



SECTION OF EARLY DETECTION AND PREVENTION (EDP)

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PREVENTION AND EARLY DETECTION, INCLUDING INTERVENTIONS TO REDUCE EXPOSURE, SCREENING, AND EARLY DIAGNOSIS, CAN DECREASE CANCER INCIDENCE AND MORTALITY AND IMPROVE QUALITY OF LIFE. UNTIL MARCH 2015, THE SECTION OF EARLY DETECTION AND PREVENTION (EDP) WAS COMPOSED OF THREE GROUPS: THE PREVENTION AND IMPLEMENTATION GROUP (PRI), THE QUALITY ASSURANCE GROUP (QAS), AND THE SCREENING GROUP (SCR). THE SECTION WAS SUBSEQUENTLY RESTRUCTURED AND NOW CONSISTS OF ONLY TWO GROUPS: PRI AND SCR. THE ACTIVITIES OF QAS DURING THE 2014–2015 BIENNIUM ARE REPORTED HERE UNDER SCR.

EDP carries out research on resource-appropriate public health policies and feasible, quality-assured, and cost-effective prevention and early detection strategies for the control of common cancers such as breast, cervical, colorectal, oral, oesophageal, and stomach cancer globally, with an emphasis on low- and middle-income countries (LMICs). Prevention offers the most cost-effective long-term strategy for cancer control. The Section's main focus areas in primary prevention are the development and implementation of safe, effective, and affordable vaccination schemes for human papillomavirus (HPV)-related cancers and the evaluation of the impact of *Helicobacter pylori* eradication on stomach cancer. The major focuses of EDP's early detection research are assessing new technologies and alternative screening approaches, as well as the impact of improved awareness and access to health services for the early detection of major cancers such as breast, cervical, oral, and colorectal cancer.

The Section designs and conducts research studies in collaboration with investigators in national cancer organizations, health services, universities, and other key groups within and outside the Agency. EDP works closely with other international organizations to develop, implement, and promote effective strategies for preventing and controlling cancer in the context of national cancer control programmes. In the Section's studies, there is a continuing emphasis on developing training resources, augmenting capacity for cancer prevention and early detection initiatives, and scaling up of prevention and early detection services within local health systems. The establishment of cancer research networks in LMICs to exchange experiences and enhance the local capacity is among EDP's priorities. The Section continues to expand its activities to implementation research, to support the efforts of national health systems to translate scientific findings into the well-being of the population.

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The Prevention and Implementation Group (PRI) investigates cancer epidemiology and prevention with a focus on human papillomavirus (HPV) vaccines, *Helicobacter pylori* eradication for gastric cancer prevention, triage methods for HPV-positive women, and the promotion and evaluation of cervical cancer control programmes. Recently, PRI began to include implementation research objectives in ongoing projects and national implementation activities.

CERVICAL CANCER STUDIES IN GUANACASTE, COSTA RICA

The Costa Rica Vaccine Trial (CVT) recruited approximately 7500 women aged 18–25 years into a randomized trial of bivalent HPV vaccine (HPV 16/18). The final results confirmed efficacy of the vaccine against HPV 16/18-related lesions and those related to other HPV types. Follow-up is continuing, and after cross-over vaccination, a new unvaccinated control group was recruited for long-term assessment of vaccine efficacy and safety (Gonzalez et al., 2015; Panagiotou et al., 2015). A combined analysis confirmed protective efficacy regardless of the number of doses (Kreimer et al., 2015a). Plans are under way for a randomized trial of one versus two doses of the bivalent and nonavalent vaccines. The efficacy of the vaccine to prevent vulvar HPV 16/18 infections was also evaluated (Lang Kuhs et al., 2014a).

