Merck's own clinical studies found -44.6% (negative) efficacy for women previously exposed to HPV infections.

Table 17. Study 013: Applicant's analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive and seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]

	Gardasil™ N=2717				Placebo N=2725					
Endpoint	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	Observed Efficacy	95% CI
HPV 6/11/16/18 CIN 2/3 or worse	156	**31**	278.9	11.1	137	**19**	247.1	7.7	-44.6%	<0.0, 8.5%

Translation: Gardasil increases the risk of cervical cancer by 44.6% in women who were exposed to HPV prior to receiving the vaccine.

STUDY: 34% OF CHILDREN AGES 2-10 HAVE HPV INFECTION DUE TO NON-SEXUAL TRANSMISSION

(BIRTH CANAL, CASUAL CONTACT)

Original Study

Genital HPV in Children and Adolescents: Does Sexual Activity Make a Difference?

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48% of women ages 26-45 are infected, according to Merck's package inserts.

(24% have high-risk strain)

Table 2
HPV Infection Characteristics in Vaginal or Cervical Samples of 95 Children and Adolescents

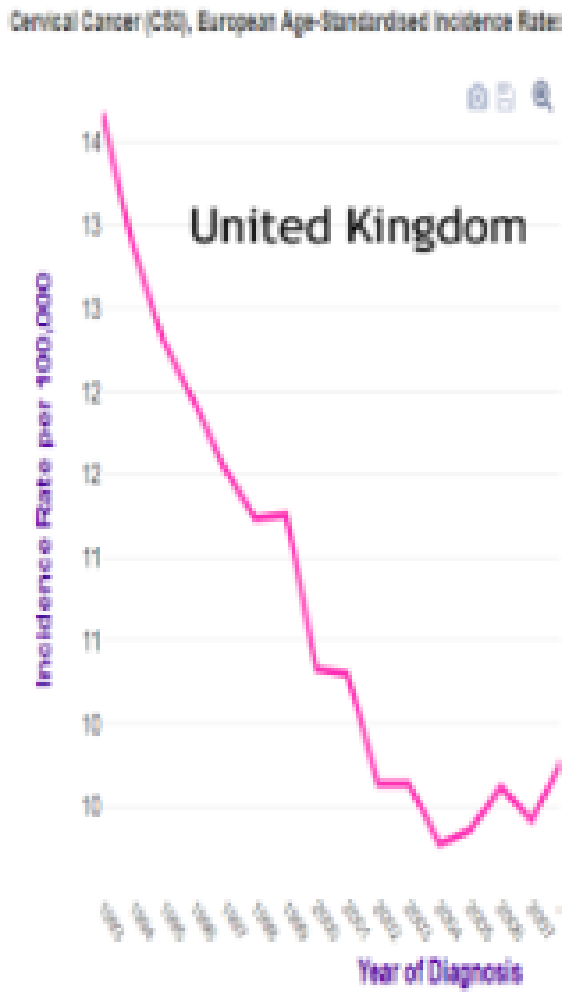
HPV Infection Characteristics	Sexually Active Adolescents	Not Sexually Active Adolescents	Prepubertal Children	Cumulative Number	*P*
Total population	n = 38	n = 28	n = 29	n = 95	
HPV infection	18 (47.4)	8 (28.6)	10 (34.5)	36 (37.9)	.27
Single infection	8 (21.1)	5 (17.9)	6 (20.7)	19 (20)	.94
Multiple infection	10 (26.3)	3 (10.7)	4 (13.8)	17 (17.9)	.21
Low-risk strain	4 (10.5)	2 (7.1)	5 (17.2)	11 (11.6)	.48
High-risk strain	18 (47.4)	8 (28.6)	7 (24.1)	33 (34.7)	.10

