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Chapter 1


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1. Introduction

1.1. For timely actions and targeted achievements—The clock ticks now

I had the privilege of reading and revising all the chapters in this book. The authors have opened up a sea of information. It is time for the Healthcare planners and providers to act now. My introductory review chapter helps in this. To sail the uncharted sea of human papillomavirus (HPV)-related diseases and prevention, we need a compass. I am pleased to provide a guiding model, in the form of a clock, which will help us to move from time to time, with specific agenda, keeping the community needs and available resources in mind. This model is universal and can be followed in any country for targeted health care services. All the research work written in this book by the eminent authors can be placed in a relevant position in this clock and the readers can pursue their research, revolving around the cycle, which will benefit the science and the society, as the two arms of the clock.

1.2. The 12’ O clock: AREA

It is imperative to have a defined geographical area and a resident population. The area could be of a relevant size with its own characteristics, such as rural, urban, hills, mountains, seashore, deserts, valleys, disaster prone, and others. Each of these will have typical populations which also differ in socioeconomic, cultural, and health standards, and all these are essential for our health programs as the types of interventions planned for need to be tailored accordingly.
1.3. The 1’ O clock: ENUMERATE

This population should be enumerated meticulously and methodologically. All the socio, demographic, and health data should be inferred, and this will provide us the denominator for all types of epidemiological studies, both observational and experimental.

The enumeration needs to be undertaken in a sustainable method using volunteers residing in the same region which will facilitate all the follow-up measures.

1.4. The 2’ O clock: INFERENCE

From the health data collected, we can analyze the health problems, their magnitude, and other related factors. HPV infections and diseases will have the data regarding risk factors, causal associations and early signs, and symptoms. Especially the factors regarding menstrual and sexual hygiene, knowledge, attitude, and practice regarding HPV infections can also be studied. This will form the basis for further interventions.

1.5. The 3’ O clock: EDUCATION

Education is one such important intervention, and this should be highly focused, organized, and the process has to be measured by input and outcome analysis. Based on the impact of our health education, the next step is planned for.

1.6. The 4’ O clock: INVITATION

The invitation is targeted and individualized, based on the outcome of previous data regarding, knowledge, attitude, practice studies, and effect of the tailored health education process

1.7. The 5’ O clock: COUNSELLING

This very important intervention should be carefully undertaken by well trained personnel who would brief to the individuals, all the interventions and outcomes and obtain informed consent. The community/study subjects would then be sincere to the interventions, which will reduce the dropout rates, attrition, and noncompliance. The unwarranted litigations would be prevented and human rights would be ensured. Usually, in public health programs, the aspect of effective counseling is neglected or overlooked.

1.8. The 6’ O clock: SCREENING

Most of the studies begin directly from this 6’O clock position thus bypassing the previous five steps and hence, might lack community compliance and success. Validity and reliability are the important characteristics of the screening tools which should also fulfill the A 6 model mentioned below. All screening programs are to be equipped to treat the disease outcome status, as otherwise people will lose faith in the screening measures. This bounds to happen in HPV screening and hence treatment of HPV positive/precancer lesions of uterine cervix is an example of offering screening outcome facilities.
1.9. The 7’ O clock: PATTERNS

All the disease patterns which are observed as outcome of the screening process, need to be well documented and adequately addressed. For example, HPV negative women should be entered in a population based “registry” and followed up for periodical checkups, HPV positive are to be advised for visual inspection acetic acid (VIA)/colposcopy/biopsy, and development of precancers, if precancer lesions develop they are to be promptly treated, and also if invasive stages are found they have to be referred to higher centers for treatment.

1.10. The 8’ O clock: CONFIRMATION

In case of HPV screening in cervical cancer screening programs, the confirmation of the precancer/cancer disease status in HPV positive cases should be done by colposcopy directed biopsy and this is called as evidence-based practice. Also it is very important to prove the disease status during follow-up, and later to declare reduction in incidence as the success of interventions.