MULTICENTRE STUDY OF HPV SCREENING AND TRIAGE (ESTAMPA)

The ESTAMPA study investigates emerging cervical cancer screening and triage techniques in Latin America. About 50 000 women aged 30–64 years will be screened with HPV testing; all HPV-positive women will be referred for colposcopy, biopsy, and treatment as needed, and recalled for a second screening after 18 months. The main outcome is advanced cancer precursors. The performance of visual, cytological, and molecular methods to identify HPV-positive women at higher risk of disease will be evaluated, contributing towards the establishment of organized screening in the region. The study began in Colombia, Paraguay, Honduras, and Uruguay (recruitment, ~8000) and will

Figure 1. ESTAMPA study: participants in the cervical pathology training course held in Cuernavaca, Morelos, Mexico, on 11–13 February 2015. © IARC/Roland Dray.



soon start in Costa Rica, Argentina, Peru, Mexico, and Bolivia (Figure 1).

EPIDEMIOLOGY AND PREVENTION OF *H. PYLORI* INFECTION AND GASTRIC CANCER

The ENIGMA study investigates the worldwide epidemiology of *H. pylori* infection and gastric cancer. The prevalence of infection, precancer, and cofactors are investigated in population samples from high- and low-risk areas. A multilevel analysis (ecological, cross-sectional, and analytical) will assess age-specific infection prevalence to predict cancer trends, as well as bacterial (including microbiome), host, and environmental factors explaining geographical patterns. ENIGMA has been completed in low- and high-risk areas in Chile (700 people each), and there are plans to expand the study to all continents.

In collaboration with the National Cancer Center of the Republic of Korea, PRI is conducting a randomized controlled clinical trial of *H. pylori* eradication for gastric cancer prevention (the HELPER study), which aims to recruit 11 000 subjects aged 40–65 years who are attending endoscopy within the National Cancer Screening Program. *H. pylori*-positive subjects are randomized to quadruple eradication therapy or placebo. All participants (current recruitment, ~1200) will be routinely screened within the National Cancer Screening Program every 2 years for 10 years.

PRI has also initiated a randomized trial with the University of Latvia to determine whether combined *H. pylori* and pepsinogen screening followed by eradication therapy in *H. pylori*-positive subjects and endoscopic follow-up of those with atrophic gastritis reduces gastric cancer mortality compared with standard care. The study aims to recruit 30 000 subjects aged 40–64 years in Latvia, Belarus, and the Russian Federation (current pilot recruitment, ~3000).

In December 2013, PRI convened a Working Group of experts to review the evidence regarding *H. pylori* eradication strategies for gastric cancer prevention. The experts recommended consideration of programmes in high-risk areas in the context of scientific assessment of the value of such interventions (Herrero et al., 2014a) (Figure 2).

CERVICAL CANCER PREVENTION IN AFRICA

PRI is collaborating with the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) and the United Republic of Tanzania in a study with more than 2000 women to build HPV testing capacity and to assess the reproducibility, feasibility, and acceptability of rapid HPV testing at different levels of the health care system (the AISHA study). Also with RHR, PRI is planning a large trial of three screen-and-treat algorithms currently recommended by WHO (the CESTA study).

Figure 2. *Helicobacter pylori* eradication as a strategy for preventing gastric cancer. The Working Group met at IARC in Lyon on 4–6 December 2013. © IARC/Roland Dray.



SUPPORT OF HPV VACCINATION AND SCREENING PROGRAMMES IN LATIN AMERICA

In the context of the National Cervical Screening Programme of Argentina, which is implementing HPV-based screening, extensive political and educational meetings have been held

and the development of guidelines and educational materials and the setting up of laboratories have been completed for the first province to implement the programme, Jujuy Province (Arrossi et al., 2015a). A cluster randomized trial within this programme demonstrated a 4-fold increase in screening participation when community health workers invited

women to self-collect their HPV tests compared with an invitation to attend a clinic (Arrossi et al., 2015b). Expansion to other provinces in Argentina is well under way. The materials developed and the experience gained should be useful for other programmes in the region, most of which also collaborate with PRI.

