup>

##### **Cervical Cancer Vaccine History in India**

In India, both the above-mentioned HPV vaccines were licensed in year of 2008 and a non-valent vaccine was licensed in the year of 2018. These two HPV vaccinations are commercially available in India and have been approved by the appropriate authority i.e. the Drug Controller General of India (DCGI). These two vaccines are globally accepted in India and they have also been authorized by the US Food and Drug Administration, European Medicines Agency and was also held qualified by the World Health Organization.

The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) had recommended

<sup>2333</sup> Villa LL, Costa RL, Petta CA, Andrade RP, Ault KA, Giuliano AR, et al. Prophylactic quadrivalent human Papillomavirus (types 6, 11, 16 and 18) L1 virus-like particle vaccine in young women: A randomized double-blind placebo-controlled multicentre phase II efficacy trial. *Lancet Oncol.* 2005;6:271–8.

<sup>2334</sup> Harper DM, Franco EL, Wheeler C, Ferris DG, Jenkins D, Schuind A, et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with Human Papillomavirus types 16 and 18 in young women: A randomized controlled trial. *Lancet.* 2004;364:1757–65.



that these vaccines are to be given as two dosages, six months apart for girls aged below 14 years.<sup>2335</sup> The vaccination was advised to females who were as young as the age of 9 as well as in those in the age group between 13–26 years who have not completed the vaccination previously.

### Efforts made in India to prevent the spread of Cervical Cancer –

Recently it can be seen that the government is making efforts to prevent the spread of cervical cancer. The National Technical Advisory Group for Immunization (hereinafter referred as NTAGI) recommended the inclusion of HPV vaccines in the Universal Immunization Programme (UIP), to prevent the spread of cervical cancer in women.

The NTAGI had recommended the introduction of the HPV vaccine into the UIP on June 28, 2022, proposing a one-time catch-up program for adolescent girls aged 9–14 years, followed by routine introduction at nine years of age.

The honorable Finance minister, in her speech for the Interim Budget for 2024–25, had indicated that the government would actively “promote” Vaccination to combat this deadly disease.

The finance minister though did not provide any specifics yet about the government’s plan with respect to this but she did state that “Our government will encourage vaccination for girls aged 9 to 14 years as a preventive measure against cervical cancer” during her budget speech.<sup>2336</sup>

### State initiatives to Curb Cervical Cancer

Delhi initiated a program for girls who are aged between 9 and 14 in 2016, achieving high coverage rates. Other neighboring states such as Punjab, Sikkim, Karnataka, Tamil Nadu,

Chhattisgarh, and Maharashtra have announced free HPV vaccination for schoolgirls in few districts as part of its pilot programs.

The state of Mizoram has also included free HPV vaccination in its routine immunization program for girls aged 10–12 years, while the state of Uttar Pradesh has also announced free HPV vaccination for school going girls in select districts as part of a pilot program<sup>2337</sup>.

Such initiatives are the reason as to cervical cancer and the ways to deal with it are coming into limelight.

The researcher is of the opinion that India has a long way to go to reach targets that have been set up 2030. In order to reach the targets, there should be small steps that are to be taken by the central government. India’s medical infrastructure is still at a developing stage. In order to reach, there has to be complex strategies that are to be devised with a greater aim.

The Indian government as making announcements should follow through with them. They should start firstly by awareness of this disease. Hospitals especially in tier 2 and tier 3 cities should take initiatives to increase awareness among regarding this disease and ways of tackling this disease. It should be promoted in a such a way that the parents feel positive about the vaccines available and should consider that if they have a daughter who fits the age group then get vaccinated. The awareness in cities should increase in a different way. Measures to curb the spread of the disease should be taught. It should instill healthy lifestyle among women who can be prone to such diseases.

India’s medical infrastructure still has a long way to go. It should take into consideration to integrate screening and treatment services. Women Clinics should be increased, especially in villages. Cervical Cancer Screening requires

<sup>2335</sup> Senapati R (2017) HPV Genotypes distribution in Indian women with and without cervical carcinoma: Implication for HPV vaccination program in Odisha, Eastern India. BMC Infect Dis 17: 30.

