

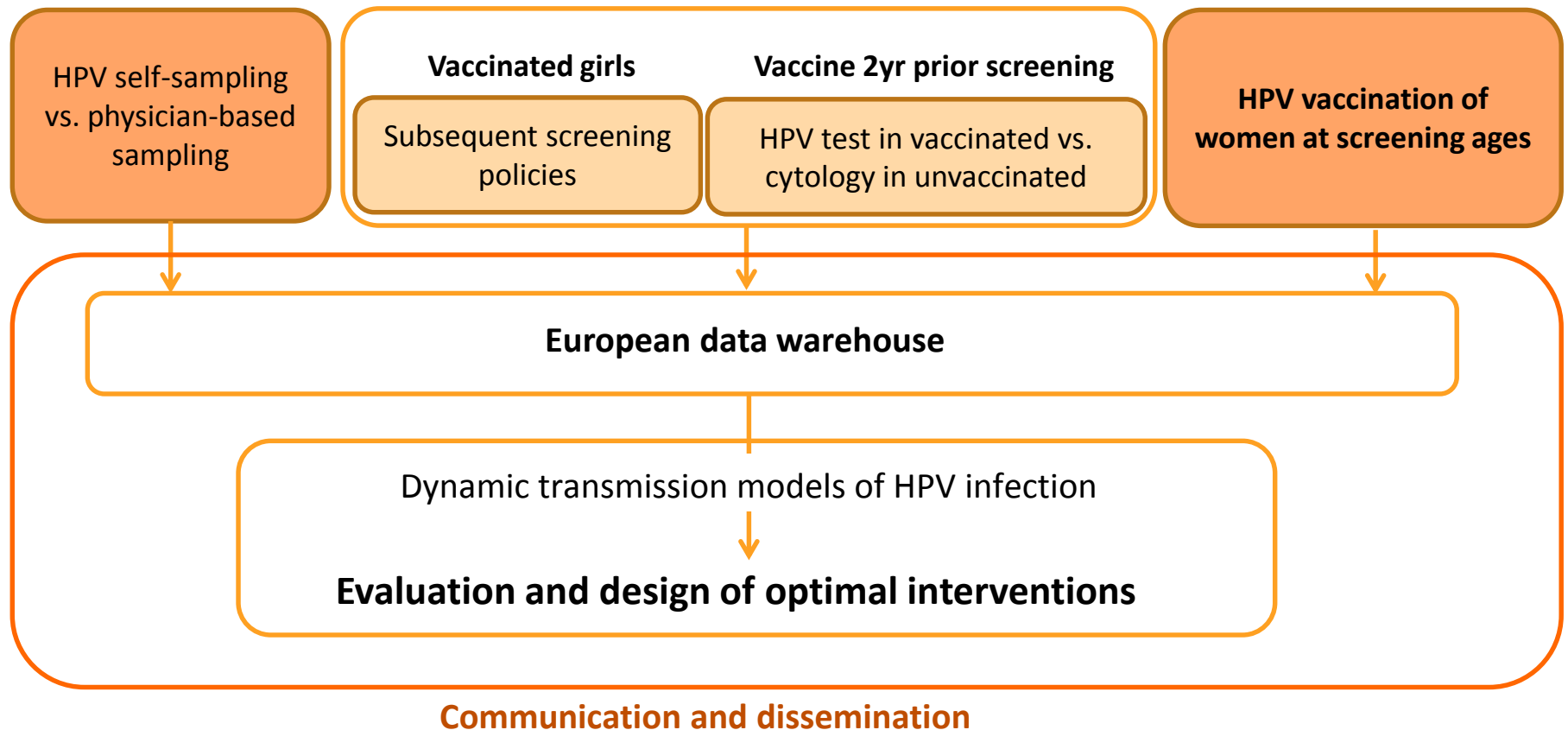
Acceptability of HPV vaccination in adult women: Coheahr WP4

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Eurogin 2016

- ❖ European-funded multidisciplinary consortium in HPV screening and vaccination.
- ❖ Aims to provide a strong evidence base to enable policy makers and other stakeholders to make informed decisions on HPV prevention strategies.
- ❖ The (cost-) effectiveness of different European preventive strategies will be compared.