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The Screening Group (SCR) conducts studies of the early detection of common cancers, predominantly in low- and middle-income countries (LMICs), evaluating the accuracy, acceptability, feasibility, safety, and cost-effectiveness of early detection methods for breast, cervical, colorectal, and oral cancers and addressing how the evidence generated can influence early detection policies in LMICs (Khuhaprema et al., 2014; Krishnan et al., 2015; Parham et al., 2015; Rajaraman et al., 2015). The Group contributes scientific evidence to support the development of resource-appropriate policies to deliver effective early detection services (Sankaranarayanan et al., 2014a). SCR evaluates selected primary prevention

initiatives and explores pragmatic ways of integrating both primary and secondary prevention strategies into cervical cancer control (Sankaranarayanan et al., 2015). SCR engages substantially in developing training resources and educational programmes.

CERVICAL CANCER CONTROL

The effectiveness of one and two doses of human papillomavirus (HPV) vaccine was compared with that of three doses among girls aged 10–18 years in preventing cervical neoplasia in a multicentre study involving 17 729 women in India. Results after 4 years of follow-up indicate that the immunogenicity of two doses was non-inferior to that of

three doses. Although the single dose evoked lower antibody levels, they are much higher than natural infection and are as avid as three-dose antibodies (Figures 1 and 2). One dose provided similar protection against incident and persistent HPV 16/18/6/11 infections as two and three doses.

The long-term impact of screening with HPV testing, cytology, or visual inspection with acetic acid (VIA) on cervical cancer is being addressed by following up about 230 000 women in India. SCR evaluated the triaging options for HPV- and VIA-positive women (Muwonge et al., 2014; Basu et al., 2015). Cytology or VIA triage of HPV-positive women substantially reduced colposcopy

Figure 1. Mean fluorescence intensity (MFI) values for HPV 16, 18, 6, and 11 L1 antibodies at different time points among girls who completed vaccination per protocol (vaccination at days 1, 60, and 180 for the 3-dose group or at days 1 and 180 for the 2-dose group) and those who did not have their complete vaccine schedules (vaccination at days 1 and 60, or a single dose). Reprinted from Sankaranarayanan R, Prabhu PR, Pawlita M, Gheit T, Bhatla N, Muwonge R, et al., for the Indian HPV vaccine study group (2015). Immunogenicity and HPV infection after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicenter prospective cohort study. *Lancet Oncol.* [http://dx.doi.org/10.1016/S1470-2045\(15\)00414-3](http://dx.doi.org/10.1016/S1470-2045(15)00414-3).