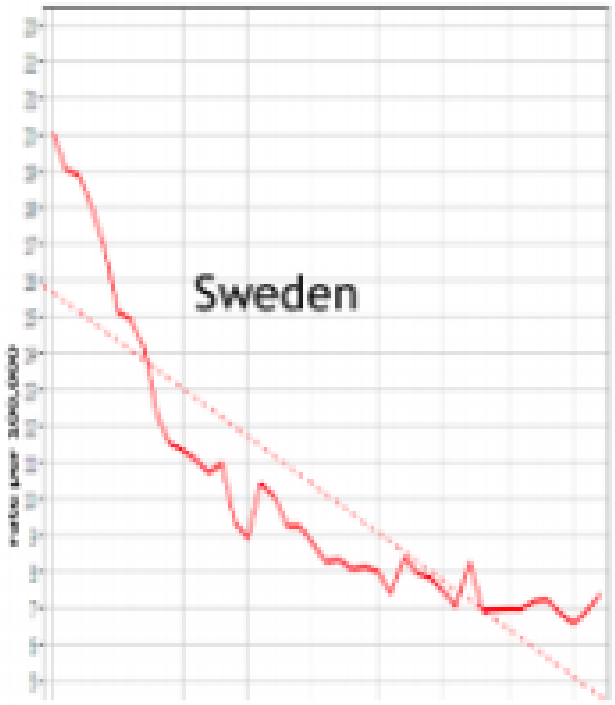
HPV, human papillomavirus
Data are presented as n (%).

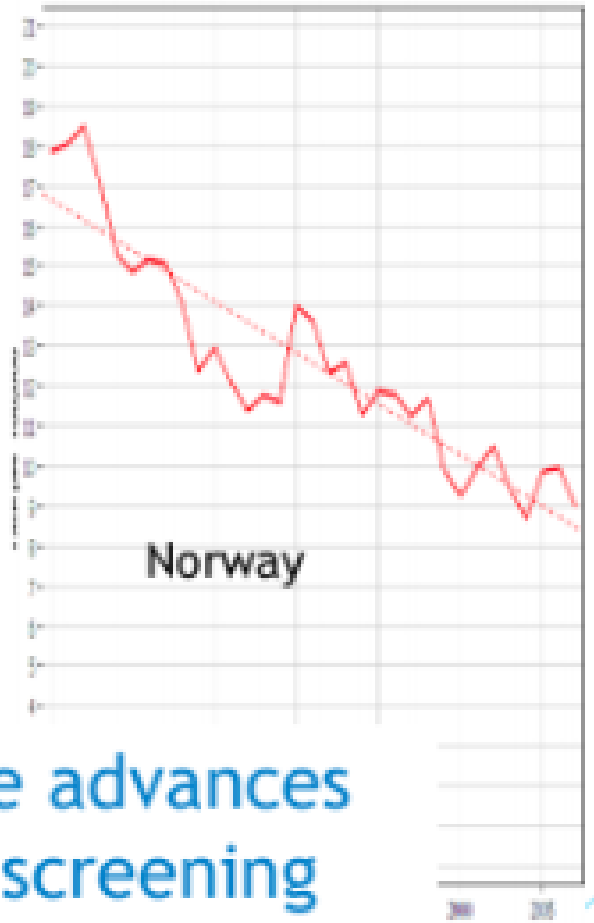
CDC recommends Gardasil for women until age 45 with no testing to determine HPV status.

