



European Centre for Disease Prevention and Control

La vaccinazione HPV in Europa

Pier Luigi Lopalco, Head of Vaccine Preventable Diseases programme

17 Aprile 2013

Chi riconosce quest'uomo?



Harald zur Hausen

**Premio Nobel per la
Medicina 2008**

Motivazione:

*"Per la scoperta che il virus
del papilloma umano causa
il cancro della cervice
uterina"*

Disponibili sul mercato europeo due vaccini con un ottimo profilo di efficacia



GUIDANCE

FOR THE INTRODUCTION OF HPV VACCINES IN EU COUNTRIES

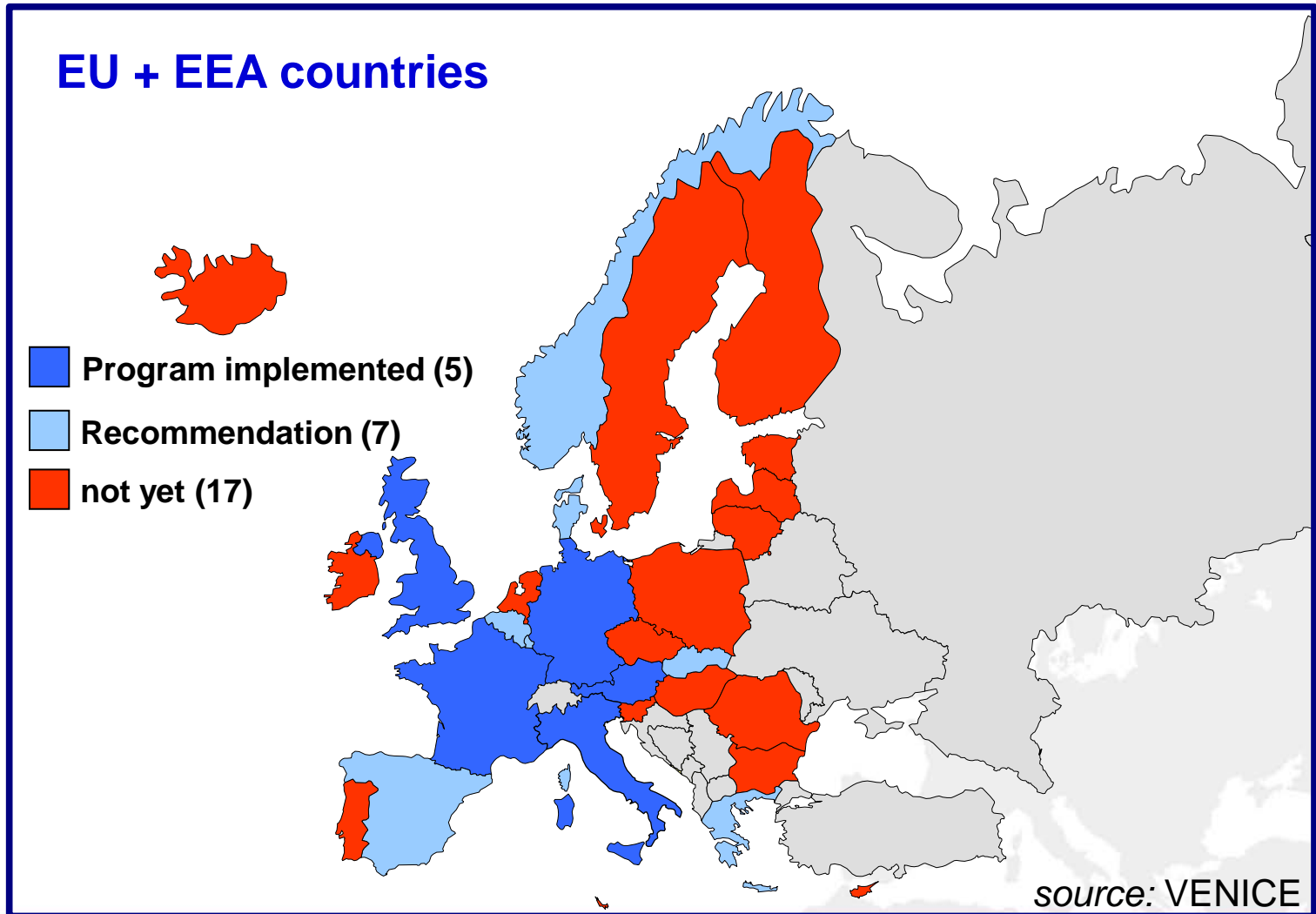
Stockholm, January 2008

Two prophylactic HPV vaccines have been licensed in Europe: the quadrivalent vaccine, Gardasil® (Sanofi Pasteur MSD) and the bivalent vaccine, Cervarix® (GlaxoSmithKline Biologicals).

