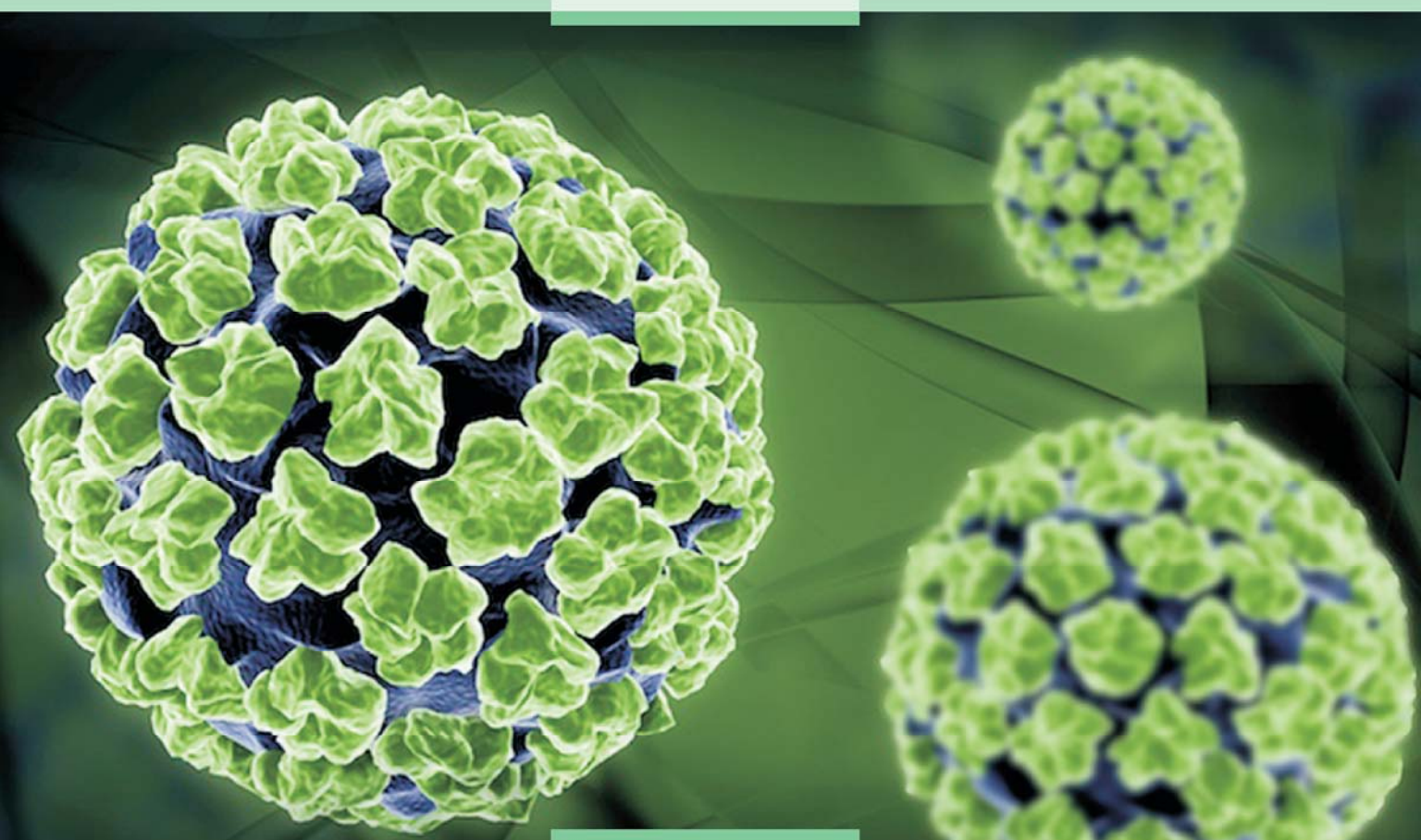




Comprehensive Prevention and Control of Cervical Cancer



SYMPOSIUM Report & Recommendations

Gangtok, Sikkim
INDIA
2015



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**Comprehensive Prevention and
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Participants of the Symposium on
Comprehensive Prevention and Control of Cervical Cancer,
Gangtok, Sikkim, India



Preface

A Two-day Symposium on “*Comprehensive Prevention & Control of Cervical Cancer in North East India*” was held at Gangtok, Sikkim on September 28-29, 2015. It was attended by healthcare policy makers, academics, and public health experts from the states of Arunachal Pradesh, Assam, Mizoram, Manipur, Sikkim and the state of West Bengal. The speakers, resource persons and discussants were from:

- ◆ Rajiv Gandhi Centre of Biotechnology (RGCB), Thiruvananthapuram
- ◆ Tata Memorial Centre (TMC), Mumbai
- ◆ Post-graduate Institute of Medical Research & Education (PGI), Chandigarh
- ◆ National Health Systems Resource Centre (NHSRC), MoHFW, New Delhi
- ◆ Immunisation Technical Support Unit (ITSU), MoHFW, New Delhi
- ◆ NCD Cell, Tamil Nadu Health Systems Project, Government of Tamil Nadu, Chennai
- ◆ Hirabai Cowasji Jehangir Medical Research Institute, JCDC and Prayas, Pune
- ◆ International Agency for Research on Cancer (WHO), Lyon, France
- ◆ Jigme Dorji Wangchuck National Referral Hospital, Thimphu, Bhutan
- ◆ American Cancer Society (ACS), USA
- ◆ Research Triangle Institute Global India Pvt. Ltd (RTI) and
- ◆ Global Health Strategies (GHS), USA

The meeting was organized under the aegis of Cancer Foundation of India (CFI), Kolkata, and convened by Prof. Maqsood Siddiqi, *Chairman, CFI and former Director, Chittaranjan National Cancer Institute & Bose Institute, Kolkata.*

The basic objective of the multi-stakeholder's roundtable was to discuss the burden of disease and explore feasible strategies and delivery models for comprehensive cervical cancer prevention and control in India which could be integrated into the public health delivery system in the country, with particular reference to North East region.

The meeting was inaugurated by Padma Bhushan Prof. N.K.Ganguly, *former Director General, Indian Council of Medical Research (ICMR), New Delhi* and the valedictory address was delivered by Dr. Kumar Bhandari, *DG cum Secretary, Department of Health Care, Human Services and Family Welfare, Government of Sikkim, Gangtok.*

Context

Cervical cancer is one of the most common cancers among Indian women, contributing over 23% of the global incidence and about 25% of mortality. Although vaccination against HPV infection and effective screening methods for its early detection and treatment are available, no serious public health interventions have been initiated for its prevention in the country, mainly due to competitive health priorities and limitations of resources. In recent years, however, several strategic steps were taken by government of India to improve public health systems and services including the introduction of preventive measures for non-communicable diseases (NCDs). Most notable among these are the formation of National Health Mission (NHM), National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) which aims at integrating the NCD interventions in the NHM framework, National Health Systems Resource Centre (NHSRC), Immunisation Technical Support Unit (ITSU), National Technical Advisory Group on Immunisation (NTAGI) and the recently introduced cancer component of NPCDCS programme (12th Plan: 2012-2017). These national health programmes and health system reforms provide adequate space to public health policy makers in the states to introduce bold interventional measures to prevent and control cancer, particularly cervical cancer – a disease that can be prevented and controlled to manageable limits if suitable intervention measures are introduced. In this context, it is encouraging to note that several states have begun cervical cancer screening under the NPCDCS programme. Furthermore, permission has been granted by the central government to introduce HPV vaccination in Sikkim, the first state in the country to receive a go ahead - a significant step towards initiating primary prevention of cervical cancer in the country as a component of comprehensive cervical cancer prevention and control (CCPC). However, states with high burden of cervical cancer that have started or plan to initiate cervical screening are seemingly reluctant to undertake HPV vaccination within the public health set up. The indecision in most cases appears to be due to the limitations of human resource, financial concerns on sustainability of programme due to high cost of the vaccine, and limited understanding of the potential of HPV vaccination in primary prevention of cervical cancer. Moreover, neither proper national guidelines for cervical screening are there nor logistical issues to integrate it into health systems have been resolved. Thus, with the objective of addressing these challenges which are hampering the adoption of CCPC in states, a roundtable of health care experts and policy makers from Northeastern (NE) States was organized by Cancer Foundation of India at Gangtok (Sikkim) with the specific objectives.

Objectives

- ◆ Discuss the disease burden and public health need for prevention, early detection and linkage with cost-effective management of cervical cancer in the country with special reference to NE states
- ◆ Recognise the vital role of support mobilization and advocacy for introducing primary and secondary prevention of cervical cancer.
- ◆ Identify the delivery model(s) for HPV vaccination in India, taking into account the experience of vaccination programme in developing countries. The possibility of using reduced dose regimen in view of recent results may also be considered.
- ◆ Develop strategic framework for comprehensive cervical cancer prevention and control (CCPC) programme that integrates screening and HPV vaccination into the public health system in the country particularly in Northeastern states.
- ◆ Detail the local barriers (across different stakeholder groups) towards adoption of cervical screening and HPV vaccination and suggest communication strategies to overcome them.
- ◆ Recommend ways to accelerate the decision making process for adoption of HPV vaccination and cervical cancer screening as an integral part of the public health systems of the states.
- ◆ Identify the role of NGOs, Civil Society and public-private partnership in addressing cervical cancer prevention and control in India.



