

**Das HPV-Management Forum unterstützt das Positionspapier der Internationalen Papillomvirusgesellschaft zur uneingeschränkten Sicherheit der HPV Impfstoffe.**

**Offizielles Statement zur HPV Impfstoffsicherheit der Internationalen Papillomavirus Gesellschaft, der Weltorganisation der Papillomvirusexperten**

Etwa 250.000 Frauen sterben jährlich an Gebärmutterhalskrebs, der durch Humane Papillomviren (HPV) ausgelöst wird. Die meisten dieser Todesfälle wären vermeidbar gewesen durch die derzeit verfügbaren HPV Impfstoffe. Tausende Männer und Frauen sterben jährlich an anderen HPV-assoziierten Krebsarten, z.B. des Anus, Vulva, Vagina, Penis und Mundrachenraumes. Es gibt jedoch heute zugelassene HPV Impfstoffe für den Schutz vor Krebs an Gebärmutterhals, Anus, Vulva, Vagina und deren Vorläuferstadien.

Diese derzeit zugelassenen HPV Impfstoffe wurden gründlich und wissenschaftlich sowohl auf ihre Effektivität als auch auf ihre Sicherheit hin überprüft. Dies wurde zuerst von klinischen Zulassungsstudien berichtet, die die Daten für die Zulassung der Impfstoffe lieferten. Nachdem nun die Impfstoffe in öffentlichen Gesundheitsprogrammen in der Standardanwendung aufgenommen wurden, haben sie weiterhin exzellente Resultate bzgl. ihrer Sicherheit- und Effektivität gezeigt.

Die Sicherheit dieser Impfstoffe wurde durch viele medizinische Behörden und Zulassungsstellen weltweit überprüft, einschließlich der Weltgesundheitsorganisation (1) und ihrer globalen Kommission zur Impfstoffsicherheit (mehrfach (2)), der Food and Drug Administration (FDA) (3), der Europäischen Medizinproduktezulassungsbehörde (EMA) (4), und der International Federation of Gynecology and Obstetrics (FIGO) (5). Die Impfstoffsicherheit wurde auch durch Gesundheitsbehörden in vielen einzelnen Ländern überprüft, wie der Medicines & Healthcare Products Regulatory Agency of the UK [MHRA] (6), der Therapeutic Goods Administration of Australia (7), und den Centres for Disease Control, USA (8, 9). Alle haben bestätigt, dass die Impfung sicher und effektiv ist. Wichtig ist, dass es keine Hinweise auf neurologische oder Autoimmunerkrankungen gibt, die durch die HPV Impfstoffe ausgelöst würden (10-13). Bis heute wurden keine Todesfälle der HPV Impfung zugeschrieben.

Die Internationale Papillomvirusgesellschaft (IPVS) ist die weltweit wichtigste professionelle Gesellschaft, die Papillomviren und durch sie hervorgerufene Erkrankungen untersucht (14). IPVS vereint Grundlagenwissenschaftler, klinische Forscher, Ärzte, Gesundheitssystemexperten, Epidemiologen und Gesellschaftsvertreter. Die IPVS empfiehlt dringend die Impfung aller Mädchen und Frauen nach den

gegebenen Indikationen und Empfehlungen durch die nationalen regulatorischen Behörden sowie die Impfung von Jungen und Männern, wo sie bereits zugelassen ist. Die IPVS bittet dringend die nationalen regulatorischen Behörden in Ländern, in denen die HPV Impfung bisher nicht verfügbar ist, die HPV Impfung für Mädchen und Frauen so bald als möglich verfügbar zu machen und die Impfung von Jungen und Männern dringend zu berücksichtigen.

### **Official Statement concerning HPV Vaccine Safety of the International Papillomavirus Society, the Worldwide Organisation of Papillomavirus Experts**

Approximately 250,000 women die every year of cervical cancers caused by human papillomavirus (HPV). Most of these could have been prevented by the currently available prophylactic HPV vaccines. Thousands of men and women also die every year of other HPV-associated cancers, including cancers of the anus, vulva, vagina, penis and oropharynx. Yet there are now HPV vaccines currently approved for the prevention of cancers of the cervix, anus, vulva and vagina and their precursor lesions.