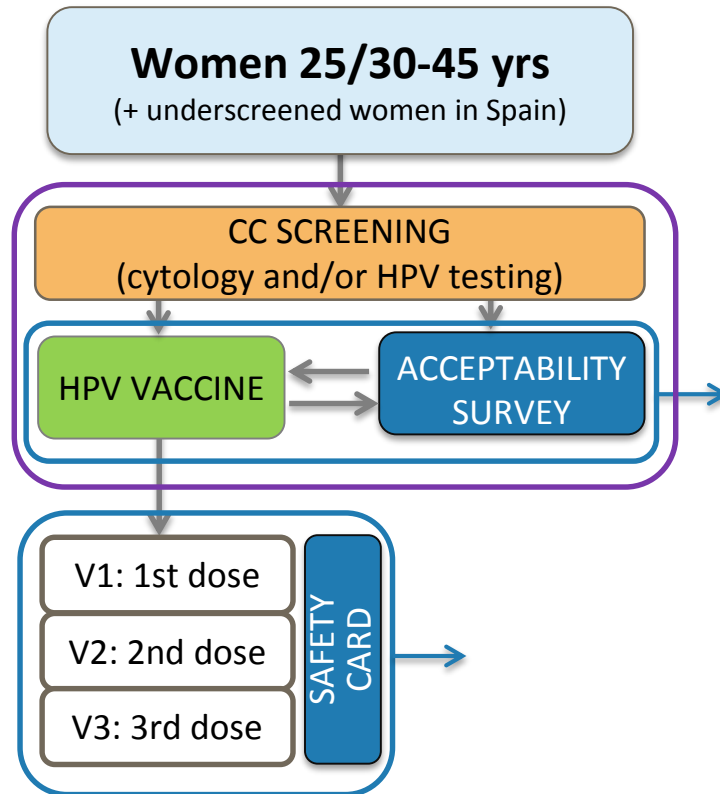


More information: www.coheahr.eu



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Study design and objectives



1. Logistic and Programmatic Issues

- What information and how is it provided?
- Vaccine management
- Best country approach

2. HPV vaccine **uptake** and acceptance **determinants**

3. HPV vaccine **compliance**

4. Monitoring of **adverse events**



Differences by country:

- Target population (age range and HPV status)
- Screening setting → recruitment strategy