<sup>2336</sup> Bhatla N, Joseph E. Cervical cancer prevention & the role of human papillomavirus vaccines in India. Indian J Med Res. 2009; 130: 334–40. Available: <http://www.ncbi.nlm.nih.gov/pubmed/19901443> PMID: 19901443

<sup>2337</sup> Neetu Chandra Sharma, Budget 2024: Gov to promote HPV vaccination for girls aged 9–14 to prevent cervical cancer, Business today, Feb 01<sup>st</sup> 2024 at 2:00.

lot of medical equipment and the test price ranges from R. 20,875 to an amount approximately of Rs. 41,750<sup>2338</sup>. These prices are very high. From the economics point of view, it can be understood that the equipment required for testing is also costly. But the issue is that a developing country like India has the majority population do not have the capacity to spend exorbitant amounts on medical care, especially tests itself. The government should devise the strategy in such a way that it can collaborate with private hospitals and cover expenses who as per their health plan or their income cannot afford such tests. There should be criteria made and met. This kind of implementation would be gradual start for increasing screening tests in India.

In the opinion of the researcher, vaccinations should increase gradually. But the access to vaccine should be easily available. The vaccines that are accepted in India are the most common vaccines for cervical cancer around the world. So, there is obviously a huge demand and there is a possibility that the demand may increase as governments at some point or the other shall start taking steps to mitigate the spread of cervical cancer. India has the opportunity take advantage of this situation as well. Even though India is still considered a developing country, it has some of the best vaccine manufacturers in the country. Manufacturing and selling of cervical cancer vaccine around the world would increase exports as well as increase the money which in turn could be put into health care and especially with respect to cervical cancer. If the government start distributing vaccines that are made in India for free at least in tier 2 and tier 3 cities and on the parallel road, it starts exporting vaccines to other countries, the cost of producing vaccines as well the vaccines that can be distributed at free of cost can be recovered.

### **Is Legal Mandate of Vaccines required to reach the Target given by WHO?**

If the history of India is taken into consideration, then India has some of the best vaccination programs. These programs can be called highly successful vaccination programs. Examples are the Pulse Polio Program and the Covid Vaccination drives. These both have been considered as the best initiatives taken by India to curb Polio as well as control the spread of Covid.

These vaccines were never made mandatory by the policy makers. It was never imposed that it was compulsory for all to take these vaccines. Other factors played a key role in making these vaccination drives a success.

Firstly, taking the pulse polio program into consideration, the steps taken by the government to maintain a polio free status are as below –

- High level of vigilance through surveillance across the entire country. Environmental surveillance through sewage sampling has been established to detect the transmission of poliovirus and a surrogate indicator of the progress as well for any programmatic interventions strategically in Mumbai, Delhi, Patna, Kolkata Punjab and Gujarat.
- All the states of the country have developed Rapid Response Teams (RRT) which are to respond immediately in the case of any polio outbreak.
- Government of India has issued mandatory guideline requirements to all international travellers before their departure to polio affected countries.
- Maintenance of community immunity through high quality National and Sub National Polio rounds each year.

Currently as of now in India there are zero polio cases. The last polio case was recorded in the year of 2012. This can be called as a successful vaccination program. It still continues as due to which there are zero cases. These vaccination programs broke the stigma of vaccinations as

<sup>2338</sup> Chatterjee S, Levin C, Laxminarayan R. Unit cost of medical services at different hospitals in India. PLoS One. 2013;8:e69728.

well as made it a success without making these vaccines mandatory.<sup>2339</sup>

### India's COVID Vaccination Drive

The COVID vaccination drive can be considered as one more example which could be called successful without having the need to mandate vaccines. India was one of the countries that had the greatest number of COVID cases. The reason for having the greatest number of COVID cases is because of the population. When the vaccines were launched, the next challenge was the reach of the vaccines. Another problem was the role of negative media spreading the failure of vaccines during a time when all the efforts were being taken by the government, the medical industry and the vaccine makers.

The drive was partly successful because the vaccines were made in India. This reduced the cost of importing vaccines. The rolling of vaccines had been a major challenge due to the great population. The success of this vaccination drive was possible due to the integration of technology to the drive.

Individual citizens had to register on an app called CoWIN or Aarogya Setu portal to receive the COVID-19 vaccination. There were limited number of vaccination slots which resulted in fewer people getting the administrations of these vaccines during the initial 5 months of the vaccination program (phase 1-4).

The Government of India had then amended the vaccination policy by waiving the requirement of preregistration and offering free vaccinations to boost the program.

The COVID-19 vaccination drive in India was launched on Jan 16, 2021. From May 1, 2021, people older than 18 years of age were eligible in phase 4 of the drive.

By July 20, 2021, 326.4 million people in India which is approximately 23.4% of the population had received the first dose of the vaccine, and 85.4 million people approximately 6.1% of the population had received the second dose.

The Government of India then implemented a centralized vaccination policy and had vaccinated more than 8.6 million COVID-19 vaccine doses on day 1 (June 21, 2021).