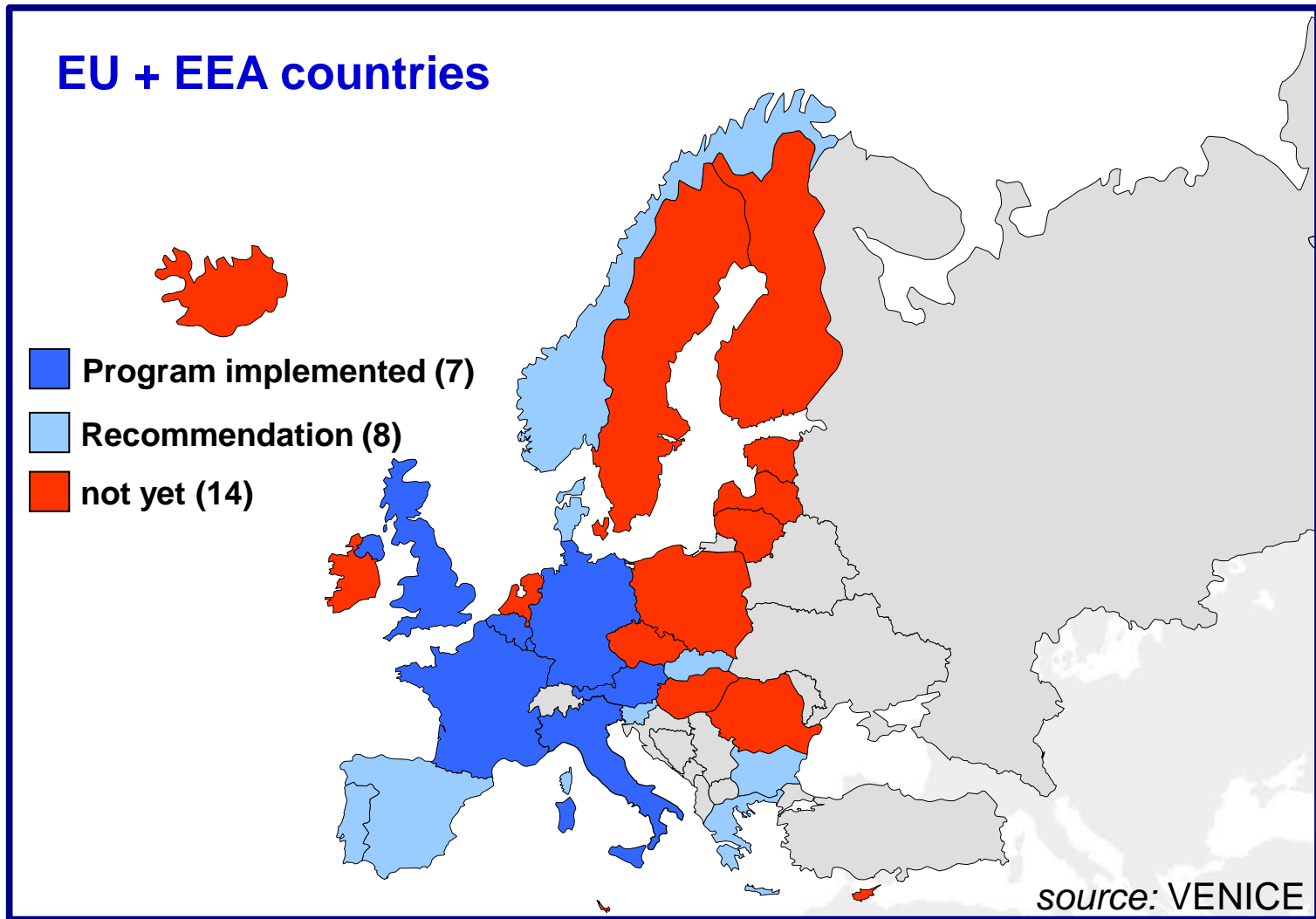
Both vaccines protect against the high-risk HPV types 16 and 18, responsible for an estimated 73% of cervical cancer cases in Europe. Gardasil also protects against HPV 6 and 11, which cause most cases of genital warts.

In large phase III trials both vaccines have been shown to prevent more than 90% of precancerous lesions associated with types 16 or 18 among HPV-naive women.