Target population

Inclusion criteria



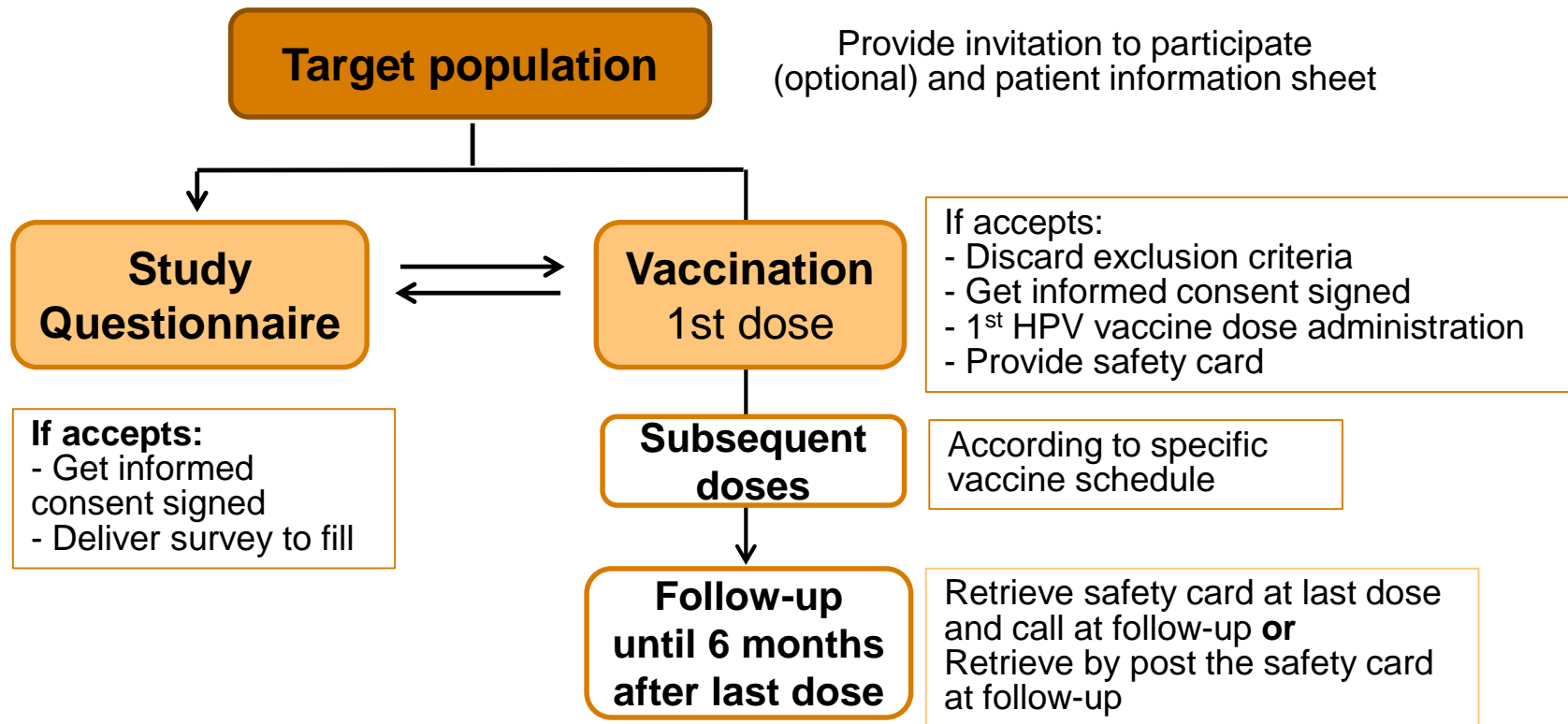
Inclusion criteria

Depends on the country

Country code	Country	Eligible women for vaccination by screening status	Age range (min-max)
1.	Netherlands	Irrespective of tests results	25-45 yrs
2.	Spain	Irrespective of tests results	30-45 yrs
3.	Finland	Screening negative	25-45 yrs
4.	UK	Irrespective of tests results	30-45 yrs
5.	Sweden	Irrespective of tests results	30-45 yrs
6.	Belgium	Irrespective of tests results	25-45 yrs
7.	Italy	Irrespective of tests results	30-45 yrs
9.	Slovenia	Irrespective of tests results	25-45 yrs
10.	Denmark	Irrespective of tests results	30-45 yrs
11.	France	Irrespective of tests results	25-45 yrs
12.	Germany	Irrespective of tests results	25-45 yrs

Study procedures

Standard study procedures algorithm



* Not previously vaccinated and country-specific for age and need of previous/current CC screening results

Data Collection

Study Questionnaire



- Self-filled by the patient or as an interview
- Can be filled in paper, in eCRF or as online survey code-protected
- Estimated time burden:
 - Filling survey: **5'-15'** (self-filled vs interview)
 - Transfer to eCRF (if necessary): **5'**
- Record data on:
 - Background information
 - Knowledge of HPV vaccine
 - Vaccine acceptability