Background

A continuous increase of non-communicable diseases (NCDs) in India is mainly attributed to the control of communicable diseases, changing life-styles and increasing trend in life expectancy. Although all NCDs need to be tackled at public health level, cancer prevention and control has emerged as one of the major challenges owing to the lack of awareness about the disease, absence of early detection facilities and high cost of treatment. In compliance with the UN declaration on prevention of Non-communicable diseases (September, 2011), the Government of India (GOI) launched a National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) by merging erstwhile national programme of cancer control (NPCC) with other non-communicable diseases under the framework of National Health Mission (NHM). Subsequently, GOI-WHO Biennial National Action Plan and Monitoring framework was developed to prevent NCDs in 2012-13. The NCD Cells were established in 16 states and 66 districts in the 11th Plan and interventions under NPCDCS up to District level are being integrated with NHM in the 12th Plan. This clearly indicates India's strong commitment in meeting the challenge of attaining 25% relative reduction in mortality from NCDs including cancer by 2025. Achieving this target would, however, require forceful policy planning and implementation strategy towards prevention and early detection of common cancers in the country such as those associated with the use of tobacco in both sexes and breast and cervical cancers among women. While a comprehensive anti-tobacco policy and a proper legislation is already in place to curb tobacco usage, the establishment of screening facilities for cervical cancer and early detection of breast cancer has become a high priority public health necessity under the NPCDCS programme.

Breast cancer is the most common cancer in the country with 144,937 incident cases and 70,218 deaths in the year 2012. Several resource-rich countries have shown notable reduction in breast cancer mortality by mammography screening with parallel improvement in survival rates due to early detection of cancer. However, mammography screening is not feasible as a public health service for low and middle income (LMI) countries such as India due to the limitations of technology and human resource as well as logistical constraints. Therefore, a planned advocacy for breast-self examination (BSE) followed by clinical breast examination (CBE) by trained nurses or doctors linked to timely access to clinical follow up is possibly the most suitable approach for early detection of breast cancer under NPCDCS programme integrated with public health system.

Next to breast cancer, cancer of cervix or cervical cancer is the most common cancer among women in India with an average age-adjusted rate of 22/year/10⁵ population. There were 122,844 women diagnosed and 67,477 died of cervical cancer during 2012. It is well established that cervical cancer and its precursor lesions are caused by persistent infection by one or more high-risk Human Papilloma Virus (HPV) types. The disease develops gradually and has a

detectable pre-neoplastic stage that can be treated successfully with proper intervention. Most of the developed countries have effectively reduced the burden of cervical cancer by providing Pap test to married women through public health programmes or health insurance coverage. For various reasons though, the use of Pap test may not be feasible in low-resource countries such as India. The visual inspection after application of acetic acid (VIA) and/or measurement of high risk HPV DNA have been found to be highly effective as a screening test in several cross-sectional studies in the country. Despite having a moderate sensitivity, the VIA test is recommended by WHO for low-resource settings because it is low cost and can be performed by trained nurses or health workers with high efficiency. The high risk HPV DNA test on the other hand is much more sensitive and also allows up to a 10 year gap for re-screening of screen-negative women, thus bringing down the overall cost of population-based screening.

The identification of certain HPV types as etiological risk factors for cervical cancer has led to the development of prophylactic vaccines against specific sets of HPV genotypes. As per recent data, the infection with HPV 16 and 18 is accounted for over 80% of cervical cancer cases in India. Thus, for a comprehensive approach to cervical cancer prevention and control, cervical screening in women should be combined with HPV vaccination of girls. The two currently available prophylactic HPV vaccines in the market are Gardasil and Cervarix. While both are against HPV type 16 and 18 infections, Gardasil in addition, protects against HPV 6 and 11 which are responsible for 90% of genital warts. Both HPV vaccines were licensed by Drug Controller General of India (DCGI) to be marketed in the country in 2008/09 on the basis of obligatory clinical trials which were subsequently validated by demonstration and research trials (2009-2015). However, despite world-wide acceptance, the uptake of HPV vaccine remained unexpectedly low in the country due to adverse media publicity and ambivalent attitude of country's policy makers towards its introduction into the public health care system. In view of overwhelming scientific data in favour of safety and the efficacy of vaccine in recent years, the central government has indicated that it may allow HPV vaccination to girls under public health system, provided the state governments can generate sufficient resources on their own for a sustainable vaccination programme.

However, at present there are no specific national guidelines for cervical cancer screening or HPV vaccination in the country and the public health systems of states by and large have inadequate infrastructure for implementation of these programmes. The symposium in Gangtok (Sikkim) therefore, endeavoured to offer a round-table opportunity for policy makers and healthcare managers from Northeastern states to interact with experts having experience of running such programmes and develop strategic framework for a comprehensive cervical cancer prevention and control (CCPC) which could be integrated into the public health delivery system in states.

Programme

DAY - 1

September 28, 2015

TIME	TOPIC	SPEAKER
9.30 - 10.00	Registration	
10.00 - 10.10	Welcome	Maqsood Siddiqi <i>Chairman</i> Cancer Foundation of India Kolkata
10.10 - 10.40	Inauguration	N K Ganguly, CHIEF GUEST <i>Former Director General</i> Indian Council of Medical Research New Delhi
10.40 - 11.00	TEA	

Scientific Session - 1

Cervical Cancer Screening - Implementation

CHAIRPERSON: Radhika Srinivasan, PGIMER, Chandigarh

TIME	TOPIC	SPEAKER
11.00 - 11.20	Lessons learnt from Screening demonstration Programme in West Bengal	Partha Basu International Agency for Research on Cancer (WHO) Lyon, France
11.20 - 11.40	Implementing Cervical Cancer Prevention Programme in a Non-Profit Organization	Smita Joshi Hirabai Cowasji Jehangir Medical Research Institute, JCDC and Prayas Pune
11.40 - 12.00	Cervical Cancer Screening Programme in Tamil Nadu	Jerard Selvam Tamil Nadu Health Systems Project Govt. of Tamil Nadu Chennai
12.00 - 12.30	DISCUSSION	

Scientific Session - 2 HPV Vaccination - Primary Prevention**CHAIRPERSON: Maqsood Siddiqi, Cancer Foundation of India, Kolkata**

TIME	TOPIC	SPEAKER
12.30 - 12.50	Study on HPV vaccination in Sikkim and Mizoram	M Radhakrishna Pillai Rajiv Gandhi Centre for Biotechnology (DBT) Thiruvananthapuram
12.50 - 13.10	Implementation of HPV vaccination in Bhutan: Lessons learnt	Ugyen Tshomo Jigme Dorji Wangchuck National Referral Hospital Thimpu, Bhutan
13.10 - 13.30	ACS's HPV Vaccination programme: Vaccinating adolescents Against Cancer	Katherine Sharpe American Cancer Society USA
13.30 - 14.30	LUNCH	

Scientific Session - 3 HPV Vaccination - Opportunity and Challenge**CHAIRPERSON: Partha Basu, IARC (WHO), Lyon, France**

TIME	TOPIC	SPEAKER
14.30 - 14.50	Challenges of Delivering HPV vaccination service in India	Suneeta Krishnan Research Triangle Global India Pvt. Ltd. New Delhi
14.50 - 15.10	Universal Immunisation Programme in India	Akash Malik Immunisation Technical Support Unit MoHFW, Govt. of India New Delhi
15.10 - 15.30	Community Participation to Address NCDs with focus on Adolescent Population and Cervical Cancer	Satish Kumar National Health Systems Resource Centre (NHSRC) MoHFW, Govt. of India New Delhi
15.30 - 16.00	DISCUSSION	
16.00 - 16.30	TEA	

DAY - 2

September 29, 2015

Scientific Session - 4 Universal Coverage of Screening and HPV Vaccination		
CHAIRPERSON: Jerard Selvam, Govt. of Tamil Nadu, Chennai		
TIME	TOPIC	SPEAKER
10.30 – 10.50	Delivering cervical cancer screening as an integrated NCD control package in India	Partha Basu International Agency for Research on Cancer (WHO) Lyon, France
10.50 – 11.00	Integrated Common Cancer Control Programme	Sharmila Pimple Tata Memorial Centre Mumbai
11.00 – 11.30	Rationale for Pragmatic introduction of HPV vaccination and screening in North East India	<i>Pre-recorded audio-visual presentation</i> R. Sankaranarayanan International Agency for Research on Cancer (WHO) Lyon, France
11.30 - 11.45	TEA	
11.45 – 13.30	Panel Discussion & Recommendations	
	Comprehensive Prevention & Control of Cervical Cancer	
	MODERATOR: Radhika Srinivasan , PGIMER, Chandigarh PANEL: K Lalpiakzuala, Goter Doke, Srabani Mittal, Sutapa Biswas, Rinzing Dorjee	
13.30 – 14.00	Valediction by Sutapa Biswas, CFI, Kolkata CHIEF GUEST: Kumar Bhandari Department of Health Care, Human Services and Family Welfare, Govt. of Sikkim, Gangtok	
14.00 - 15.00	LUNCH	

Rapporteur : *Suneeta Krishnan, Srabani Mittal*

Inaugural Session

September 28, 2015 - Day 1

Maqsood Siddiqi

Chairman, Cancer Foundation of India, Kolkata

OPENING REMARKS

Welcoming the chief guest Padma Bhushan Professor Dr. Nirmal Kumar Ganguly, the former Director General of Indian Council of Medical Research, (currently Professor of Eminence, DBT, Ministry of Science & Technology, Government of India), the resource persons, invited participants and guests, Professor Siddiqi explained the main objectives of the meeting and emphasized the need to develop strategic framework for comprehensive cervical cancer prevention and control (CCPC) in the country.

He underscored that three things have changed since 2005 when the last national guidelines for cervical cancer screening were developed. First, that we have improved data on the epidemiology of cervical cancer due to expansion of the network of PBCRs in the country. Second, that the central government has introduced the cancer component of NPCDCS in 12th Plan: 2012-2017 that integrates NCD interventions in the NHM framework. The operational guideline of NPCDCS recommends cervical cancer screening though implementation issues are left unresolved. And thirdly, since the last national guidelines, HPV vaccination has been accepted as a preferred method of preventing HPV infections and thereby providing primary prevention of cervical cancer. It is important to know, he added, that government of India has already agreed in principle to allow introduction of HPV vaccination as a public health service by states if they can manage a sustainable vaccination programme from their own resources.