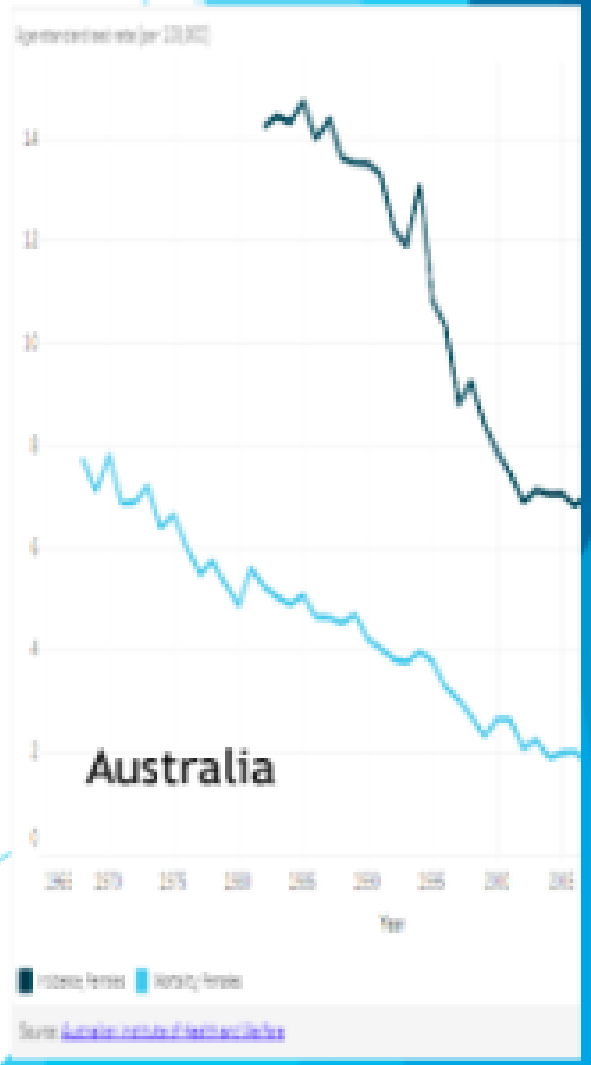
RESULTS : PRE VACCINATION PERIOD

During the 1989-2007 period, the incidence of invasive cervical cancer declined continuously in all countries with pap screening