These currently licensed HPV vaccines have been reviewed extensively and scientifically, for efficacy as well as safety. This was first reported from clinical trials that provided evidence supporting licensure of the vaccines. As the vaccines have been incorporated into public health programs in real world situations, they have continued to show excellent safety and effectiveness outcomes.

The safety of these vaccines has been reviewed by multiple medical authorities and regulatory agencies globally, including the World Health Organisation(1) and its Global Advisory Committee on Vaccine Safety (on multiple occasions(2)), Food and Drug Administration (FDA)(3), European Medicines Agency (EMA)(4), and International Federation of Gynaecology & Obstetrics (FIGO)(5). Vaccine safety has also been reviewed by health authorities in many individual countries such as the Medicines & Healthcare Products Regulatory Agency of the UK [MHRA](6), the Therapeutic Goods Administration of Australia(7), and Centres for Disease Control, USA(8, 9). All have endorsed them as safe and effective. Importantly, there is no evidence for neurological or autoimmune diseases caused by the HPV vaccines (10-13). To date, there have been no deaths directly attributed to HPV vaccination.

The International Papillomavirus Society (IPVS) is the world's leading professional society devoted to the study of papillomaviruses and the diseases that they cause (14). IPVS is comprised of basic scientists,

clinical scientists, clinicians, public health experts, epidemiologists, and community advocates. IPVS strongly endorses HPV vaccination of all girls and women per the indications specified by the relevant national regulatory authorities and vaccination of boys and men wherever already approved. IPVS urges national regulatory authorities in countries where HPV vaccination is not currently available to implement HPV vaccination in girls and women as soon as possible and to strongly consider vaccination of boys and men.

**IPVS Policy Committee members:**

**Prof Suzanne M Garland MBBS MD FRCPA FRANZCOG Ad  
Eundem FACHSHM, FASM, FFSc(RCPA)**

Director of Microbiological Research and of Clinical Microbiology and Infectious Diseases, The Royal Women's Hospital, Professor, Department of Obstetrics, Gynaecology, University of Melbourne, Victoria, Australia.

**Professor Margaret Stanley OBE FMedSci HonFRCOG**

Department of Pathology  
Cambridge

**A/Prof Julia Brotherton B Med (Hons,) MPH (Hons), Grad Dip  
App Epi, FAFPHM, PhD**

Medical Director, National HPV Vaccination Program Register, Victorian Cytology Service, Australia  
Honorary Principal Fellow, School of Population and Global Health, University of Melbourne, Victoria, Australia

**Professor Anna-Barbara Moscicki, MD ,**

Department of Pediatrics,  
Chief, Adolescent & Young Adult Medicine  
Professor of Pediatrics  
David Geffen School of Medicine  
University of California, Los Angeles, USA

**Dr Neerja Bhatla, MBBS, MD, FICOG, FIMSA, FAMS,**

Professor, Department of Obstetrics & Gynaecology,  
All India Institute of Medical Sciences  
Chairperson, FIGO Committee for Gynaecologic Oncology  
President, AOGIN; President, AGOI

Chairperson, Oncology & Trophoblastic Tumours Committee,  
FOGSI  
Board Member, IFCCP

**PD Dr. Andreas M. Kaufmann, PhD**

Gynaekologische Tumorimmunologie, Charite-  
Universitaetsmedizin Berlin, Campus Benjamin Franklin,  
Berlin, Germany

**Prof R. Sankaranarayanan, M.D.**

Head, Early Detection & Prevention Section (EDP) and Head,  
Screening Group (SCR)  
International Agency for Research on Cancer (WHO-IARC)

**Prof Joel Palefsky, Past-President IPV**

Professor of Medicine  
Division of Infectious Disease  
University of California  
San Francisco

On behalf of IPVS (This document was approved by the IPVS  
members on the 19<sup>th</sup> of September, 2015 ).

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