Clinical Data collection

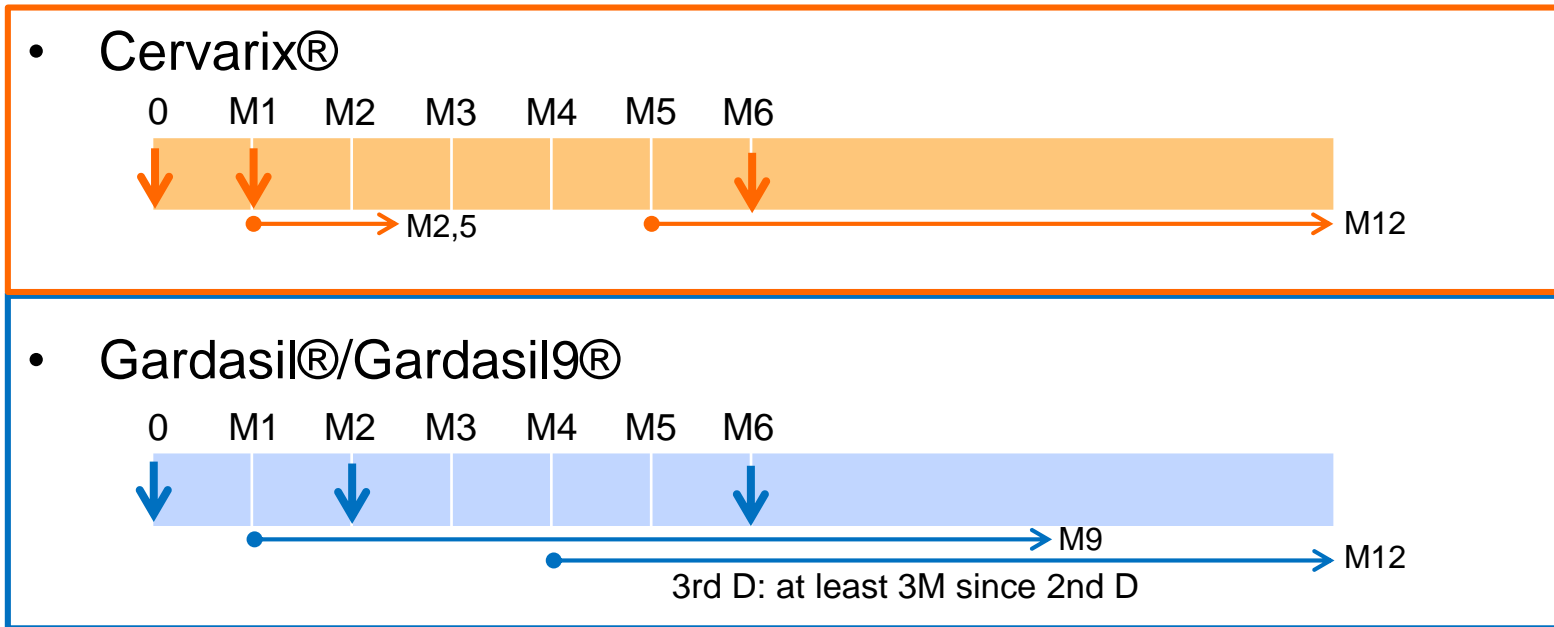


- **Only** for women accepting vaccination
- Record data on :
 - Date and results of recent screening tests performed
 - HPV vaccination dates, batch and reasons for delay, if any
 - Adverse events- Transfer the data from the safety card to eCRF

HPV vaccine Schedule



	NL	SP	FI	UK	SE	BE	IT	SI	DK	FR	DE
Cervarix®	X	X		X		X	X				
Gardasil®									X	X	X
Gardasil9®		X	X		X	X		X			