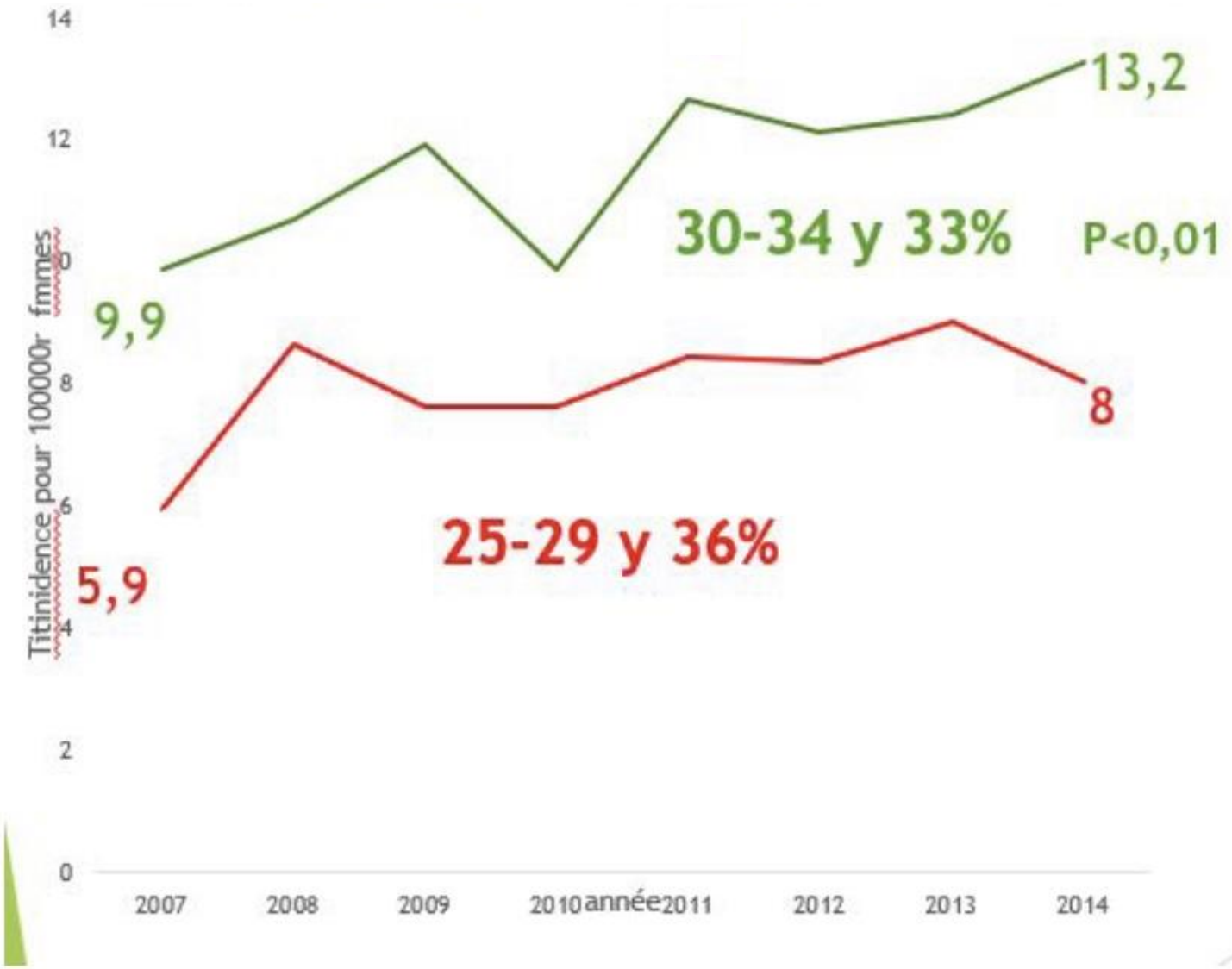




These impressive advances are due to pap screening

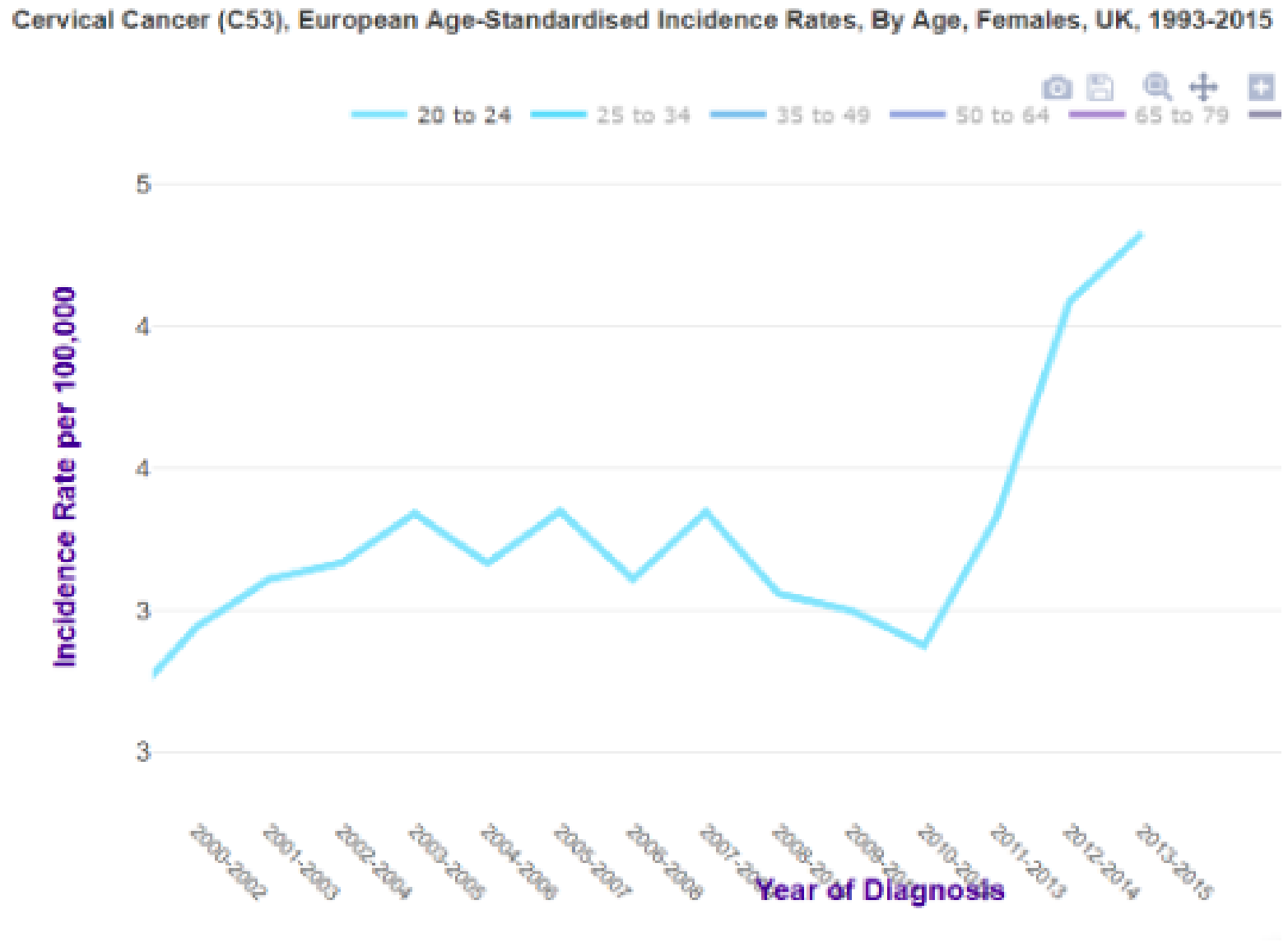
Cervical cancer increase in Australia following vaccine introduction.