Professor Siddiqi expressed hope that the present assembly of public health experts and policy makers will deliberate and explore the programmatic feasibility and logistical issues and develop a road map for cervical cancer prevention and control which can be embedded in public healthcare system in the country.

*Padma Bhushan***Nirmal Kumar Ganguly**

Former Director General, Indian Council of Medical Research, New Delhi

INAUGURAL ADDRESS

Prof. Ganguly gave a detailed overview of the global and national burden of cervical cancer and presented chronological advances in epidemiology, prevention, early detection and treatment of the disease. He stressed the need for population based screening of women for cervical cancer with high coverage in India and presented data indicating that the cumulative risk of cervical cancer in the country is nearly double compared to the rest of the world (2.4% vs 1.4%). He emphasized that if appropriate steps are not taken, there will be a 45% increase in the incidence of cervical cancer among women 0-64 yrs and 86% in the age group of 65+ by 2025. Similar increase is predicted in the mortality rates. He presented a comprehensive review on the progress of global research, clinical trials and implementation of HPV vaccination and hoped that primary prevention will soon become a part of our cervical cancer prevention initiatives. Although many technical questions remain unanswered such as acceptability of vaccination by parents and whether it can be co-administered with other adolescent vaccines (rubella, tetanus), but these can be resolved when more demonstration trials are carried out in the country, he said. On the cost effectiveness of vaccination and screening in India he presented data showing that HPV vaccination of girls and three times screening of women between 35-45 yrs is estimated to reduce 61% cervical cancer in India. While vaccination and one time screening is estimated to lessen the disease burden by 52%; HPV vaccination alone will reduce the disease to 44%, assuming 70% coverage of the preventive efforts. He underlined the need of more carefully designed vaccine trials in India to understand the transmission dynamics, cost effectiveness and social acceptability. He also stressed on the cost reduction of vaccine for financial sustainability in the public health programmes. In his concluding remarks, he considered cervical cancer prevention as a women's rights issue and thus women should lead a strong advocacy movement to eliminate cervical cancer by engaging cancer survivors. He ended his presentation by expressing optimism on tackling cervical cancer in Northeastern states due to a high social development index, high literacy and adequate women empowerment.

Summary of Presentations

Scientific Session - 1

Cervical Cancer Screening – Implementation

Partha Basu IARC (WHO), Lyon, France

Smita Joshi H.C.J. M.R.I, JCDC and Prayas, Pune

Jerard Selvam NCD Cell, TNHSP, Govt of Tamil Nadu, Chennai

CHAIRPERSON :

Radhika Srinivasan PGIMER, Chandigarh

Partha Basu

Cervical Cancer Screening Demonstration Project in South Bengal – Lessons Learnt

A demonstration project on cervical cancer screening (Cervical cancer Prevention and Control Initiative- CPCI) was conducted by Chittaranjan National Cancer Institute (CNCI), Kolkata, in a southern district of West Bengal. The CPCI programme started in 2010 with a target of screening 50,000 women (30-59 yrs) in five years. Screening was done using VIA and HPV DNA tests. VIA positive women had immediate colposcopy followed by biopsy if colposcopy examination was abnormal. HPV positive women were recalled for colposcopy examination. They were biopsied, irrespective of colposcopy findings. Village ASHA workers (Accredited Social Health Activist) were trained for community mobilization and recalling women for diagnosis, treatment and follow up. ASHAs were also given a booklet of FAQs. The community mobilization involved networking with identified stakeholders and reaching out to local community leaders. Screening was done in rural Primary Health Centres (PHCs) / Community Health Centres (CHCs) or premises provided by local NGOs or schools. Community Health Workers (CHWs) did house to house visits and women were given a specific date and time of screening. Non-specialist clinicians did colposcopy/biopsy and cryotherapy in the same sitting. More than 44,000 women were screened between 2010 and 2015. The VIA positivity was 7%, which was seen to fall with age. On the other hand, HPV test performance was constant across ages at nearly 5%. The HPV test detection rate was found to be higher than VIA at all ages. Sensitivity of HPV test was 91% as compared to VIA sensitivity of 67%. The team that implemented the project comprised of 3 health workers, 2 social workers and 1 non-specialist doctor. Screen test positivity was found to be a good way to assess the performance of team workers. Colposcopy was performed on 100% VIA positive and 78% on HPV positive women. 261 cases of Cervical Intraepithelial Neoplasia CIN2/CIN3 and 61 invasive cervical cancers were detected. Over 90% cervical cancer cases were treated at CNCI hospital. While in the present study 70% cervical cancer cases were detected at stage I, only 10% cases seen at OPD of CNCI hospital, showing a good example of the down-staging of cervical cancer. On the basis of the experience from this project, CNCI has been invited by the government of West Bengal to extend the study to 2 districts in the state which is likely to be a beginning of cervical cancer screening in the state.

Smita Joshi*Implementing Cervical Cancer Prevention Programme in a Non-Profit Organization*

Prayas, a nonprofit NGO started cervical cancer screening of HIV positive women in 2010. It is known that there is a bilateral association between HIV and HPV infection. The reported HPV prevalence in HIV infected women is 20-50% in Asians. Women who are living with HIV may not clear HPV leading to persistent infection, thus having an increased risk of infection with multiple HPV types and therefore increased rate of cervical cancer. The screening of HIV positive women was started at the age of 35 (or sometimes as young as 21). Repeated screening was done due to faster progression and positive cases received clinical follow up on priority. The HIV infected women need continuous motivation and counseling for added disease burden. Since the National AIDS Control Organisation (NACO) guidelines for screening are vague and do not mention screening interval, more work is needed to develop screening guidelines in HIV positive women. The present study on cervical cancer prevention in HIV infected women, therefore, looked at different screening tests and HPV type distribution. A good sensitivity for sequential testing with VIA/VILI was observed. 41% of screened women had high risk HPV infection. The distribution of HPV types was, HPV 16 (58.5%), HPV 31 (22.6%), HPV 56 (13.2%), HPV 18 and 68a (11.3%), HPV 33, 35 and 51 (9.4%) and HPV 70 (7.5%). In addition to screening, Prayas also offered affordable services, subsidized treatment cost and conducted awareness programmes. The study faced several challenges such as sustainability of programme, low awareness and misconceptions among women about cervical screening.

Jerard Selvam*Cervical Cancer Screening Programme in Tamil Nadu*

The Tamil Nadu Health Systems Project (TNHSP) on Non-communicable Diseases (NCDs) control programme was conducted in a pilot mode between 2007 and 2010 on cervical cancer screening and hypertension in 6 districts. This gave a deep insight into a number of challenges which were carefully addressed before up-scaling it to 32 districts in Tamil Nadu in two phases; 16 districts each in 2012 and 2013. The up-scaled programme also included breast cancer screening and diabetes testing. This is the first large-scale NCD control programme of its kind supported by World Bank in the country. While the public health care structure of the state was used for various project activities, dedicated NCD staff was employed as the main functionaries of TNHSP. The project included 2,432 NCD Staff Nurses, 6,323 Medical officers, 1,748 Lab technicians, 2,348 Pharmacists and 11,462 Field staff. It involved 1,753 Public Health Centres

(PHC), 270 Govt. Hospitals (GH), 23 Govt. Medical College Hospitals (GMCH) and 100 selected Municipal Health facilities. The programme also involved several other government departments for achieving the NCD goals which included cervical cancer screening. The cervical screening used VIA / VILI method while breast screening was done through clinical breast examination (CBE) of 30+ women at PHC, GH, GMCH, ESIC and Municipal dispensaries and hospitals. Staff Nurses did the screening services and referred positive cases for colposcopy to dedicated hospitals. The Secondary evaluation using Colposcopy / Mammography / Fine Needle Aspiration Cytology (FNAC), Biopsy, Nipple secretion cytology are done at all GH, GMCH, ESIC and municipal hospitals, while microscopic confirmation through Histology was done at all Govt. Medical College Hospitals. The clinical follow up was done at Govt. Medical College Hospitals. The IEC materials and Clinical protocols for all four interventions included Hoardings, Posters, Stickers and Flip charts. Additionally, CDs were made on clinical procedures, CBE/measuring BP / VIA / VILI and short tele-films were produced by TNHSP for public awareness. For data recording and storage, dedicated NCD online screens were developed and deployed on the existing HMS platform. NCD Screens were deployed for use in PHCs and GHs. The final statistics of the opportunistic cervical cancer screening under TNHSP (July 2012-July 2015) is as follows: Total Screened for Cancer Cervix - 98,38,058; VIA /VILI positive women - 3,43,965 (3.49%). The profile of histology examination was, Normal- 39,552 (82 %), CIN 1 - 4,018 (45.1 %), CIN 2 - 1,732 (19.4%), CIN 3 - 1,141 (12.8 %) and invasive cancers - 2,029 (22.7 %). In the up-scaling, the average cost per woman screened was INR 84.05 as against INR 102.0 in the pilot programme.