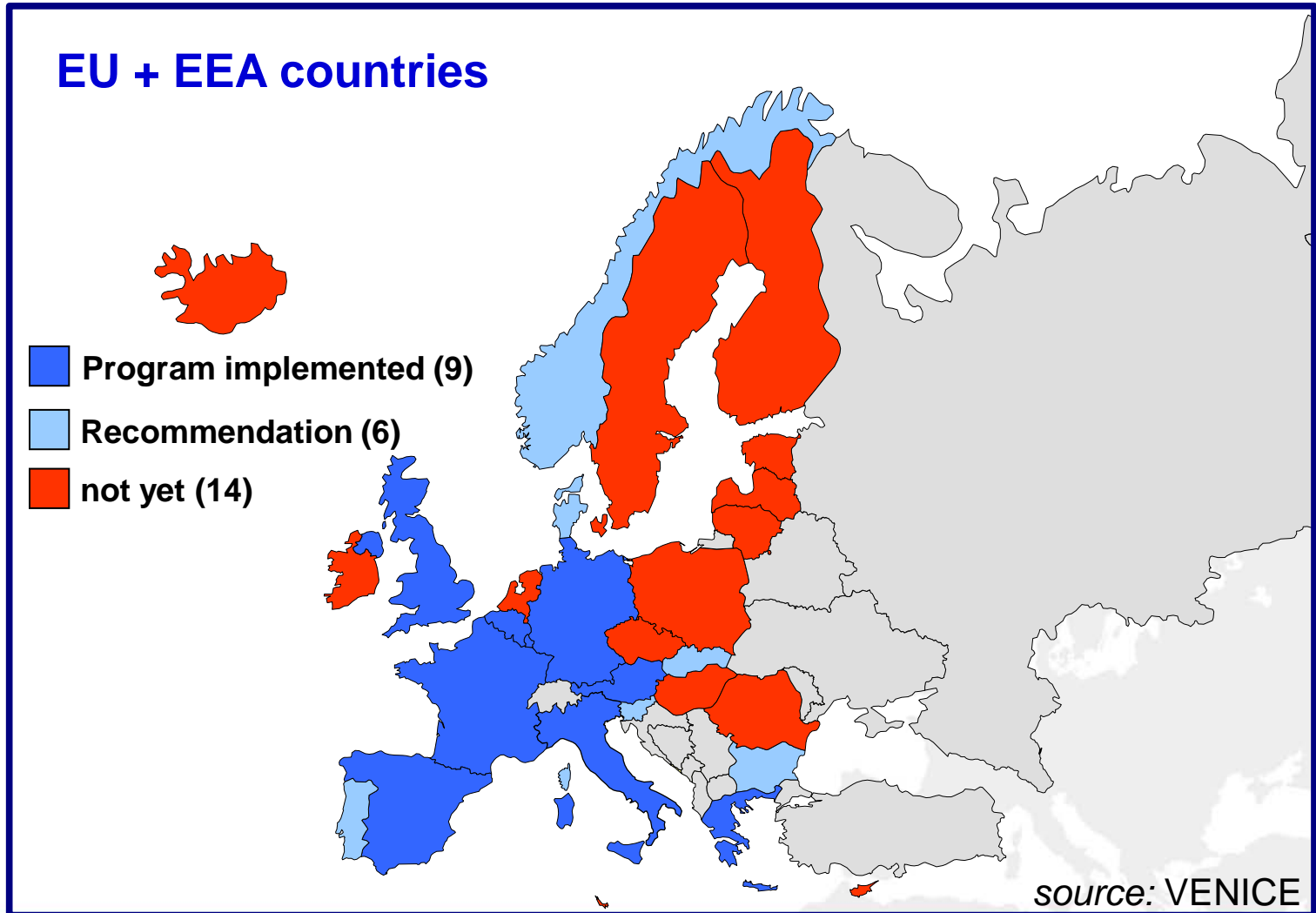
Stato dell'introduzione della vaccinazione HPV in UE (2007)



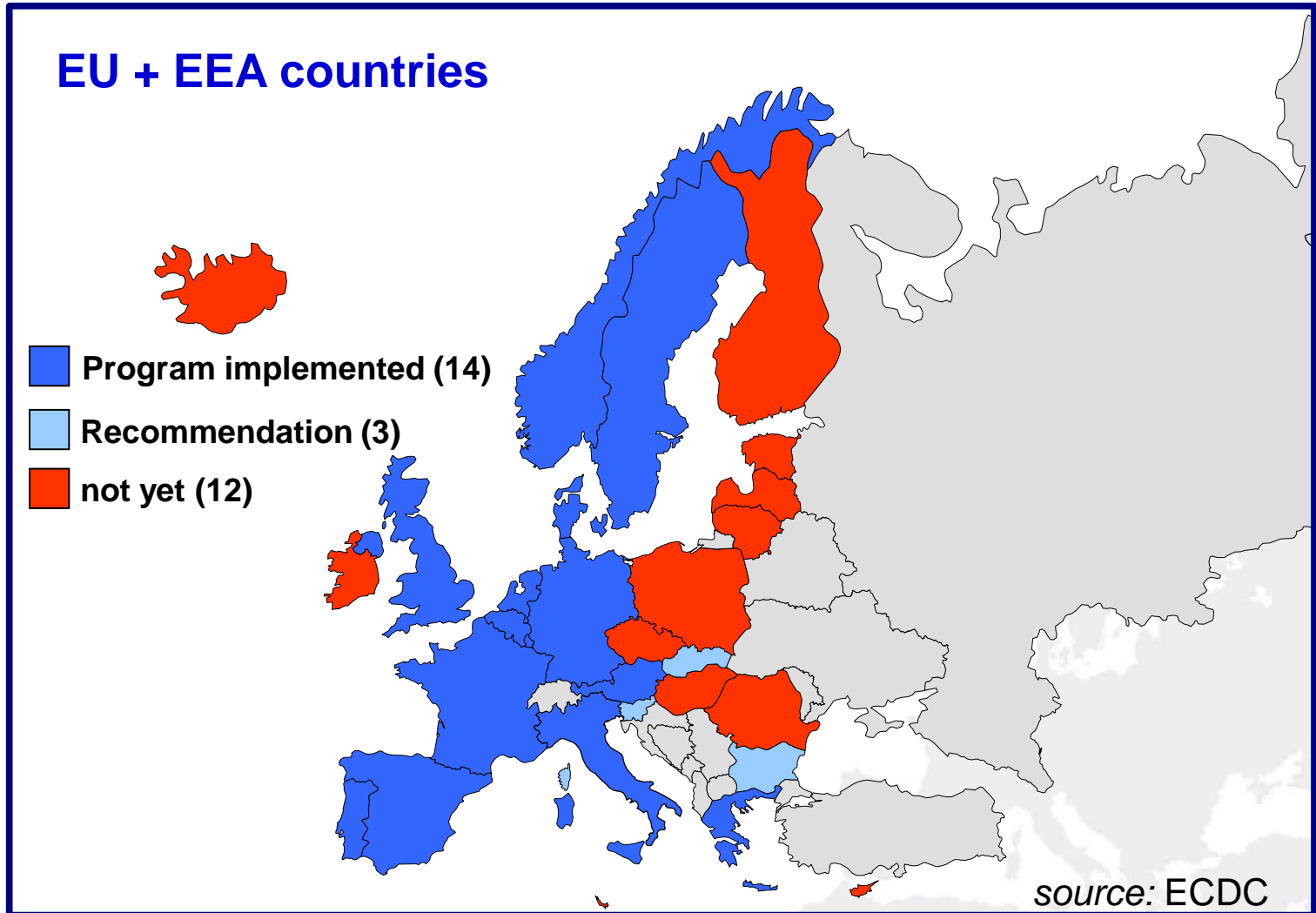
Stato dell'introduzione della vaccinazione HPV in UE (2008)