Australia Increase of incidence after << catch up vaccines (14-26 y in 2007, 21-33 in 2014) >>



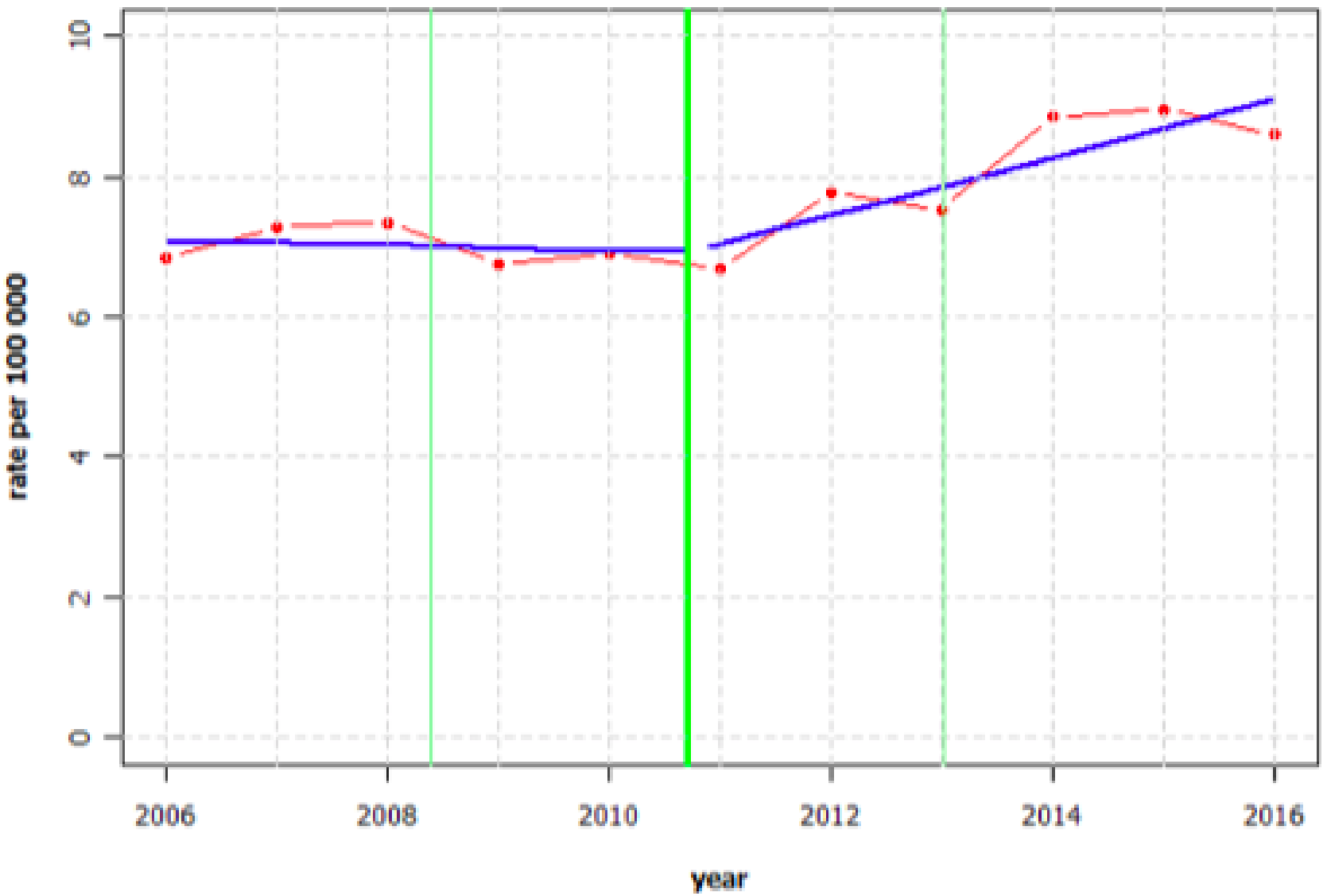
Cervical cancer increase in United Kingdom following the start of the HPV vaccination program.