Scientific Session - 2

HPV Vaccination – Primary Prevention

M Radhakrishna Pillai RGCB (DBT), Thiruvananthapuram
Ugyen Tshomo JDW National Referral Hospital, Thimpu, Bhutan
Katherine Sharpe American Cancer Society, Atlanta, USA
 CHAIRPERSON
Maqsood Siddiqi Cancer Foundation of India, Kolkata
 CO-CHAIRPERSON
Sharmila Pimple Tata Memorial Centre, Mumbai

M Radhakrishna Pillai*Study on HPV vaccination in Sikkim and Mizoram*

A cluster randomized trial led by IARC (WHO), Lyon to study the efficacy of 2-vs-3 doses of quadrivalent HPV vaccination in 10-18 year old unmarried girls at eight collaborating centres is being conducted in India since 2009. It is the first large trial of HPV vaccine outside the pharmaceutical industry in the country. The basic objectives of the project include obtaining evidence on the efficacy of 2-dose as compared to 3-dose HPV vaccination and to disseminate the information about feasibility, effectiveness, safety and acceptability of the vaccination approaches. The immediate end-points are i) to measure relative type specific immunogenicity of serum neutralizing Ab to HPV types included in vaccine, ii) measure geometric mean titres (GMT) of serum anti-HPV16/18/6/11 L1 antibody (sL1Ab) at months 7,12,24, 36, and 48 after the first dose of vaccine, iii) study the frequency of incident and persistent HPV16 and 18 infections in married girls and also to measure the frequency of incident infection by non-targeted high-risk HPV types. The long-term end-points are HPV-16 and -18 associated CIN2/3 lesions, adeno-carcinoma in situ and invasive cervical cancers and CIN lesions and invasive cancer associated with other HPV types in vaccinated girls compared to unvaccinated girls. However, due to the suspension of the project mid-way it resulted in four study groups instead of two. Thus, the overall figures from all centres showed that 4,950 girls received 1 dose Default (day 1), 3,452 - 2 doses Default (day 1-60), 4,979-2 doses (day 1-180+) and 4,348 girls received 3 doses (day 1-60-180+). Of the 1,000 girls from Sikkim and Mizoram in the trial, the figures are 1-dose D (day 1) -34, 2-dose D (day 1, 60) -19, 2-dose (day 1, 180+) – 471 and 3-dose (1, 60, 180+) - 476. The immunogenicity and frequency of incident and persistent HPV 16, 18, 6 and 11 infections (12-month definition) were compared in the 1-dose/D, 2-dose/D and 2-dose groups with the 3-dose group. The GMT of anti-HPV16/18/6/11 L1 antibody were measured in 10,940 samples with Multiplex HPV serology using Luminex x-MAP technology. The results show that the

immunogenicity of the 2-dose (days 1, 180) schedule was non-inferior to the 3-dose (days 1, 60, 180) standard schedule. However, the immunogenicity of 2 dose or a single dose (for girls who missed further doses by default due to the suspension of vaccination) were inferior to the immunogenicity of 3-dose (days 1, 60, 180) standard schedule. Cervical cells were collected and analyzed for HPV infection by genotyping from vaccinated girls once a year starting 18 months after marriage or 6 months after child birth, and compared with girls from a cohort of unvaccinated married girls. The frequency of HPV 6, 11, 16 and 18 was as follows: 3-dose – 0.6%, 2-dose – 1.0%, 2-dose D – 2.0%, 1-dose D – 1.6% and unvaccinated married women – 6.1%. The results clearly show significant protection to HPV infection provided by the vaccine used in the trial. We have also studied persistence of HPV infection and non-vaccine included HPV types in cervical cells of vaccinated and unvaccinated cohort which confirm the efficacy of quadrivalent HPV vaccine used in the trial.

Ugyen Tshomo

Implementation of HPV vaccination in Bhutan: Lessons learnt

In Bhutan 95% population is covered by government health services. Cervical cancer is the most common cancer in Bhutanese women. To help prevent this disease, Bhutan already has cytology based screening programme since 2000. Despite a robust call-recall system where screen positive women were actively followed to colposcopy clinics, the uptake of screening has been low. Therefore, after considering the disease burden, poor coverage by screening, poor outcome associated with late diagnosis of cervical cancer, Bhutan decided to adopt HPV vaccination of 12 year old girls with quadrivalent HPV vaccine with one time catch-up campaign for 13-18 year old girls in the year 2010. Vaccination was done in the schools, and out of school girls were invited to health centers. From 2011, HPV vaccination entered into routine immunization schedule using public health center delivery. 130,000 doses of Quadrivalent vaccines were administered in 2010. 3-dose coverage of 12 year old girls was 100% and that of 13-18 year olds was 89%. Vaccine was well tolerated and no severe side effects were reported. From 2011-13, vaccine was given to 12 year olds through health centers. Three-dose coverage was only 67-69%. In 2014, when vaccine delivery shifted back to school-based programme, coverage increased to 90%. Rapid implementation with high coverage in Bhutan was due to strong political commitment, robust primary health care system and good support from the Education sector. School-based programme seems to be superior for achieving high coverage. Bhutan's lesson for other low and middle income countries include superiority of school-based programme and feasibility of a broad catch-up campaign in the first year.

Katherine Sharpe*ACS's HPV Vaccination programme: Vaccinating adolescents Against Cancer*

There are 18,000 women and 9,000 men diagnosed each year in the United States for cancers caused by HPV. Nearly 330,000 women undergo treatment for pre-cancers but even with highly efficient cervical cancer screening programme in the United States about 11,000 women get cervical cancer. Vaccination is the best way to prevent HPV associated cancers. However, HPV vaccine 3-dose coverage is much lower in US (33.4%) compared to Australia (71.2%) and United Kingdom (60.4%). There are financing, acceptance and delivery system challenges that affect its uptake in US. Thus, the focus is on to build systems capacity to increase uptake. In 2012-2013, to improve efforts to reach the HPV vaccines' potential to prevent cancers, the President's Cancer Panel recommended a multipronged strategy to accelerate vaccine uptake in the United States and globally. In order to accelerate HPV Vaccine uptake two major steps are taken up by American Cancer Society. First, to form a National HPV Vaccination Roundtable which is a network of organizations involved in cancer prevention, immunization, health care delivery, and public health. The aim of the Roundtable is to use electronic office systems to support HPV Vaccine by providers to parents, caregivers and adolescents and also to improve communication strategies to increase knowledge regarding cancer prevention benefits of the vaccine, its efficacy and safety. And the Second step was the start of HPV VACs (Vaccinate Adolescents against Cancers) programme to increase HPV vaccination rates for adolescents across the nation through improved provider awareness and education and improved system-wide processes—with a focus on adolescents of ages 11 to 12. The HPV VACs programme has four strategies, i) clinician outreach and training, ii) providing educational materials, iii) developing partnerships and iv) pushing for prioritization of vaccination. The efficient implementation of both these ACS' programmes is expected to improve uptake of HPV vaccination in US.

Scientific Session - 3

HPV Vaccination – Primary Prevention

Suneeta Krishnan RTI International India Pvt Ltd, New Delhi

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CHAIRPERSON

Partha Basu IARC (WHO), Lyon, France

Suneeta Krishnan

Challenges of Delivering HPV vaccination service in India

There are several challenges to be faced in delivering HPV vaccine as a part of public healthcare system in India. The system level barriers in public healthcare mainly consist of (a) delivery problems due to adolescent age group not being served by the current routine immunization programme, (b) lack of accurate data on this age group and (c) challenges related to vaccine delivery logistics. Some of these challenges can be addressed by leveraging other platforms and strategies such as adopting a combination of delivery strategies for high coverage, e.g. schools-based and community outreach to improve uptake across sites replicating the Vietnam and Bhutan model. Human resource challenges can be tackled by integrating with other health promotion efforts such as de-worming, other adult vaccines and routine school health programmes. Financing constraints can be minimized by procuring vaccine through the Global Alliance for Vaccines and Immunization (GAVI). Additional financial resources can also be managed by mobilizing resources through public-private partnerships and by encouraging indigenous production for long term benefits. Socio-cultural challenges such as lack of information/knowledge, concern about safety and side-effects, complexity of messaging on HPV vaccine and stakeholder diversity (parents, girls, teachers and community health workers) can be addressed by providing accurate, easily understandable and science-based information through credible channels. Support to social science and clinical research is also essential for generating context-specific evidence on vaccination safety, acceptability and feasibility. We must also employ a range of communication strategies before the launch of vaccination programme by mobilizing civil society organizations, local communities, and opinion leaders. Also publicise endorsements of vaccine safety and benefits by government leaders and community elders. Political barriers which are mainly due to limited political commitment to cancer prevention and fragmented advocacy efforts can be addressed by a coordinated evidence-based advocacy efforts involving government policy makers, NGOs, pharmaceutical companies. Consistent messaging is also important to avoid confusion.

Akash Malik*Universal Immunisation Programme in India*

The Universal Immunization Programme (UIP) was initiated in 1985 in 31 districts with a plan for country-wide expansion. In 1997, UIP became part of the Reproductive and Child Health (RCH) programme and in 2005 it became part of overall umbrella health programme under National Rural Health Mission (NRHM). Japanese Encephalitis (JE) vaccine was also introduced in the same year. In 2010, measles' second dose and Hepatitis B was included in the UIP. From recent evaluation of data it was found that the coverage of full immunization of children below 12 months increased from 43.5% in 2005 to 65.2% in 2013; in children of 12-23 months coverage increased from 61% to 65% in the same period and that of DPT3, 72% to 75%. In 2013-14 it was estimated that nearly 1.5 million children had not taken any vaccine. Most of the left out children were from poor families (urban- 8%; Rural- 5%). Among the major reasons for children being missed under UIP are awareness and information and fears of after effects, thus effective communication is a major issue. Despite a successful UIP programme, there are several challenges yet to be resolved such as lack of adequate number of ANMs and ASHAs, logistic issues and programme monitoring problems, policy matters like limited evidence for introducing a new vaccine and inadequate surveillance and monitoring. Mission Indradhanush has been started to close the immunization gap. It is focused on 201 districts with largest number of partially vaccinated and left-out children. The basic strategy for Mission Indradhanush is to improve the number and duration of immunization rounds. The children of two years of age and pregnant women are the main beneficiaries though children above two years of age, seeking vaccination at Indradhanush session, are not denied. Several new vaccines are also being either pilot tested or likely to be introduced soon in the country. It has been already decided in 2014 to introduce four new vaccines against preventable diseases – Rotavirus-Diarrhoea, Measles-Rubella, Inactivated Polio Vaccine (IPV-single dose) and JE vaccine which is to be extended to adults. It may be noted, that an effective vaccine logistics and cold chain system is an essential prerequisite for an Immunization programme. Several national initiatives have been taken in this domain by Govt. of India to provide hands-on technical training to cold chain technicians. The deployment of a nationwide cold chain Management Information System (NCCMIS) to track cold chain equipment inventory, availability and functionality and the formation of National Cold Chain and Vaccine Logistics Action Plan (NCCVLAP) are other new steps being taken to strengthen cold chain system in the country.