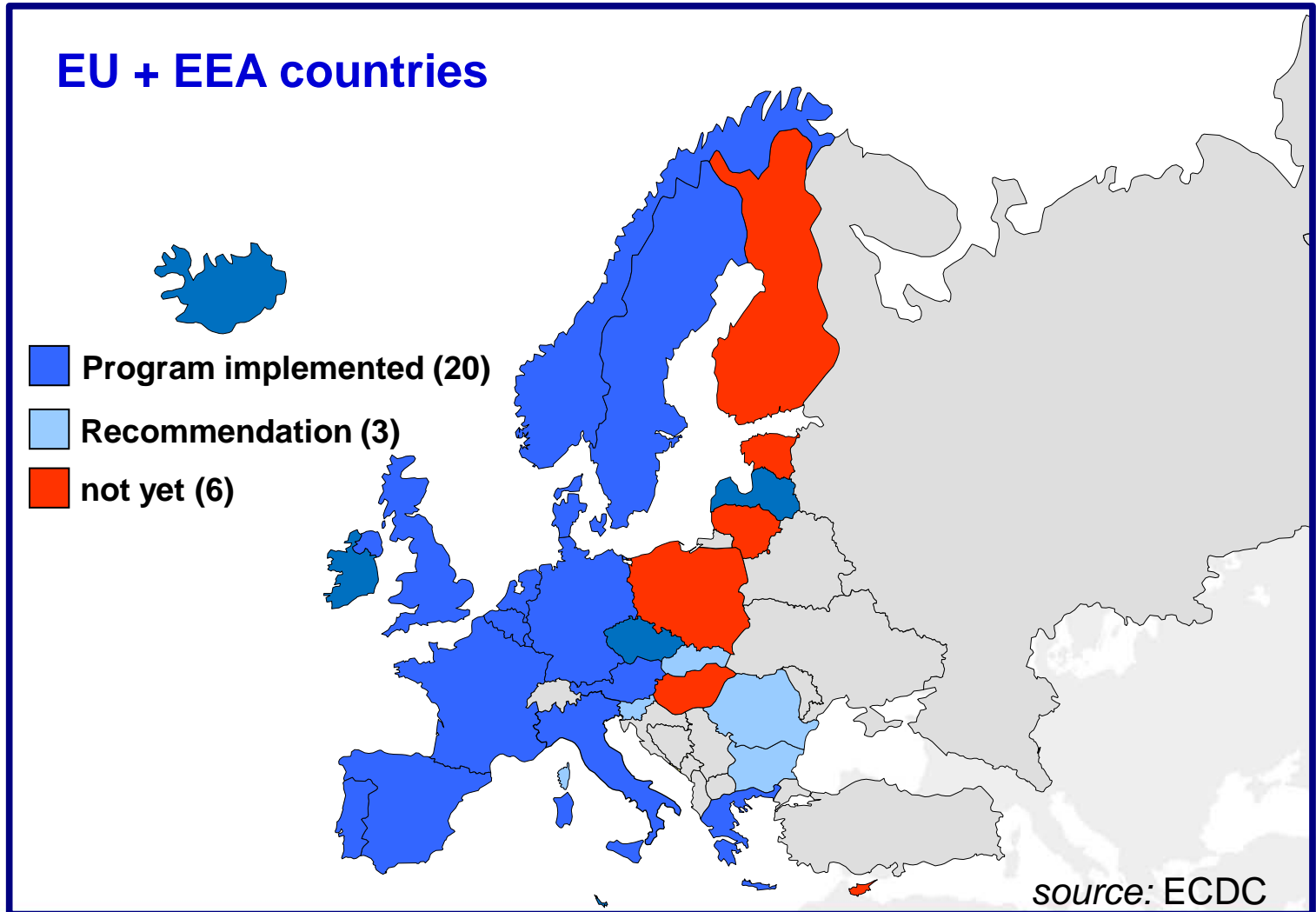
Stato dell'introduzione della vaccinazione HPV in UE (2009)



Stato dell'introduzione della vaccinazione HPV in UE (2010)



Stato dell'introduzione della vaccinazione HPV in UE (2012)



	Years														
	9	10	11	12	13	14	15	16	17	18	19	25	26	29	
Austria	HPV ¹														
Belgium				HPV ²											
Belgium (Vlaamse Gewest)				HPV ³											
Bulgaria															
Cyprus															
Czech Republic					HPV ⁴					HPV ⁵					
Denmark				HPV											
Estonia															
Finland															
France															
Germany				HPV ³											
Greece			HPV ⁶												
Hungary															
Iceland				HPV ²⁷											
Ireland			HPV ⁸												
Italy			HPV ³												
Latvia				HPV ⁷											
Liechtenstein			HPV ⁹				HPV ¹⁰				HPV ¹¹				
Lithuania															
Luxembourg				HPV ⁷			HPV								
Malta				HPV ¹²											
Netherlands				HPV ³											
Norway				HPV ¹³											
Poland															
Portugal					HPV ³										
Romania															
Slovakia															
Slovenia			HPV												
Spain						HPV ¹⁴									
Sweden		HPV ³													