Figure 1 UK. In the vaccinated age group (20-24) the incidence of invasive cancer jumped up in 2011, (3 years after start of school vaccination campaign. (graphic from cancer Research UK)



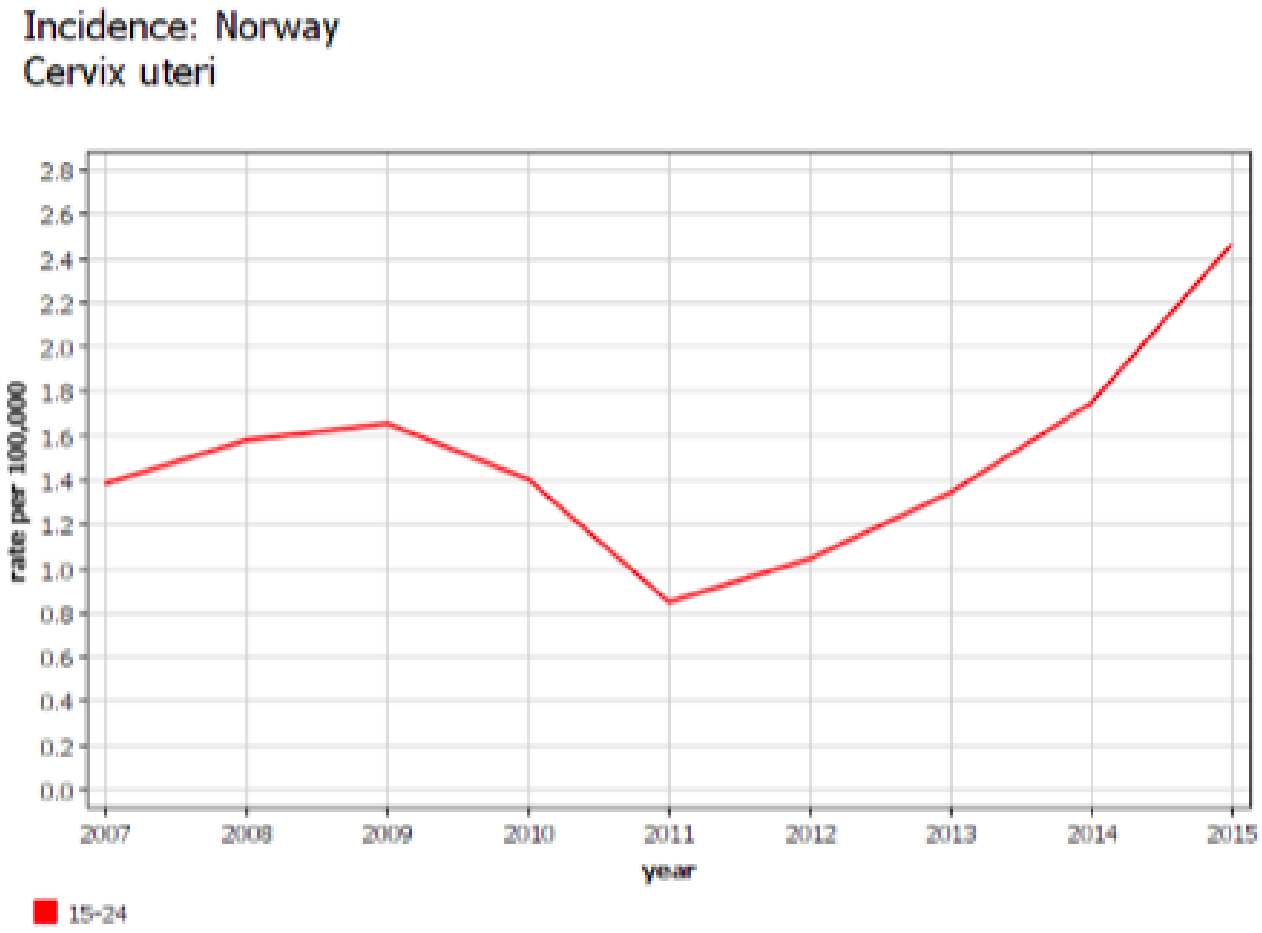
Cervical cancer increase in Sweden following vaccine the start of HPV vaccine campaign.

Figure 2 Sweden. In Sweden breakpoint analysis : the incidence of invasive cancer climbed up from 2011, 2 years after vaccination campaign (graph published by Nordcan 2019 05 29)



Cervical cancer increase in Norway following the beginning of HPV vaccine campaign.