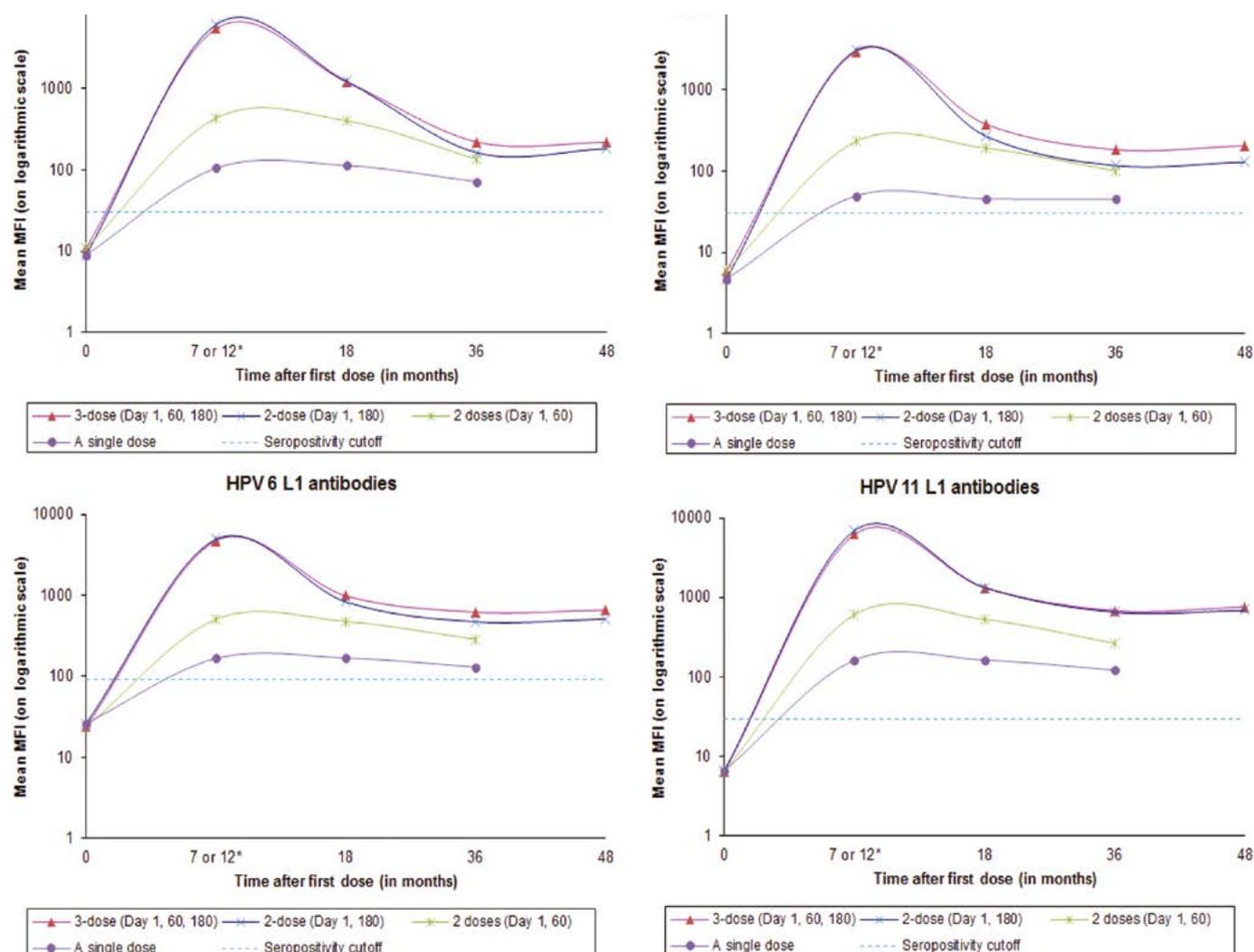
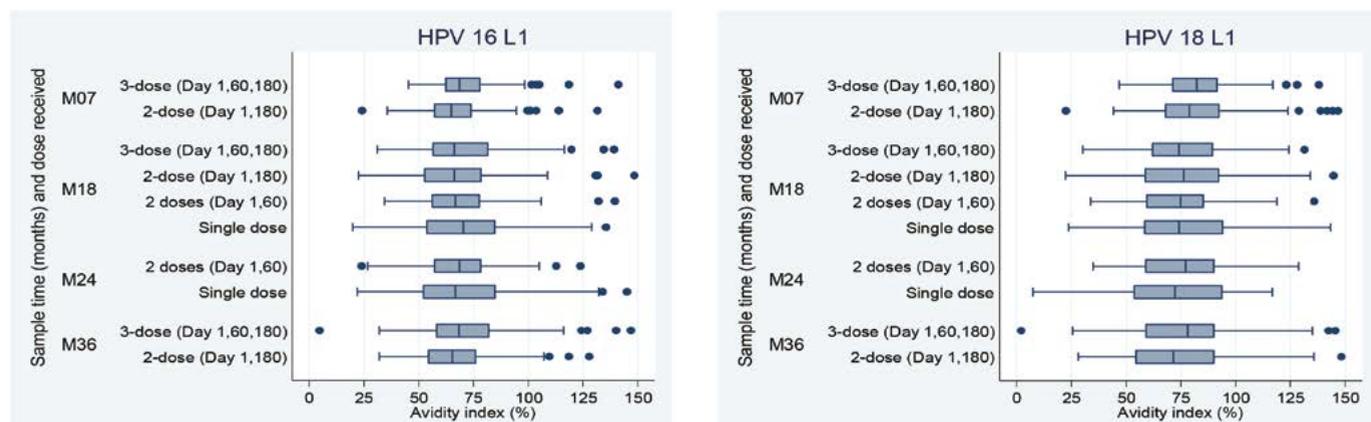