ECDC Vaccine Scheduler

*(versione beta:
dati provvisori)*



Campagna vaccinale HPV in UK

- Quasi 300.000 ragazze in ogni coorte di età
- Copertura superiore a 90% per la prima dose
- Coperture >85% per la terza dose



Come demolire un successo

Morte improvvisa di una adolescente dopo vaccinazione HPV



Angst vor neuer Krebs-Impfung

Zweites Mädchen (15) aus OÖ nach Impfung auf der Intensivstation

Die meisten Eltern auf dem Gelände von ÖSTERREICH über die HPV-Impfung als Gesundheitsrisiko.

Wien/ÖÖ. Nach dem dritten Todesfall bei einer 15-jährigen Schülerin in der OÖ ist die öffentliche Diskussion über die HPV-Impfung in Österreich wieder aufgeflammt. Die Eltern der betroffenen Mädchen fordern eine Überprüfung der Impfung. Die Gesundheitsministerin Elisabeth Kocher (SPÖ) hat sich bereits mit dem Bundesgesundheitsminister Gernot Blümel (FPÖ) über die Situation beraten. Die Eltern fordern eine Überprüfung der Impfung. Die Gesundheitsministerin Elisabeth Kocher (SPÖ) hat sich bereits mit dem Bundesgesundheitsminister Gernot Blümel (FPÖ) über die Situation beraten. Die Eltern fordern eine Überprüfung der Impfung.



Ein Opfer packt aus

Krebs-Impfung: Schon acht bedenkliche Fälle

Die Tochter der 15-jährigen Schülerin, die nach der HPV-Impfung starb, hat sich in einem Interview geäußert. Sie berichtet über die Ereignisse rund um den Tod ihrer Tochter. Die Eltern fordern eine Überprüfung der Impfung. Die Gesundheitsministerin Elisabeth Kocher (SPÖ) hat sich bereits mit dem Bundesgesundheitsminister Gernot Blümel (FPÖ) über die Situation beraten. Die Eltern fordern eine Überprüfung der Impfung.



vaccino hpv effetti collaterali



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[Vaccino anti papilloma virus: Stupro Sanitario o Equivoco Mediatico?](#)

[www.controcampus.it/.../vaccino-anti-papilloma-vi...](#) - [Translate this page](#)

Jan 21, 2013 – **Effetti collaterali**. Le principali segnalazioni relative alla somministrazione del **vaccino anti HPV** concernono reazioni locali nella sede di ...

[Gravissima bambina di 12 anni dopo vaccino contro papilloma](#)

[www.disinformazione.it/vaccino_papilloma_coma...](#) - [Translate this page](#)

papilloma, **vaccini**, **vaccinazioni** contro papilloma, cancro collo utero, ceppi, bambine, HPV, pillole, anticoncezionale, **effetti collaterali**, zoely, estradiolo, ormoni, ...

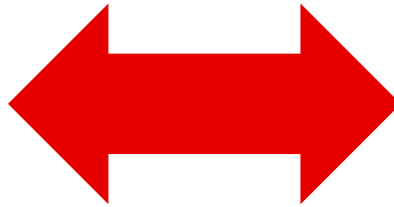
[Vaccinazione Papilloma virus - Vaccino HPV](#)

[www.my-personaltrainer.it/.../papilloma-virus-vac...](#) - [Translate this page](#)

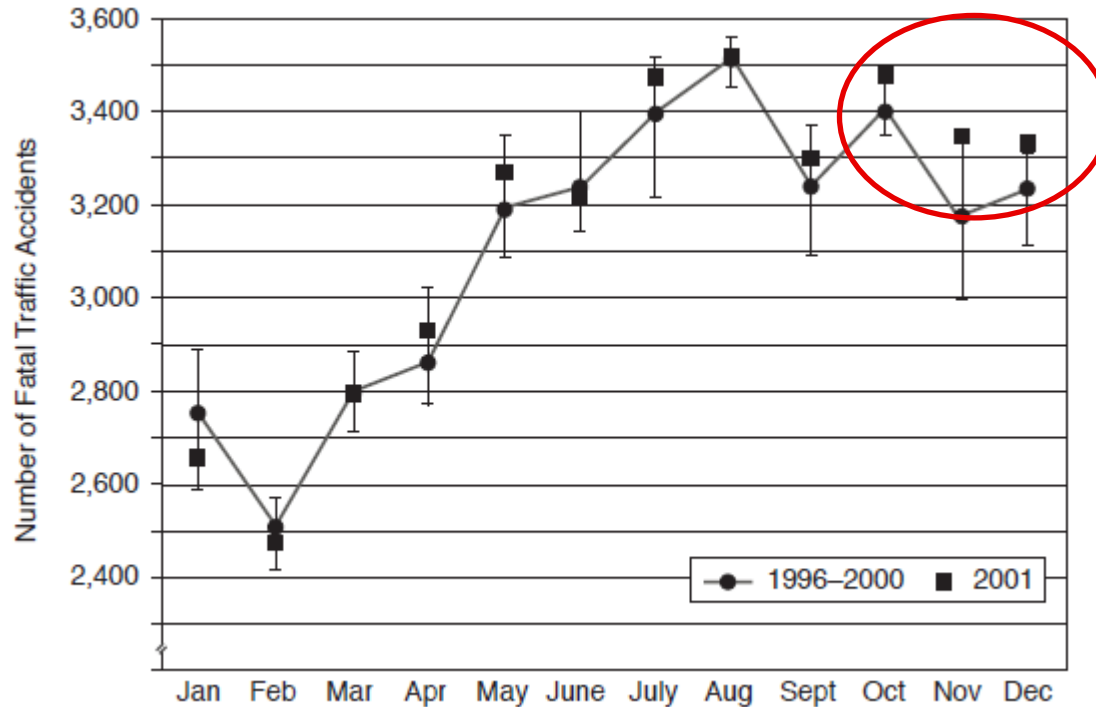
Jump to [Effetti avversi](#): Come ogni farmaco, anche il **vaccino anti HPV** può originare spiacevoli **effetti** indesiderati, presto risolvibili; tra i più diffusi, ...