HPV vaccine schedule

Flexible recommended schedule

Current status of the project

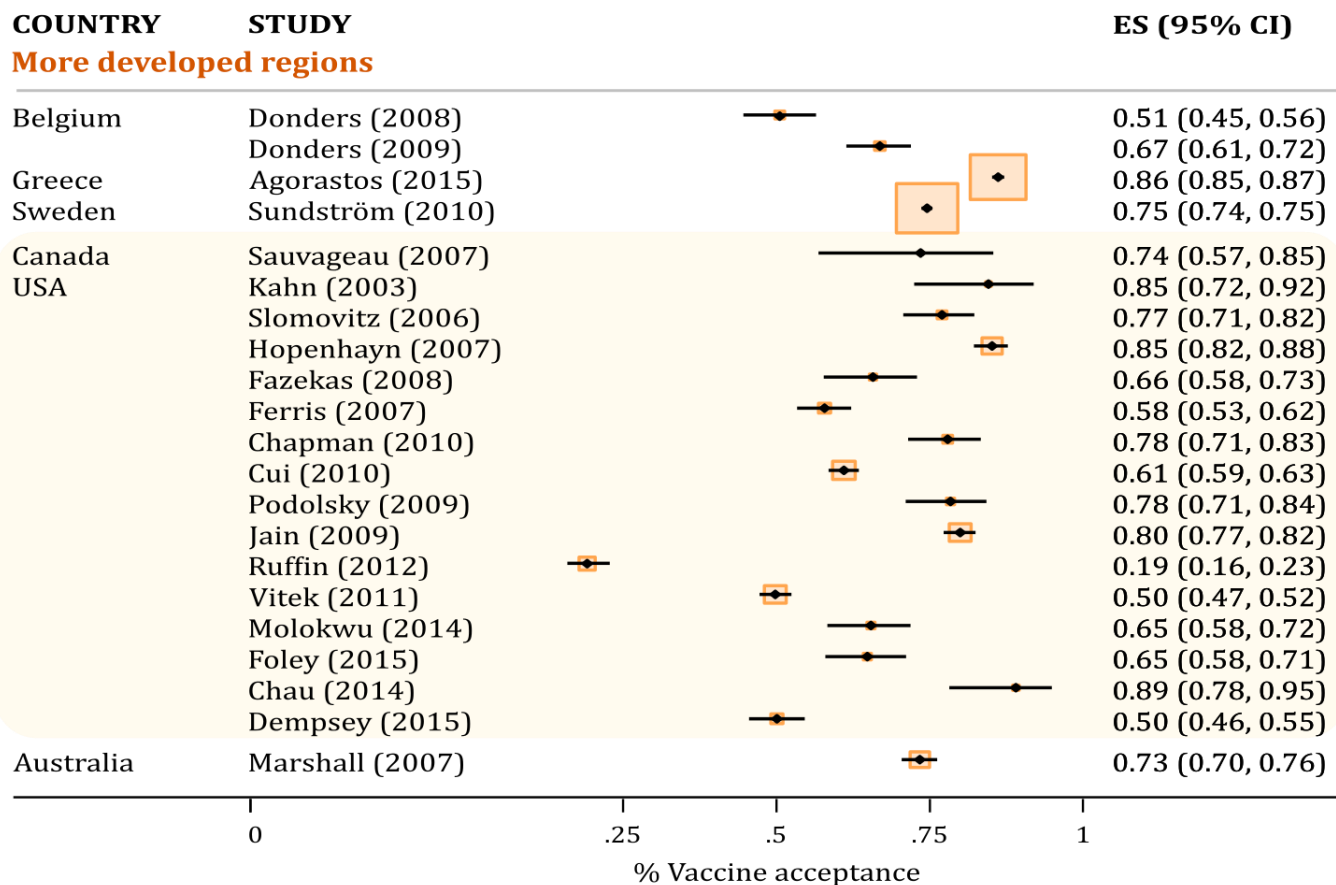


- 11 countries involved in the study
- To our knowledge:
 - 7 Ethics Committee approvals (DK, SP, BE, FR, SL, DE* & FI)
 - 7 Regulatory Authority approvals (DK, SP, BE, FR, SL, DE* & FI)
 - 4 submissions pending of approval (UK, NL, SE & IT)
 - 3 Studies already initiated (BE, FR & SP & DK & DE)