1.11. The 9’ O clock: TREATMENT

Most of the cervical cancer screening programs, especially in the resource limited settings, are not able to offer treatment for precancer lesions. The “see and treat” policy programs are able to overcome this constraint by offering cryotherapy/loop electro excision procedure (LEEP) services, under one roof, in the same sitting. The services are usually provided by specially trained nurses and doctors. This ensures prevention of the development of precancers in to invasive cancers and is an important outcome measure of screening programs.

1.12. The 10’O clock: FOLLOW-UP

Meticulous follow-up, both socially and medically, earns good reputation for the intervention programs and will provide histopathological evidence of the disease status in the study population. Only with a stable and resident population, long-term follow-up is possible, and we can arrive at intermediate and terminal epidemiological indicators such as the incidence rate and prevalence rate.

1.13. The 11’ O clock: MONITORING, EVALUATION, AND REPLAN

Periodical and continuous monitoring is essential for the appropriate management of the resources. Initial, concurrent, and terminal evaluations done be internal and external quality assurance teams are vital for the programs to achieve their objectives. The lessons thus learned by the program managers, lead to modifications, restructuring, and redefining the targets and replan the next intervention for better cost–benefit and cost effectiveness, and focus further for achievement of our mission and vision.

1.14. Community-based 12 O’ clock model

1. AREA—define a geographic area for your study/services
2. ENUMERATE— the resident population, document the sociodemographic data
3. INFRINGEMENT— prevalence of HPV-related diseases—Establish REGISTRIES
4. EDUCATION— about prevention at individual, family, and community levels
5. INVITATION— to attend awareness programs, screening, and vaccination
6. COUNSELLING— the participants about possible outcomes and solutions
7. SCREENING— Acceptable, Available, Accessible, Affordable, Answerable, Achievable — the A-6 model for screening and vaccination programs
8. PATTERNS— of diseases detected in screening— Disclosure of results— individualized, ensure confidentiality and offer solution for health problems
9. CONFIRMATION— diagnosis— at screening and follow up stages
10. TREATMENT— of the HPV infections and related diseases, pre cancer lesions and ensure the availability of post-treatment services
11. FOLLOW-UP— by confirmation of disease free status, counseling, and referrals to the Government/Private health systems
12. MONITORING, EVALUATION, REPLAN— Effectiveness of interventions, Health Economics and advocating prevention policies.

Figure 1. Community-based 12 O’clock model.
2. The community-based HPV and related diseases prevention model

2.1. The Raj’s CANCER CONTROL CLOCK®

2.1.1. Dedication

This chapter is dedicated to the healthcare planners and providers, serving in various parts of the world in different levels of resources, diverse communities, and varied cultures. The editor presents his grass-root level practical experiences in a remote corner of rural India. If this could inspire others to take up challenges and serve for the underserved and reach the unreached and offer dedicated services for the prevention and control of HPV infections and related diseases, the mission of the Intech publishers, their team along with the inputs from the editor and valuable contributions from various authors, would be achieved.

2.1.2. Implementation of a large-scale cervical cancer screening and HPV study program in India: The challenges and solutions

The editor narrates the experiences which are riddled with various constraints and challenges. Poverty, illiteracy, ignorance, conservative women community, inaccessible terrains, no gynecologists, no pathologists, and no electricity were some of the challenges, when the editor initiated the Cervical Cancer Screening Programs and HPV surveys, during 1996–2007. To overcome the challenges, women self-help groups (SHGs) were started, cottage industries, farming, dairying, provided small income, and evening classes were conducted to educate women and several role-plays, skits, street plays, drama, and puppet shows were organized for health education, and we walked our way through where there were no roads, in the hills, valleys, and mountains. As there was no electricity, we took portable generators run with kerosene oil. The nurses were trained, and they provided diagnostic and therapeutic services under the supervision of junior doctors.

The village communities were met and local health volunteers were selected and trained. These volunteers were very influential in the community and were able to motivate large number of women for the screening camps.

The local women were much resistant to enter the mobile health clinics, usually set up in big vans or bus. The women feared stigma attached to gynecological examinations and were not comfortable with unfamiliar environment. Hence we set up health clinics in the community friendly areas, such as schools, ration shops, and local government buildings, to which the people were accustomed to.