Figure 3. Norway. In the vaccinated age group (15-24) the 3 years smothed incidence of invasive cancer climbed up from 2011, 2 years after vaccination campaign (graph published by Nordcan)



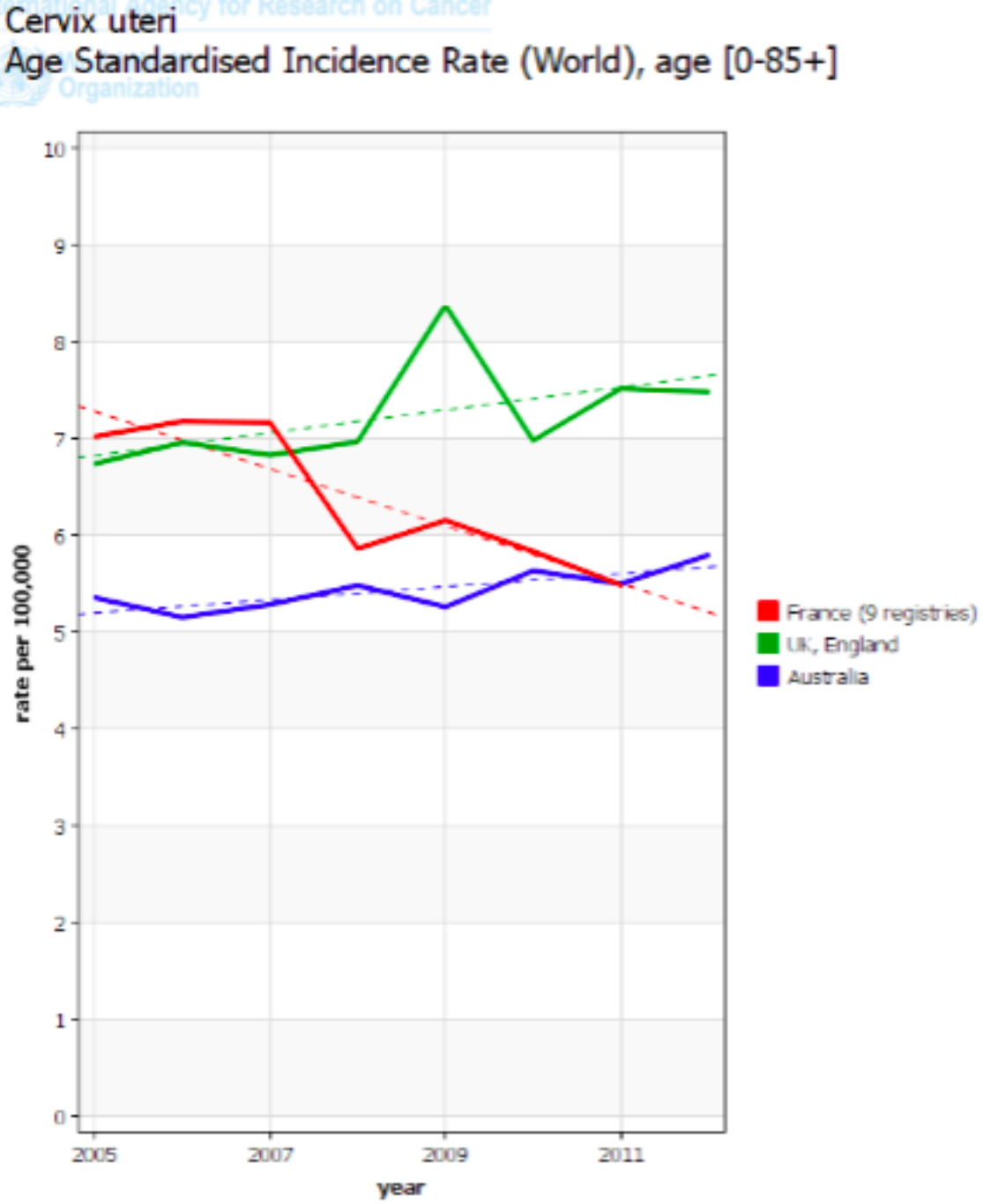


Figure 4: Comparison of the trends of incidence of invasive cervical cancer during the first years of vaccination (2007-2012). The incidence of cervix cancer improved in France and worsened in countries with large vaccination uptake.