Satish Kumar*Community Participation to Address NCDs - Adolescent Population and Cervical Cancer*

In 2010, NCDs accounted for more Disability-adjusted Life Year (DALYs) in India than communicable diseases – approx. 235 million vs. 222 million DALYs respectively. 80% of all NCD related deaths are attributed to CVDs, cancers, chronic respiratory diseases and diabetes due to a cluster of risk factors. Community participation in disease control has therefore become essential due to health transition in the country where Non-communicable diseases (53%) have overtaken communicable diseases and other causes of mortality. Participation of individuals, families, or communities assume greater responsibility for their own health welfare and for developing a capacity for community's health development. Community participation in primary healthcare can be improved by engaging peer groups who provide support and continuity for behavioural change, by participation in quality improvement processes. This would also require nomination of volunteers who can facilitate early referrals, information sharing and capacity building of care givers. Some of the potential mechanisms for community participation are school management committees, village health sanitation and nutrition Committee, Rogi Kalyan Samiti, adolescent health forums and District Cancer Committees. In 2014 Rashtriya Kishor Swasthya Karyakram (RKSK) was launched which envisages a universal coverage of adolescents, realigns the existing clinic-based curative approaches to a holistic model promoting community-based health promotion and preventive care. As regards cervical cancer, India has an age-adjusted incidence rate of 27 against 15.3 per year/ 100,000 globally. Similarly, mortality rate due to cervical cancer is higher than global rate (15.2 vs. 7.8 per 100,000). In low-resource settings like ours, cervical screening using visual inspection with acetic acid (VIA) has been recommended. For primary prevention, HPV vaccination is recommended prior to sexual debut for young adolescents (9–13 years of age). However, there are several challenges in rolling out HPV vaccination in the country including attaining a high coverage, the social and cultural factors and fear of making girls sexually promiscuous. Thus, for primary prevention of NCDs including cancer we need to involve community in prevention of tobacco and alcohol use through peer educators and Adolescent Friendly Health Clinic (AFHC) counsellors, develop school health programme to emphasize healthy lifestyle – eating plenty of fruits/vegetables, have adequate physical activity. Sex education under Adolescent Education Programme of NACO should also include information on transmission and prevention of HPV in order to de-stigmatize vaccination against HPV.

Summary of Presentations

Scientific Session - 4

Universal Coverage of Screening and HPV Vaccination

Partha Basu IARC (WHO), Lyon, France

Sharmila Pimple Tata Memorial Centre, Mumbai

R. Sankaranarayanan IARC (WHO), Lyon, France

CHAIRPERSON

Jerard Selvam NCD Cell, TNHSP, Govt of Tamil Nadu, Chennai

Partha Basu

Delivering cervical cancer screening as an integrated NCD control package in India

There are common underlying risk factors for the leading NCDs, which also tend to co-occur. While many countries have NCD policies, only a third have programmes that address their NCD burden. Presently 40 million people die of NCDs and 10 million from cancer. The major risk factors of cancer are tobacco, obesity, air pollution, poor diet, lack of exercise and alcohol abuse. These are also risks for diabetes, hypertension, asthma and stroke. Thus, cancer prevention needs to be integrated with the primary health care of NCDs which require a practical referral linkage between different levels in primary health care for successful integration. The WHO Package of Essential NCD Interventions (PEN) begins with actions at the community level initiated by community health workers (CHW) who are drawn from the community and should be trained to carry out one or more functions of health care such as home visits, health education and surveillance. The primary healthcare centres (PHCs) can address the main health problems in the community by providing preventive and curative services, whereas the district hospitals (DHs) can provide first level hospital care for the district which is comprehensive. The DHs can also coordinate with referrals from community and can act as points of referral to higher levels of care, wherever necessary. Currently recommended norms for primary and secondary prevention of three main cancers in India are: Cervical cancer: HPV test if feasible and sustainable or else VIA to screen women (HPV: 30-60 years; VIA: 30-49 years) once in lifetime at least. Oral Cancer: Oral Visual Examination (OVE) by trained health workers in tobacco/alcohol abusers combined with tobacco and alcohol reduction counseling (at age 30-60 years) once in 3 years, and for Breast cancer: awareness and education (starting at age 30 years) supplemented with CBE screening/early detection (at age 40-60 years) once in 3 years. All the key players in a primary health care system are important in the chain of care for a patient at risk or already diagnosed with NCDs. A link between and among each level of the primary healthcare system are important as it facilitates care that is comprehensive and coordinated. A coordinated care also minimizes service overlap and inefficient use of resources.

The suggested model of primary health care to control NCDs including cancer in public health system is: Community Health Workers (CHW) - counseling, detection of obesity, check BP & random blood sugar (RBS), advise symptomatic patients and perform VIA screening and follow up. Primary Health Centre (without MD) - blood biochemistry, lipid profile, monitoring BP, conducting VIA screening, CBE and OVE and HPV vaccination. Primary Health Centre (with MD) - treatment of uncomplicated hypertension, diabetes, heart disease, cryotherapy, follow up and palliative care. At the District Hospital - emergency management, specialized treatment, surgical and/or gynaecological consultation, colposcopy / treatment, pathology investigations and referral to tertiary care hospital.

Sharmila Pimple

Integrated Common cancer control Programme

Tata Memorial Centre, Mumbai has a rural outreach programme for evidence based study on cervical cancer screening by VIA, clinical breast examination for breast screening and oral visual inspection for tobacco users and alcohol users. Based on our experience from there, an integrated model under NRHM was developed for Ratnagiri and Sindhudurg districts in Maharashtra for population-based screening of Oral, Cervix and Breast Cancer. Planning is done at *Tehsil* level with health awareness and household survey, registration and documentation. The integrated programme includes 1,526 villages in Ratnagiri district and 742 villages in Sindhudurg district. Training will be conducted for District Medical Officers, District Program Officer (NCD, NRHM), Taluka Health Officer (THO), Medical and Para Medical Staff recruited under the NCD at District Hospital, Sub district hospital and Rural hospitals and Medical and Para Medical Staff at Primary Health Centre (PHC) and Sub Centre (SC). Cancer control programme activities will be rolled out *Tehsil*-wise. *Tehsil/Taluka* level training will include personnel from community health centres (CHCs), primary health centres (PHCs) and sub-centres (SCs). At the Sub Centre, cancer education will be provided to the people along with organized screening or opportunistic screening for Oral, Breast and Cervical cancers and data recording and reporting. At the Primary Health Centre (PHC) also similar services will be provided in addition to generating referral list for CHC/District NCD cell. At CHCs (NCD cell) Colposcopy, Biopsy, FNAC, Pap cytology and cryotherapy will be provided in addition to basic services of cancer education and screening of oral, breast and cervical cancers. The NCD Clinic

at District hospital will provide colposcopy, biopsy, FNAC, Pap cytology, nipple discharge cytology, HPV Testing and mammography. Treatment of pre-cancers of cervical and oral cancers will also be undertaken and difficult cases will be referred to tertiary care centres.

R Sankaranarayanan

Rationale for Pragmatic HPV vaccination and screening in North East India

India is a major contributor to cervical cancer and we are lagging behind in controlling a preventable cancer. Socio-economic development and women's empowerment are important factors for its reduction but beyond a limit, interventions like HPV vaccination and screening, early diagnosis and treatment are needed to comprehensively control cervical cancer. With these interventions, the elimination of cervical cancer can be possible. HPV vaccination has been introduced as part of National Immunization Programmes (NIP) in 66 countries. Australia, UK, USA and Canada were among the first countries to implement HPV vaccination. In Europe, the countries implementing HPV vaccination as part of NIP rose from 3 in 2007 to 22 in 2012. In LMIC, Bhutan, Panama and Rwanda were among the first to implement HPV vaccination in NIP. Europe and Africa are far ahead of Asian countries which are lagging behind in introducing HPV vaccination. In Asia only 8 countries: Bhutan, Brunei Darussalam, Israel, Japan, Lao People's Democratic Republic, Malaysia, UAE and Uzbekistan have introduced vaccination programme as a part of NIP. GAVI is indeed the major stimulator in introducing vaccination in LMIC. Taking example of Bhutan where HPV vaccination was started as pilot phase in 2009. It was school based and 94% coverage was achieved. The programme was scaled up from 2010, when school going 47,888 girls 12-18 year old eligible, 96% coverage of 3rd dose was recorded; health clinics based delivery to 12 year olds (2012-13) (3rd dose coverage 69%) and School based delivery (2014), 90% 3rd dose coverage was achieved. The Bhutan HPV vaccine programme is a model for other developing countries that aspire to implement national HPV vaccination programmes. Another example from Asia is that of Malaysia where due mainly to government's strong commitment the vaccination programme is going on achieving 94.33% coverage of 11-13 years old girls despite having an anti-vaccine lobby. In 2014 SAGE (WHO) recommended 2-dose vaccination with 6-months or 1-year gap between the two doses when vaccination is initiated prior to 15 years of age and a 3-dose schedule if initiated after 15th

birthday. The 3-dose schedule is also recommended for immune-compromised individuals, including HIV infected persons. In India, from our study, the frequency of persistent HPV 16 and 18 infections in 3, 2 and 1-dose (by default), no incident infection was observed. Similar results have been reported from Costa Rica. Therefore, several countries such as Canada, Chile, Colombia, Ireland, Mexico, South Africa, Switzerland and UK are now implementing a 2-dose vaccination regime. In addition to vaccination, screening is an important intervention to control cervical cancer. There are several efficient tools for screening such as Cervical Cytology, Visual Inspection with acetic acid/visual inspection with Lugol's iodine (VIA/VILI) and HPV-DNA testing. The most critical challenges for success of cervical cancer screening are the quality assurance and the link with diagnosis and treatment. An important example in India is that of Tamil Nadu state where due to government's commitment they have been able to screen more than half a million women i.e., 54% of the eligible women in two years. Bangladesh is another example where cervical screening has been going on at national level. Thus a pragmatic approach with strong policy with good investment and advocacy is needed to control cervical cancer.