The healthcare providers, at first-level contact, were the public health nurses, who are usually the local girls who have completed high school level and trained for couple of years in primary health care and midwifery. Hence the women were comfortable in seeking medical help from these nurses who also did the screening, for HPV and cervical cancer. The screening tool was VIA, which was not very expensive. The positive cases underwent colposcopy and directed biopsy, but were treated in the same sitting by cryotherapy.
The earlier step was the HPV prevalence survey in which the cervical cell samples were collected by cyto-brush and sent to designated laboratories for HPV study.

The editor, thus advocates the 6 “A” s strategy for the success of cervical cancer screening camps in limited resource settings. The strategy is explained as follows:

Acceptable: Screening was done by the public health nurses, from the local community. The screening camps were held in local buildings, not strange to the community. The screening procedure was not complicated and not painful. The treatment of precancers was cryotherapy, done in the same sitting and the procedure was painless.

Available: The manpower—nurses were always available for the community health needs.

Accessible: The screening and treatment centers were in the same locality and no need of travel, especially in the scorching sun, heavy rains, and on bad roads.

Affordable: The screening tool was VIA, and treatment was cryotherapy, which were not of high cost and affordable by the healthcare systems, providers, and beneficiaries.

Answerable: This is a symbiotic responsibility. The healthcare providers and beneficiaries are holding equal stake in the health programs. They are to understand each other and are answerable to all the inputs and outputs of the screening and treatment programs.

Achievable: It is essential to show that the objectives of the health programs are achievable, and the community should know that their expectations in attending the screening and treatment programs would be fulfilled. Thus the A-6 model ensures the success for screening, and it can be followed for HPV vaccination programs.

### 2.1.3. The experiences are the sources of inspiration

The editor was the principal investigator for initiating the First Population-Based Cancer Registry, in Tamil Nadu, south India, during 1996, in collaboration with the International Agency for Research on Cancer—IARC/WHO. The registry inferred that cervical cancer was very high among the rural women. A community-based screening program for cervical cancer was started in 2001 in collaboration with IARC/WHO. The program used VIA as the screening tool. The village health nurses offered the screening and precancer treatment services. In a period of about 3 years more than 30,000 women were screened, about 10% of the women were screen positive, and the disease was confirmed by colposcopy directed biopsy. Precancer lesions were treated by Cryotherapy/LEEP.

A 5-year follow-up of the treated women proved that the women treated for precancer lesions did not develop invasive cancers. The incidence rate for cervical cancer was brought down by 25% and mortality due to cervical cancer was reduced by 35%. Thus, it was proved that screening, early diagnosis, and prompt treatment of precancers will bring down the HPV associated cervical cancer. The editor emphasizes this strategy for developing and underdeveloped countries.

HPV prevalence studies were also undertaken, by the editor, in collaboration with IARC/WHO, for the first time in south India, during 2005, which revealed that about 14% of the
women were HPV positive. They were infected with multiple strains, and the infection rate was persistent among all age groups, suggesting low clearance of the viral infection and repeated infections.

3. Conclusion

The readers are welcome to read the publications of the editor enumerated in the references, and also to contact the editor, for more details and possible collaborations, to address the important problem of HPV and related diseases. The editor had the privilege of serving all the above programs as principal investigator and as his personal opinion, he recommends simple models, as illustrated above, for the prevention and control of HPV infections and cervical cancer. Hope that these suggestions would specially inspire grassroot-level health workers, in resource-limited settings, to initiate community-based programs for the prevention and control of HPV infections in general and cervical cancer in particular.

RECOMMENDATION

The editor / author endorses the following recommendation to all researchers in the medical domain. It is the "QUEEN concept of Raj, in Research". (copyright Dr.R Rajkumar)

Q = Question - the research question and its validity, thus avoiding bias
U = Use - of research findings to the universal benefit for community.
E = Effectiveness - whether the findings are scientifically and socially acceptable and effective
E = Extrapolate - we should be able to extrapolate the findings of research,
N = New - what are the unique, novel, innovative findings, and their applications, implications

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