Nessun sito istituzionale nella prima pagina di risultati Google

Scienza vs Disinformazione



L'essere umano non è necessariamente razionale



After 9/11 it has been estimated an excess **350** people dying after car accident due to increased car traffic

People feared flying

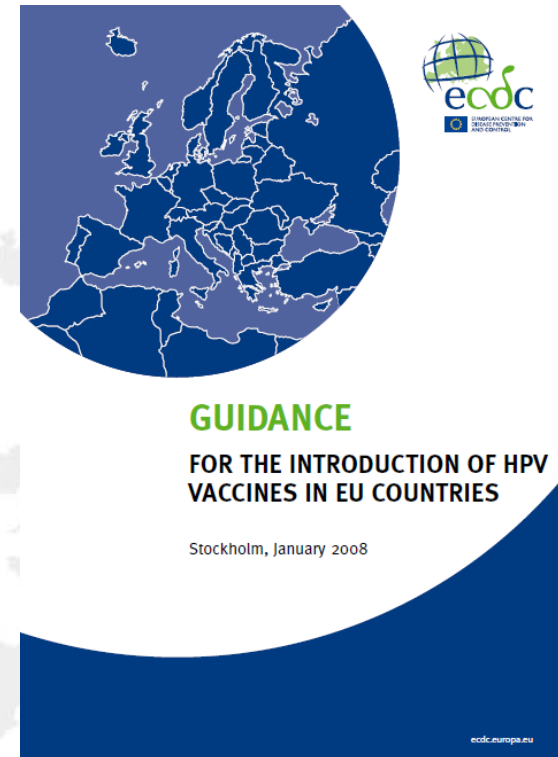
Those summed up to the **266** victims in the planes during the terrorist attack

La potenza della "a"

	Vaccination YES	Vaccination NO
Adverse event YES	a	b
Adverse event NO	c	d

ECDC Guidance on HPV introduction in Europe - 2008

- The reviewed data covered local and systemic events in short-term and long-term events up to six years, including pregnancy events. They concluded that the **current evidence on the safety of HPV vaccines is reassuring** *
- During adolescent vaccine campaigns, some **mass sociogenic illnesses** such as postvaccination dizziness and syncope have been reported *



*Data review by the WHO's Global Advisory Committee on Vaccine Safety

ECDC update on 2008 Guidance

published September 2012

	Vaccination YES	Vaccination NO
Adverse event YES	825	829
Adverse event NO	21091	21111

- 7 randomised controlled trials selected
- 44,000 females
- Risk of serious adverse events equal between vaccinated and not vaccinated

Lu B, et al. Efficacy and safety of prophylactic vaccines against cervical HPV infection and diseases among women: a systematic review & meta-analysis. BMC Infect Dis, 2011

EMA statements after vaccine scares with Gardasil



- January 2008. Two reports concerning the sudden and unexpected deaths of two young women in Austria and Germany. [...] On the basis of the currently available evidence, the EMEA's Committee for Medicinal Products for Human Use (CHMP) is of the opinion that the **benefits of Gardasil continue to outweigh its risks** and that no changes to its product information are necessary.
- February 2009. Two cases of status epilepticus with myoclonus reported in two girls vaccinated with the cervical cancer vaccine Gardasil in Spain. The EMEA's CHMP has concluded that the **cases are unlikely to be related to vaccination** with Gardasil and that the benefits of Gardasil continue to outweigh its risks.

EMA statements after vaccine scares with Gardasil (2)



- September 2011. Letter in response to concerns by Sane Vax Inc. The CHMP noted that the presence of recombinant **DNA fragments** does not represent a case of contamination and is not considered to be a risk to vaccine recipients. The information brought to the attention of the CHMP by Sane Vax Inc. is not considered to provide new information about the quality of the vaccine.
- Concerning the highlighted case of **Juvenile Rheumatoid Arthritis** observed in association with a third dose of Gardasil, the information is very limited. In view of the total number of doses of Gardasil distributed since launch in 2006, i.e. more than 79 million doses worldwide, this case might well be **within the expected number** of Juvenile Rheumatoid Arthritis cases in the vaccinated population but coinciding with vaccination.

SaneVax, Inc.

Safe, Affordable, Necessary & Effective Vaccines and Vaccination Practices

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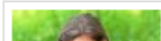
Welcome to Sane Vax

S.A.N.E. VAX, INC.