Such a vaccination strategies were helpful in achieving mass vaccination against COVID-19. However, ensuring the consistent vaccine supply was a substantial challenge to maintaining such a high pace and achieving coverage for the entire nation.<sup>2340</sup>

It can be seen that the vaccination drive did take some time to achieve maximum coverage but it was never legally mandated to take the vaccines. But the policies for the vaccinations also played a major role.

Such as travelling from one city of the country to another city or from India to another country required the mandate of vaccines as per the travel guidelines of the government. And these guidelines till date are in place.<sup>2341</sup>

So, when it comes to a disease like cervical cancer. In India mandating vaccines would not be coming in good light. As per the opinion of the researcher, the first step is to break the stigma and educate the citizens in the most positive way possible.

Adding Cervical Cancer Vaccines to the national immunization program would be the next step. That would be adding it to the national health mission of the country.<sup>2342</sup>

From the aforementioned analysis it can be interpreted that there are better steps that can be taken to curb the spread of the disease, rather than mandating the vaccines. Much severe disease such as COVID which was an air-borne disease and was at a higher rate was dealt with, without mandating vaccines.

### CHAPTER 5 – Conclusion & Suggestions

In conclusion, the researcher is of the opinion that, if the government of India aims to

<sup>2340</sup> Ministry of Health and Family Welfare . Government of India; 2021. Cumulative coverage report of COVID-19 vaccination

<sup>2341</sup> <https://www.mohfw.gov.in/>

<sup>2342</sup> <https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=824&lid=220>



eliminate cervical cancer, the path has to be multifaceted. The path has to include prevention through vaccines, early detection through increasing screening and access to treatment as well. The path should also include awareness campaigns as well.

The researcher is of the opinions that mandating of the vaccines even though increases the rate of vaccinations, it carries more disadvantages.

It gives rise to ethical and legal issues. It gives rise too the legal issue regarding the freedom of choice. It may be perceived as infringement of personal rights and over reach of the government. The mandating of vaccines especially in country like India, where the medical infrastructure is still improving would give rise to logistical challenges. Mandating vaccines requires a robust medical infrastructure and access to resources. At this point if there is a mandate on legal vaccines, it would put a lot of pressure on the health care system of India, which the researcher is of the opinion that the healthcare system of the country cannot take. Mandating of vaccines would also give rise to a lot of litigation issues and would fire backlash through political controversies. Health care system should be one of the sectors that should be away from political controversies and the decisions should be taken by professionals as per the scale of the industry.<sup>2343</sup>

Implementation of vaccine mandate would also cause a possible diversion of resources. This would cause unequal distribution of resources. This cannot be afforded especially when there are limitations to the access of resources.

India in the past has had successful vaccination drives and can continue to do so with respect to the cervical cancer vaccines as well. These all in the past happened not by making mandate of the vaccines but due to several key factors that played a role.

India can promote cervical cancer vaccines in order to reach the targets set by WHO, if it the below stated factors are embedded in the policies with respect to the vaccination drive –

1. Integration with the Immunization programmes – the existing immunization program of India should integrate Cervical cancer vaccines. It can be done through health care canters, school-based vaccination programs and outreach camps as well.
2. Target outreach – Educating people about the advantages of these vaccines. This should be done through education institutes such as school and colleges. In tier 2 and tier 3 cities of India, there should be awareness campaigns through the medical institutions as well.
3. Affordability and Accessibility – the access and affordability of vaccines is key issue that is to be resolved. To reach the targets these vaccines should be available as much as possible and people should also be able to afford these vaccines. This can be possible through different ways. At the moment the best way to increase accessibility is the collaboration between NGOs, medical institutes and the government. This would increase the availability of the vaccines.
4. Data Monitoring – keeping track of the immunization programs, even with respect to cervical cancer vaccines would help in giving proper data, that could be used to improve the plans with respect to the vaccination programs.
5. Prior Experience – Medical Institutions should collaborate with victims who fought with cervical cancer. These patients sharing their experience could be a major booster factor for people to make attempts towards the vaccines.

<sup>2344</sup>

From the submitted data and theory, the researcher is of the opinion that it is nearly impossible for India to meet the targets set out by WHO by the year of 2030. The targets can be

<sup>2343</sup> Limentani A.E. The role of ethical principles in health care and the implications for ethical codes. J Med Ethics. 1999;25:394–398

<sup>2344</sup> Mulira RS, Salas AS, O'Brien B. Quality of life among female cancer survivors in Africa: an integrative literature review. Asia-Pacific Journal of Oncology Nursing. 2017;4(1):6–17. doi:10.4103/2347-5625.199078

met only with gradual improvements but it would take time.

The aforementioned steps taken can give a significant boost to the cervical cancer vaccination drive.

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