Figure 2. Geometric mean fluorescence intensity (MFI) avidity index of HPV 16, 18, 6, and 11 L1 antibodies at 18 months after the first dose among girls who completed vaccination per protocol and those who did not have their complete vaccine schedules. Reprinted from Sankaranarayanan R, Prabhu PR, Pawlita M, Gheit T, Bhatla N, Muwonge R, et al., for the Indian HPV vaccine study group (2015). Immunogenicity and HPV infection after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicenter prospective cohort study. *Lancet Oncol.* [http://dx.doi.org/10.1016/S1470-2045\(15\)00414-3](http://dx.doi.org/10.1016/S1470-2045(15)00414-3).



referral, although 16–18% of cases of cervical intraepithelial neoplasia grade 2 or 3 (CIN2/3) were missed. HPV testing could triage VIA-positive women very efficiently, with an insignificant drop in sensitivity (Basu et al., 2015). The validity of colposcopy by nurses was addressed in a follow-up study (Thulaseedharan et al., 2015a). A study among 1109 HIV-positive women in India observed 41.0% high-risk HPV positivity (Joshi et al., 2014). Meta-analysis of the efficacy of cold coagulation demonstrated a 95% cure rate for CIN2/3, comparable to that of cryotherapy or excision (Dolman et al., 2014). Scaling up of the VIA screen-and-treat programme in Zambia was evaluated (Parham et al., 2015). HPV viral load was observed to have a key role in colposcopy.

A pilot study involving 6000 women to implement HPV screening and triage by liquid-based cytology and HPV genotyping in Thailand has been completed. A study involving 592 midwives in Government Health Services in Côte d'Ivoire indicated that despite sufficient knowledge about cervical cancer prevention, the attitudes and practices of midwives need improvement by capacity-building activities (Tchounga et al., 2014).

BREAST CANCER SCREENING

In a randomized trial involving 130 000 women in Trivandrum, India, the second

round of screening by clinical breast examination (CBE) has been completed and the third round is in progress. The role of breast awareness in improving early detection and survival of breast cancer patients is being investigated at other sites in India.

ORAL CANCER SCREENING

The natural history of oral precancerous lesions is being addressed in the randomized trial of oral visual screening in Kerala, India. The cohort has substantially contributed to addressing mortality related to cardiovascular disease, tobacco, and obesity in South Asia (Zheng et al., 2014). The inputs and impact of “social marketing” to increase awareness for early detection are being evaluated in Sri Lanka.

COLORECTAL CANCER SCREENING

A pilot study in Thailand involving 130 000 people indicated that colorectal cancer screening with immunochemical faecal occult blood testing (iFOBT), triage colonoscopy, and treatment of adenomas and early cancers by endoscopic resection can be implemented successfully in government health services (Khuhaprema et al., 2014). SCR is currently providing technical support in scaling up colorectal cancer screening in five provinces in Thailand.

TECHNICAL SUPPORT TO NATIONAL CANCER CONTROL PROGRAMMES

SCR provided technical support to national cancer control programmes in Albania, Algeria, Bosnia and Herzegovina, Cambodia, China, Fiji, Georgia, Lebanon, Madagascar, Mauritania, Morocco, Myanmar, Papua New Guinea, Sri Lanka, Thailand, Timor-Leste, Tunisia, and Uzbekistan in collaboration with national governments, World Health Organization (WHO) headquarters and regional offices, the International Atomic Energy Agency (IAEA), and the United Nations Population Fund (UNFPA).

CONTINUED ACTIVITIES OF THE QUALITY ASSURANCE GROUP (QAS)

SCR is contributing to the preparation of the European Screening Report, which will describe the current coverage and status of breast, cervical, and colorectal cancer screening programmes in 28 European countries. The supplements to the second edition of the European Guidelines for Quality Assurance in Cervical Cancer Screening have been published (Anttila et al., 2015; von Karsa et al., 2015). The European Code Against Cancer, a collection of key recommendations to promote primary and secondary prevention of cancer, was launched in October 2014.

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