Safe Affordable Necessary Effective

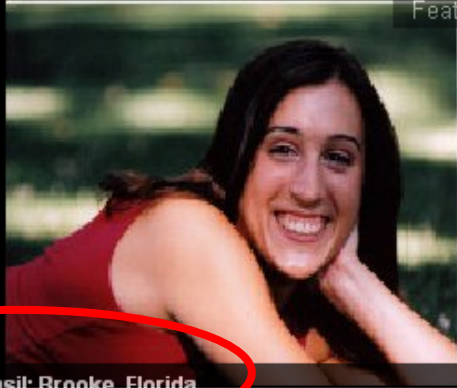
The Sane Vax Mission is to promote only Safe, Affordable, Necessary & Effective vaccines and vaccination practices through education and information.

VICTIMS



How Gardasil Changed My

Featured Articles



Gone After Gardasil: Brooke, Florida
Brooke Petkevicius - Florida 19 year old. Written by: Cynthia Janak Brooke was enrolled at the... [more]

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THIS WEEK'S VICTIM



ECDC update on 2008 Guidance

published September 2012



- Data on safety in males are indicating the same safety profile as in females:
- Giuliano AR, et al. Efficacy of quadrivalent HPV vaccine against HPV Infection and disease in males. N Engl J Med. 2011
- Moreira ED, et al. Safety and reactogenicity of a quadrivalent human papillomavirus (types 6, 11, 16, 18) L1 viral-like-particle vaccine in older adolescents and young adults. Hum Vaccin. 2011
- Petäjä T, et al. Immunogenicity and safety of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine in healthy boys aged 10-18 years. J Adolesc Health. 2009
- Block SL, et al. Comparison of the immunogenicity and reactogenicity of a prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in male and female adolescents and young adult women. Pediatrics. 2006

Adverse event surveillance in the US



Vaccine Safety Datalink:

In 2011, VSD active looked at specific adverse events following more than **600,000** doses of Gardasil, such as Guillain–Barré Syndrome (GBS), stroke, venous thromboembolism, appendicitis, seizures, syncope, allergic reactions, and anaphylaxis.

No statistically significant increased risk for any of these adverse events was detected after vaccination.



ECDC update on 2008 Guidance

published September 2012



- Attitude of Family Doctors in Europe:

Lutringer-Magnin et al. 2011: A total of 80.8% of GPs reported a favourable opinion of HPV vaccination, 17.4% were uncertain and 1.8% were opposed. The main difficulties in providing HPV vaccination were patients' concerns about potential side effects (cited by 37% of the respondents)

Piana et al. 2009: In this study, 89.6% of family physicians answers were in favour of HPV. The family physicians most in favour of vaccination were those who were confident of the vaccine's safety [...]

News > UK news

Schoolgirl dies after cervical cancer vaccination

- HPV vaccine batch quarantined as 'precautionary measure'
- Vaccination part of national immunisation programme

Jo Adetunji

The Guardian, Tuesday 29 September 2009 01.49 BST

[Article history](#)



Natalie Morton, aged 14, from Coventry. Photograph: Caters News Agency Ltd

News > Society > Health

Girl who died after cervical cancer injection had tumour in her chest

Death of Natalie Morton due to underlying medical condition, inquest hears

Owen Bowcott

guardian.co.uk, Thursday 1 October 2009 11.36 BST

[Article history](#)