Scientific Session - 4

Panel Discussion & Recommendations

K. Lalpiakzuala Govt. of Mizoram, Aizawl
Srabani Mittal Cancer Foundation of India, Kolkata
Goter Doke Govt. of Arunachal Pradesh, Itanagar
Rinzing Dorjee Govt. of Sikkim, Gangtok
Sutapa Biswas Cancer Foundation of India, Kolkata

MODERATOR : **Radhika Srinivasan** PGIMER, Chandigarh

After brief and meaningful inputs from the panelists, the moderator invited comments from all participants on final recommendations. This led to an in-depth discussion lasting over 90 minutes on the feasibility of various recommendations for primary and secondary prevention of cervical cancer in India. The discussion was based on scientific evidence, real situation experience and keeping the public health system in view. The proposed recommendations were recorded and are being presented in the following pages. Participants from several Northeastern states and West Bengal were highly enthusiastic and actively took part in the discussion. Sikkim has already started cervical cancer screening under state-wide Chief Minister's Comprehensive Annual and Total Check-up for Healthy Sikkim (CATCH) programme and hoping to take up vaccination soon whereas Tamil Nadu Health Systems Project (TNHSP) on NCDs started cervical cancer screening in 2012.

It was agreed that cervical screening initiatives in states should be a part of NCD control under NPCDCS programme of National Health Mission, whereas HPV vaccination can either be included in the proposed adolescent vaccination programme or remain part of NPCDCS programme if it is logistically found feasible.

Recommendations for a Comprehensive Cervical Cancer Prevention and Control Programme

It is well known that cervical cancer develops gradually and has a long detectable pre-cancer condition that can be treated successfully with proper intervention. In order to achieve this, however, a planned awareness and education campaign in the community followed by the availability of screening facilities are necessary. The identification of certain types of HPVs as etiological risk factors for cervical cancer which led to the development of prophylactic vaccines against specific sets of HPV genotypes. Thus another feasible opportunity to reduce cervical cancer burden through primary prevention of HPV infection has emerged. Therefore, HPV Vaccination of 9-13 yr old girls along with population-based screening of 30 plus women using VIA or HPV-DNA detection method is the most practical way to prevent and control cervical cancer.

Overarching Recommendations

- ◆ A holistic approach for improvement of women's health is needed which can be promoted through the National Health Mission – particularly through the NPCDCS and adolescent health programmes, e.g. *Rashtriya Kishore Swasthya Karyakram* (RKSK).
- ◆ A situation analysis to assess resource availability, needs and cost of CCPC is an essential first step in programme planning.
- ◆ CCPC programme should be piloted in a couple of districts embedded in the public health system of the state and then scaled up based on lessons learnt.
- ◆ Effective linkages between screening, early detection, diagnosis and treatment must be established.

Recommendations on HPV Vaccination for Primary Prevention

It is now well established that cervical cancer and its precursor lesions are caused by persistent infection by one or more high-risk HPV types. As per recent data, the infection with HPV 16 and 18 accounts for over 80% cervical cancer cases in India. The identification of high-risk HPV types as etiological factors for cervical cancer has also led to the development of prophylactic vaccines against specific sets of HPV genotypes. Thus, HPV vaccination provides the most practical way to reduce cervical cancer burden through primary prevention of HPV infection.

- ◆ **Communication and Advocacy:** Robust advocacy with continuous and consistent evidence-based education focused on policy makers, health care providers and communities is needed. The role of print and electronic media (FM, Radio, TV) is paramount and should be made best use of.
- ◆ **Partnerships:** Engage with CSOs/NGOs and private sector; develop mechanisms for communication and community mobilization and its participation.
- ◆ **Models for vaccine delivery service:**
 - Efforts should be made to follow WHO recommendations of vaccinating 9-13 year old girls. A catch up campaign through outreach and health facility based delivery should be included.
 - Delivery points: School based delivery with support from the health care delivery system was deemed the most feasible approach. Vaccine delivery should be led by the existing health service manpower (PHC/CHC/DH) taking into account school schedule.
 - UIP includes TT, Rubella up to 15 years – or through Adolescent Vaccination Programme under Rashtriya Kishor Swasthya Karyakram (RKSK) - these are the opportunities for including HPV vaccine. HPV vaccination can be included in the immunization card.
- ◆ **Dosage:** The 3-dose regime as recommended. The WHO-SAGE recommendation of 2- dose regime can be followed after more data is available.
- ◆ **Procurement, logistics of supply and distribution:**
 - States' existing cold chain space will need to be expanded to accommodate HPV vaccination without compromising the existing programmes.
 - Availability of multi-dose vials should be negotiated to economize on cold chain space.
 - Procurement should be done as per government rules.

- ◆ **Financing:**
 - Mechanism such as GAVI and other funding sources can be pursued once a decision is taken by the state government for introduction of vaccination.
 - Support under Corporate Social Responsibility (CSR) and from Indian foundations should be explored once a robust policy is articulated by the state government. Other government schemes such as RKSK, Beti Bachao Beti Padhao (BBBP) Yojana may also be explored.
 - Utilization of NPCDCS funds should be examined.
 - Before starting the HPV vaccination programme a sustainability plan should be developed.
- ◆ **Training of Health Staff:** Vaccination by existing immunization staff along with additional staff under the programme must be adequately trained. NGOs with experience in HPV vaccination and follow up be associated with the programme.
- ◆ **Monitoring and Evaluation:** An internal M&E system should be established. Vaccine coverage should be monitored.
- ◆ **Consent:** An opt-out approach (as in Bhutan) may be followed. No Informed Consent is required for introducing HPV vaccination.
- ◆ **Impact analysis:** Population-based cancer registry should be strengthened /established to facilitate impact analysis data.

Recommendations on Cervical Cancer Screening for Secondary Prevention

A high incidence and mortality rates of cervical cancer in low and middle income countries is mainly due to a lack of organized population-based or opportunistic screening and early detection services. In the recent Guidelines on comprehensive cervical cancer control, the World Health Organization (WHO) strongly recommended the use of Visual Inspection after Acetic Acid application (VIA) as the primary screening test for cervical cancer in low and middle income countries (LMICs). To ensure strong linkage between screening and treatment WHO also recommended that the VIA positive women should be assessed immediately for suitability of treatment by ablative method, since colposcopy services are complex, expensive and need highly trained clinicians.

- ◆ **Logistics in public health system:** Situational analysis needed to identify existing resources (manpower, laboratory services, treatment, and infrastructure) and augmentation of equipment and manpower for management of cervical pre-cancers and cancer needed.

- ◆ **Target population:** Women 30-49 years for VIA as per WHO guidelines and 30-60 yrs with HPV DNA test.
- ◆ **Community mobilization and advocacy:** It is most important and an essential component of population-based cervical screening programme. Engagement of ASHAs at sub-centre, PHCs CHCs and District Hospitals. Involvement of NGOs, private sector and public- private partnership is recommended. The criteria of referral to upper level of healthcare system must be decided.
- ◆ **Modality of Screening:** Micro-planning for programme. Do opportunistic screening with population-based mobilization through ASHAs/CHW. Integrate with broader NCD screening and treatment package.

Screening Test:

- VIA may be the most feasible test at this point in time as recommended by WHO.
- However, infrastructure for high risk HPV-DNA testing (centralized testing center) should be developed. Issues such as testing platform should be examined. Primary screening with HPV-DNA testing is the most reproducible and sensitive approach since a highly sensitive test such as HPV detection needs less frequent screening and could save programme costs. Triage with cytology and/or referral to colposcopy at CHCs and District Hospitals/Medical Colleges is recommended.
- ◆ **Maintenance of Records:** Dedicated Health Information Management System should be developed to facilitate follow up and re-screening of screened women.
- ◆ **Training and quality assurance:** By NCD team and additional dedicated staff under NPCDCS programme. Comprehensive training of Nurses / CHW / Medical Officers by qualified gynaecologists is recommended under the public healthcare system.



Valediction

CHIEF GUEST

Kumar Bhandari DG cum Secretary
Department of Health Care, Human Services and Family
Welfare, Govt. of Sikkim, Gangtok

Ms. Sutapa Biswas, Executive Director of Cancer Foundation of India invited Dr. Kumar Bhandari to deliver his Valedictory address. Dr Bhandari expressed happiness on the high standard of the deliberations at the symposium. He appreciated the concern of CFI and the participants for prevention of cancers affecting women. He said that Sikkim is very concerned about cervical cancer in women and mentioned about the CATCH programme that has incorporated early detection of oral, breast, and cervical cancers. Since last year instructions have been given to all health facilities in the state to offer complete CATCH services in addition to such facilities being given through health camps. Dr Bhandari was appreciative that Sikkim was the part of IARC (WHO) trial on HPV vaccine. State of Sikkim he said is developing a comprehensive cancer prevention programme which would include health education, IEC activities, condom use, education to girls and boys, along with vaccination and screening of women. He expressed hope that the recommendations from this important meeting will be of great value in guiding NE states to start their cervical cancer prevention programmes. He said states are at liberty now to introduce HPV vaccination and eventually it would lead to a national programme. He assured Sikkim will start the vaccination programme but only after considering its financial sustainability. He also said that Sikkim is in the process of establishing a 1,000 bed hospital with a cancer division with linear accelerator and cobalt therapy facilities. He concluded by thanking the organizers for inviting him for the Valediction of the meeting.

Ms. Sutapa Biswas, Executive Director, CFI, then thanked all the participants, governments of NE states for nominating their representatives, the speakers and panelists and Dr. K. Bhandari for his gracious presence at the Valedictory function. She expressed hope that the minutes and recommendations of the meeting will soon be sent to the Health Departments of various states. The participants from NE states, she wished, would be able to encourage and motivate their respective governments in taking the lead in launching HPV vaccination and Screening programmes under NHM. She thanked Destination Holidays, Gurgaon, the travel partners, and the management and staff of Denzong Regency, Gangtok for their utmost cooperation. She also acknowledged the support received from donors and well wishers that made it possible for CFI to hold this meeting.

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Annexure I

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Annexure II



CFI's Role in Promoting Cervical Cancer Prevention

Maqsood Siddiqi

Chairman, Cancer Foundation of India, Kolkata

Cancer Foundation of India (CFI) from its inception has addressed cervical cancer prevention in a holistic manner encompassing a range of activities facilitating prevention and control of the disease. These include, cervical screening using VIA / VILI, cryotherapy treatment of early lesions, HPV epidemiology, HPV vaccination and training of doctors, nurses and social workers in cervical screening. In addition, CFI publishes manuals and information brochures on cervical screening and prepares innovatively designed communication material such as leaflets, posters, flipcharts and films, in English and various Indian languages. CFI also conducts multi-stakeholder's meetings and symposia providing a forum for exchange of new research information on cervical cancer prevention and control.

Cervical Cancer Screening

While serving community through education and awareness, cervical cancer screening has been the mainstay, advancement of knowledge, generation of new data and improvement and innovation of methods and techniques for cervical cancer prevention remain an important goal of our initiatives. A brief overview of CFI's screening projects is given below.

- ◆ A cross-sectional study on cervical cancer screening and intervention through cryotherapy in the treatment of histologically confirmed cervical intraepithelial neoplasia



(CIN) was conducted in three districts in the state of West Bengal (eastern India). The villages were located in Singur block of Hoogly district, Diamond Harbour, Sonarpur blocks in South 24 Parganas and Tamluk block in Midnapore district. Health workers were trained to perform cervical screening on women (25 to 59 years) using visual inspection with acetic acid (VIA) followed by visual inspection with Lugol's iodine (VILI). Colposcopy was performed only in VIA positive cases. The study screened a total of 3,051 women, on an average 100 women from each of the 30 villages attended the clinic for screening. Those found with histopathology proven CIN 1, 2 and 3 were subjected to cryotherapy as per the protocol of the study. The study provided the test characteristics of VIA and VILI done by trained health workers in detecting high grade cervical cancer precursors and also evaluated the efficacy of single- and double-freeze cryotherapy techniques in controlling different grades of cervical intraepithelial neoplasia (CIN).

◆ In another study, 2,834 eligible women (25-59 yrs) were screened using (VIA/VILI) in two separate locations in Nadia and South 24 Parganas districts of West Bengal. The main objective of the study was to sensitize the target women on cancer awareness using different modules of IEC in order to develop a model communication strategy to convince and motivate asymptomatic women to attend cervical cancer screening clinic. Women who were detected with early lesions or malignancy were provided appropriate treatment. In module A, women were directly told about the issues of cervical cancer prevention and need of undergoing screening as part of health check up. Whereas in Module B, the same information was staggered in 4 phases – general health issues, simple ailments which can become chronic on neglect, health and lifestyle issues of women and prevention of cervical cancer by screening. The



women were sensitized with the aid of leaflets, flip-charts, puppet film and interactive discussions. The study showed that flip charts are the most effective mode of communication. The results also showed that proper training of field-level communicators was the key to the success of cervical cancer screening programmes. Moreover, since screening is related to gynaecological issues it needs a sensitive approach to draw asymptomatic women to clinics for check up.

◆ Inhabitants of several districts in West Bengal, state of India, are facing severe Arsenic contamination of groundwater. Several studies have reported pre-clinical and clinical manifestations among the inhabitants of arsenic endemic districts. It is also well established globally that arsenic-induced early clinical manifestations if left unattended, present a high risk of cancers of various internal organs (lung, liver and bladder) and skin. However, so far there are no reports of arsenic-induced cervical cancer from anywhere worldwide. Taking lead from hospital records in Kolkata showing increased number of patients from arsenic endemic districts, it was considered necessary to investigate the role of arsenic in increasing the risk of cervical cancer among chronically exposed women. Therefore, cervical screening using VIA method was conducted on 1,435 eligible women from villages in Nadia district with high arsenic content in ground water (100-300 $\mu\text{g/l}$) and the prevalence of high grade HPV infection (HC2 method) in VIA positive women was compared with 1,286 women living in low arsenic villages in South 24 Parganas (<25 $\mu\text{g/l}$). Preliminary data indicate that women who are chronically exposed to high levels of arsenic through ground water may have a higher risk of pre-malignant cervical lesions and high grade HPV infections compared to those living in low arsenic areas. It is a continuing study to test the hypothesis.



HPV Epidemiology

◆ In order to determine HPV genotype distribution in cervical cancers from different regions in India, a total of 278 cervical cancer cases were enrolled from various cancer centers (New Delhi, Kolkata, Nagpur and Bangalore). Cervical biopsy specimens taken prior to treatment were tested for HPV DNA using the MY09/11 L1 consensus PCR method followed by sequencing for genotyping, as well as for HPV mRNA utilizing the PreTect™ HPV-Proofer assay. The study showed that HPV DNA and/or mRNA were detected in 91.7% of the cases. HPV genotype 16 and 18 alone or in co-infection with each other were detected in 76.3% cases. Genotype 33 was the third most common type. Overall, genotypes 16, 18, 31, 33, and 45 were the five most common types, detected in 87.1% of the total cases. There were no significant regional differences. Thus, the study showed that the currently available HPV prophylactic vaccines targeting types 16 and 18 have the potential to reduce the burden of cervical cancer in India by over 75%.

◆ In another multi-centric collaborative study in which CFI participated, the HPV genotypes and their L1 and E6 variants from 667 histopathology confirmed cervical cancer biopsy samples were collected from north, south, west, east and north-eastern states of India. Infection with single High Risk (HR) type was seen in 86.8%; predominant types being HPV-16 followed by HPV-18, and 45. Human papillomavirus type 16/18-positive fraction formed 79.6%; other types comprised 12.4%. Thus, the results corroborated with our earlier study showing that the prophylactic HPV-16/18-L1 vaccines would provide greater than 75% protection against Squamous Cell Carcinoma (SCC) in India. The objective of this multicenter study was also to identify HPV-16 E6, E7 and L1 variants prevalent in India and their possible



biological effects. Similar distribution of the variants was seen from different regions in the country, with the European variant E350G being the most prevalent (58%), followed by the American Asian variant (11.4%).

HPV Vaccination

◆ In a nation-wide ongoing multicenter study led by Dr. R. Sankaranarayanan of IARC (Lyon, France) in which Cancer Foundation of India (CFI) is one of the 8 collaborating centres, the main objective is to prevent cervical cancer through a sustained HPV vaccination programme and to examine if the prescribed 3-dose regime can be reduced to a 2-dose. CFI started the proposed study as per approved protocol in selected districts in Mizoram and Sikkim, states of India, in January 2010, in partnership with state government health services and local collaborators. The study design was of a cluster-randomized clinical trial, the randomization unit being villages. The eligible participants were 1,000 healthy, ambulant, unmarried girls aged 10-18 years residing in the selected villages. The villages were randomly allocated to one of the two groups to receive vaccine. Group 1: 500 eligible girls received 2 doses and in Group 2: 500 girls received 3 doses of quadrivalent HPV vaccine targeting HPV 16, 18, 6, 11 types. Blood was collected at 1 month after the last dose and after 18 months from dose-1 from all girls and from a smaller cohort of the girls on baseline and at yearly interval to evaluate sero-conversion and serum HPV 16 and 18 antibody titres. All vaccinated girls are being followed up for 5 years after the last dose of vaccine, to document outcomes and/or adverse events. Preliminary unpublished results show that the immune response in the 2-dose group was non-inferior to that of the 3-dose group and cervical cell samples showed no persistent HPV 16 and 18 infections in any of the study groups.



Human Resource Development

India is in a transition from its emphasis on creating cancer treatment facilities to recognizing the importance of prevention and control of the disease. Until very recently there were no organized screening programmes in the country. One of the major factors, beside financial constraints, for the absence of organized cervical cancer screening remains the unavailability of trained manpower in cancer public health. Cancer Foundation of India, therefore, considered it necessary to organize workshops comprising of lectures, group discussions and hands-on practice sessions so that the participants can learn simple and low cost methods of identification of early lesions of cervical cancer which invariably go undetected and undiagnosed due to lack of proper knowledge and training.