Natalie Morton, aged 14, from Coventry. Photograph: Caters News Agency Ltd

A comprehensive model to improve vaccine uptake

social support

Safe and
effective vaccines

accessibility

vaccination

availability

Individual risk
perception

high quality
vaccination services

A comprehensive model to improve vaccine uptake

marginalised
groups

social support

Safe and
effective vaccines

accessibility

vaccination

availability

Individual risk
perception

high quality
vaccination services

A comprehensive model to improve vaccine uptake

middle-class
hi-education level

social support

Safe and
effective vaccines

accessibility

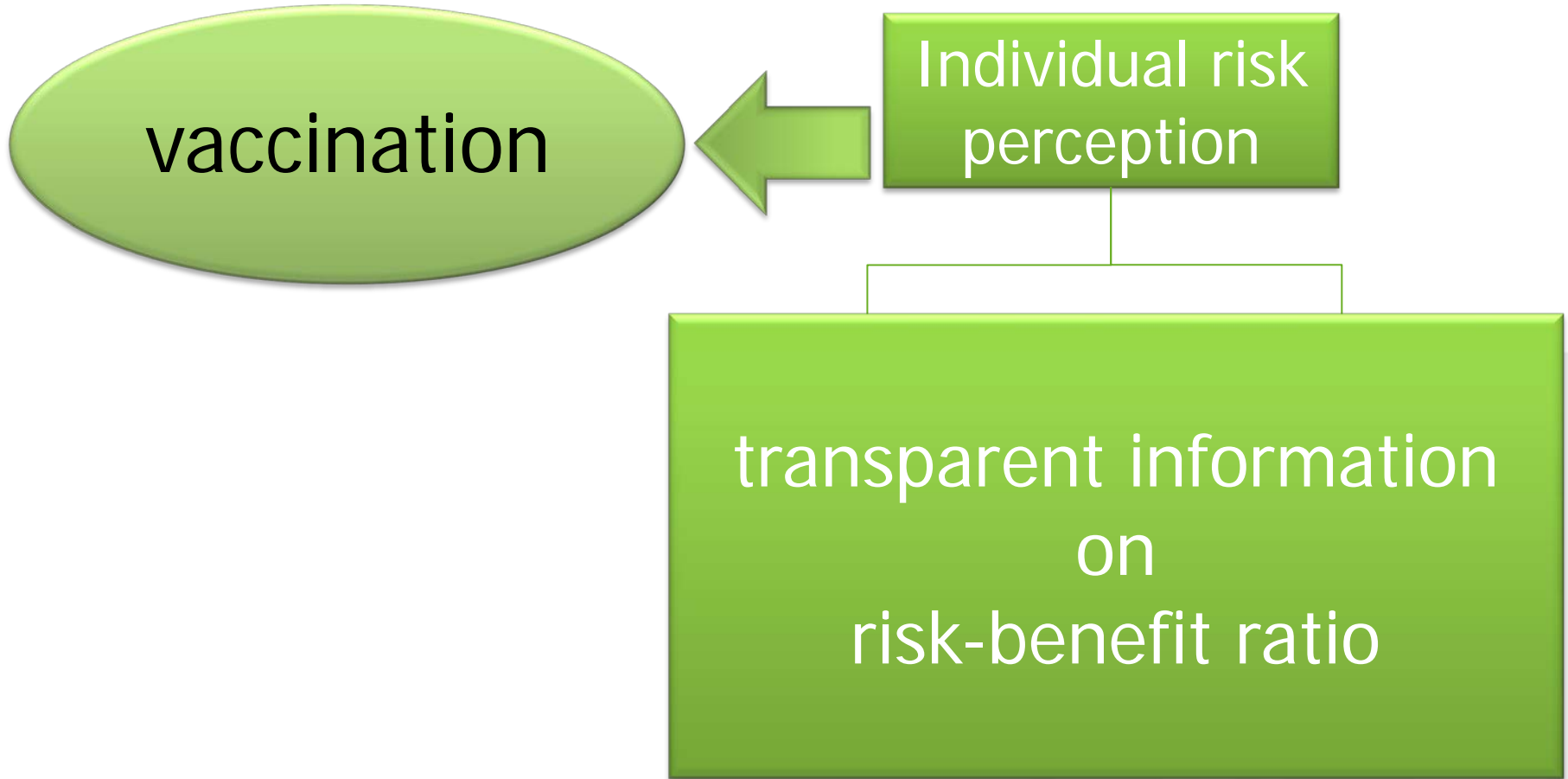
vaccination

availability

Individual risk
perception

high quality
vaccination services

Central role of risk perception



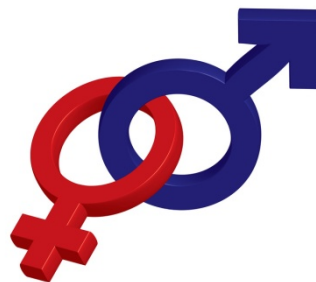
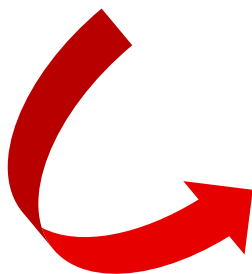
Una nuova frontiera della vaccinazione HPV



50%



50%



50%



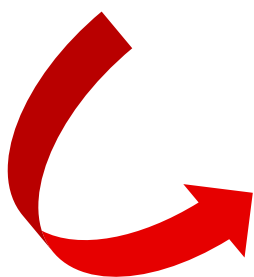
Una nuova frontiera della vaccinazione HPV



100%



0%



100%



ECDC update on 2008 Guidance

published September 2012



④ La vaccinazione anti-HPV nel maschio:

- il vaccino tetravalente è **efficace** nella prevenzione di infezione persistente e patologie HPV-correlate (es. condilomi, cancro anale e orofaringeo)
- è **sicuro e ben tollerato** ma, gli studi di efficacia, immunogenicità e sicurezza nel maschio sono limitati e relativamente recenti
- la vaccinazione universale dei maschi sarebbe capace di prevenire anche le patologie nelle femmine (herd immunity), tuttavia è **improbabile che sia costo-efficace nelle attuali condizioni economiche**
- la maggior parte analisi economiche mostrano un più elevato rapporto costo-efficacia per le **azioni intese a migliorare i tassi di copertura vaccinale nelle donne**
- il rapporto costo-efficacia di inserire i ragazzi in programmi di vaccinazione HPV potrà essere rivalutato ridotti in futuro, se i **costi** della vaccinazione saranno significativamente ridotti
- **campagne di vaccinazione mirate ai MSM** possono produrre maggiori benefici (vantaggi della vaccinazione anche dopo il debutto sessuale e l'esposizione a infezioni da HPV)

ECDC update on 2008 Guidance

published September 2012



- ④ La costo-efficacia dei 2 vaccini, confrontata in diversi modelli – se pur pieni di limiti – non è sovrapponibile, sptto per le nuove evidenze relative al burden dei condilomi anogenitali: il **vaccino bivalente dovrebbe costare 20-42 euro in meno.**
- ④ La vaccinazione anti-HPV è costosa e difficile da completare: spiega in parte le basse CV. Possibilità che **schedule ad 1 o 2 dosi** siano ugualmente efficaci di quella raccomandata a tre dosi: se risultati confermati, grande impatto sui costi e le strategie per i programmi di vaccinazione HPV.
- ④ Evidenze di non-inferiorità di programmi alternativi, in cui il ciclo di tre dosi è completato in >6 mesi (es. 3° dose a 12 mesi)
- ④ **Necessità di aumentare le conoscenze tra i genitori e tra gli operatori sanitari attraverso politiche ad hoc.**

Chi vincerà?





Grazie

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