Workshops in Northeastern States

The main objective of the workshops was, therefore, to provide hands-on training in the methods and techniques of identifying early lesions of cervical cancer to in-service Medical Officers, Nurses and Health Workers posted in District Hospitals, private hospitals and Medical Colleges. These workshops were conducted at Gangtok (2005), Guwahati (2006), Aizawl (2007) and Shillong (2009) where more than 150 participants drawn from the States of Assam, Arunachal Pradesh, Meghalaya, Mizoram, Manipur, Nagaland, Sikkim, Tripura, and from Darjeeling, District of West Bengal, were trained. This manpower resource is still available to these states which can be utilized in the recently started NPCDCS programmes.

Symposium on Cervical Cancer Prevention

- ◆ CFI organized a National Symposium on Cervical Cancer Control in India at Kolkata



on December 4, 2009. It was attended by almost all the clinical groups working on cervical cancer screening in the country - past and present, along with over 120 stakeholders in the field of cervical cancer prevention and control such as oncologists, scientists, policy makers, health providers, community workers and students from India and abroad. The keynote address was delivered by Nobel Laureate in Medicine, 2008, Professor Harald zur Hausen of German Cancer Research Centre, Heidelberg, on "Papillomaviruses in human cancers: from basic research to preventive vaccines". The Symposium outlined the current advancements in cervical cancer control in India along with the recommendations on future course of action.

Symposia on HPV Vaccination

◆ HPV vaccines were licensed in India in 2008 / 09. However, due to an untoward incidence in a demonstration project (post-licensure) in 2010, an inquiry committee was appointed by the government which while pointing out certain procedural deficiencies, gave a positive report on the safety of the vaccine. Notwithstanding the report, and overwhelming scientific data in favour of safety and efficacy of the vaccine, the media continued its tirade against the vaccine creating doubts and misgivings in the minds of the parents of girls and medical practitioners with regard to the safety of the vaccine as such. The meaningless controversy also led to a noticeable reluctance among policy makers to introduce HPV vaccine in public health care system - even when 120 countries had licensed the vaccine and 66 countries included it in their national immunisation programme.

In this scenario, Cancer Foundation of India, fully committed to prevention of cervical cancer in the country, decided to conduct 3 symposia in 2014 at Gangtok in Sikkim, New Delhi and Chennai in Tamil Nadu, placing the latest results on HPV vaccine emerging from world-wide



trials before the participants which were mainly policy makers and those who may indirectly influence country's health policy. The Symposia were inaugurated by eminent persons like Dr. K.Bhandari, Secretary Health, Govt. of Sikkim (Gangtok), Dr. Jagadish Prasad, Director General of Health Services, Govt. of India (New Delhi) and Dr. V. Shanta, Chairperson of Cancer Institute (WIA) in Chennai. The symposia succeeded in forcefully placing the view before the participating policy makers that HPV vaccination provides the possibility to reduce cervical cancer burden through primary prevention of HPV infection and thus its relevance in Indian context cannot be overemphasized.

Foundation Lecture

◆ In our endeavor to motivate and expand the participation of civil society in the advancement of the knowledge-base of cancer prevention, control and treatment in the country, CFI organizes Biennial Foundation Lectures. These are public lectures delivered by persons of eminence who have distinguished themselves in various fields of human endeavour impacting the cause of alleviation of human suffering from cancer.

The First Foundation Lecture was delivered on 3rd December 2009 by Professor Harald zur Hausen of German Cancer Research Centre (DKFZ), Heidelberg, Germany who was awarded Nobel Prize in Medicine, 2008, for the discovery of Human papilloma viruses. He spoke on "*The search for infectious agents in human cancers: a continuous challenge*". This being his first lecture in India after receiving the Noble Prize, a large number of medical scientists had come from all over the country to attend his lecture.



Books and Manuals

PRE-FIELD TESTING OF C4-GEP

◆ The Pre-field testing of the draft version of “Comprehensive Cervical Cancer Control – A Guide to Essential Practice (C4-GEP)” prepared by Department of Reproductive Health and Research (RHR), World Health Organisation (WHO), Geneva, was conducted by CFI in its capacity as country coordinator for India in 2005. The basic objective was to obtain feedback on the suitability of its technical format for use as perceived by stakeholders in a chosen country. This was assessed through a desk review by invited participants using a standardized questionnaire of RHR, followed by Focused Group Discussions (FGDs) involving Community Health Workers, Health Policy makers and Healthcare Providers dealing with tertiary care treatment services.

MANUAL ON VIA FOR CERVICAL NEOPLASIA IN BENGALI

◆ One of the major handicaps of expanding the reach of cervical cancer screening programmes is lack of proper training material in cervical pathology and early detection of cervical cancer for para-medical staff. The Community Health Workers or ANMs in the country, who are vital to any cancer screening initiative, are generally educated only up to secondary school level where the medium of instruction is vernacular language of their region and not English. This places the para-medics at a disadvantage in their efforts to learn the methods and procedures from instruction manuals mainly written for English knowing readers. Therefore, there has been a long felt need of a comprehensive and well illustrated Handbook or Manual in vernacular languages on methods and procedures for cervical screening programmes in different states in India for social workers, community health workers or ANMs involved in



such work.

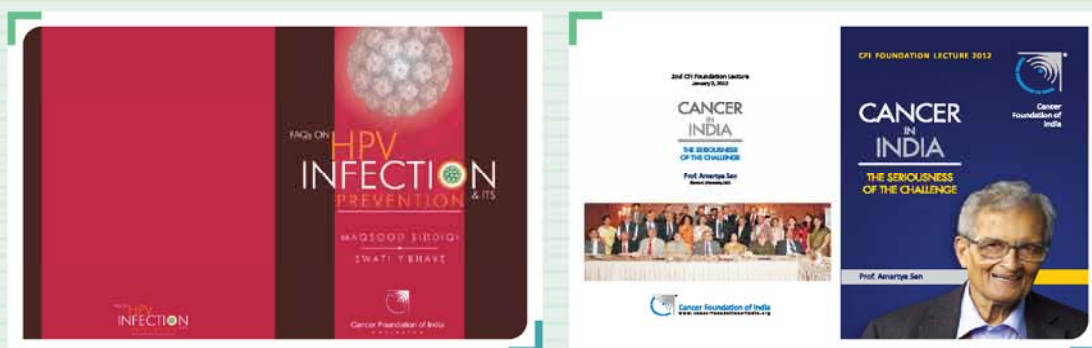
Bangla (Bengali) is the most widely spoken, read and understood language in eastern India and Bangladesh. Therefore “A Practical Manual on Visual Screening for Cervical Neoplasia” by R.Sankaranarayanan and R.S.Wesley (IARC Technical Publication No. 41) was translated into Bengali by CFI to facilitate cervical screening programmes in Bengali speaking populations in South Asia. The Manual is highly popular both in India and Bangladesh among field workers involved in cervical cancer screening programmes.

FAQs ON HPV INFECTION & ITS PREVENTION

◆ Two prophylactic HPV vaccines were licensed and introduced in the Indian market in 2008 and 2009. But soon after, due to an untoward happening a media tirade against the vaccine started. Although there was no ban on the sale or use of vaccine, doctors were reluctant and parents of girls became apprehensive about the safety of the vaccine. In order to properly educate the medical fraternity and people in general, the CFI considered it prudent to publish a booklet “FAQs on HPV Infection & its Prevention” in collaboration with Association of Adolescent and Child Care in India. The Publication was released by Professor Harald zur Hausen during his visit to CFI in December 2009. The booklet became quite popular and so far 20,000 copies have been printed and distributed in public interest to medical practitioners and others interested in HPV vaccination.

CANCER IN INDIA: THE SERIOUSNESS OF THE CHALLENGE

◆ The Biennial Foundation Lectures are public lectures organized by CFI which are delivered by persons of high eminence and scholarship whose work impacts on our fight



against cancer. The 2nd Foundation Lecture was delivered by Bharat Ratna Professor Amartya Sen, Nobel Laureate in Economics 2002, of Harvard University, Cambridge, USA, on 2nd January 2012. Professor Sen, himself a cancer survivor has worked extensively on health economics, permitted his lecture to be published as a book by CFI entitled “*Cancer in India: The Seriousness of the Challenge*”. The book outlines for the first time Professor Sen's views on economic, psychological and gender issues associated with the social epidemiology of cancer in India.

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Cancer Foundation of India (CFI), Kolkata is a voluntary organization (NGO) dedicated to cancer prevention and control in the country.

The Foundation has 4 focal themes which include (i) **Cancer Communication**, to disseminate authentic information on cancer risk factors and their prevention by developing new communication strategies and advocacy methods. (ii) **R & D in Cancer Prevention & Control**, on topics of critical interest to the country such as epidemiology, lifestyle associated risk factors, chemoprevention, cancer vaccines, early detection methods and tests. (iii) **Development of Human Resource**, in cancer prevention and control by holding workshops, training programs, seminar/symposia/conference and capacity building of medical and paramedical professionals, and (iv) **Patient Service & Support**, by providing clinical and psychosocial support services to cancer survivors.

CFI has received grant in aid for its projects from national and international health research support agencies such as IARC (WHO), Lyon, WHO, Geneva, American Cancer Society, USA, Bloomberg Initiative, USA, Department of Science & Technology (DST) and Department of Biotechnology (DBT), Ministry of Science & Technology, and Indian Council of Medical Research (ICMR), Min. of Health Research, Govt. of India. CFI is recognized as a Scientific and Industrial Research Organization (SIRO) by DSIR, Ministry of Science & Technology, Government of India for R&D work in cancer.

CFI is supported by a large number of clinicians, scientists, social workers and health care volunteers committed to a holistic approach to cancer control in the country. CFI's Management Committee is headed by its founder Prof (Dr) Maqsood Siddiqi, former Director of Chittaranjan National Cancer Institute and later that of Bose Institute in Kolkata. Ms. Sutapa Biswas is the Secretary & Executive Director of the organisation.

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