*Approved as a non-interventional study

HPV vaccine acceptance by mid-adult women

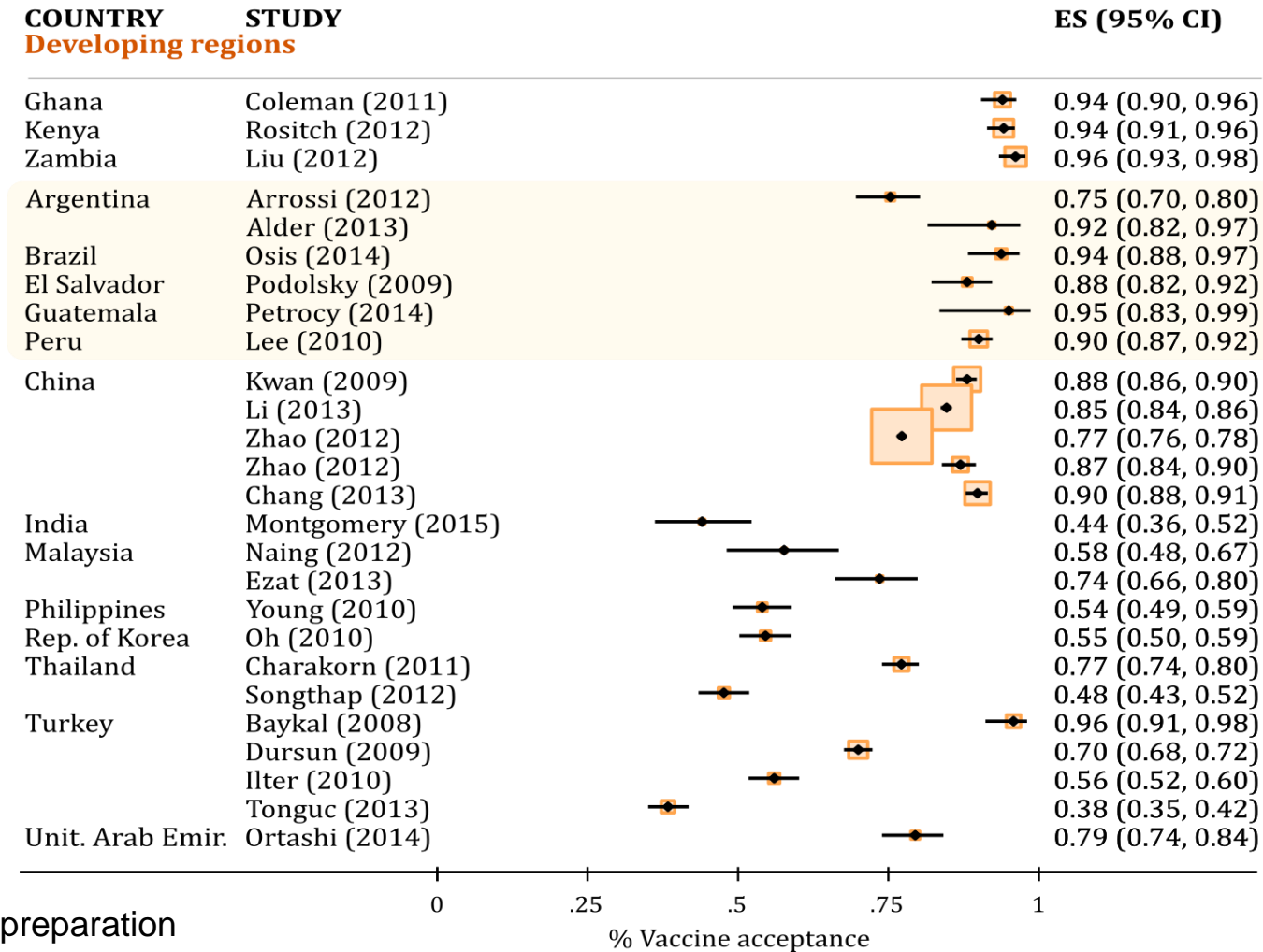
Developed regions



Robles et al. in preparation

HPV vaccine acceptance by mid-adult women

Developing regions



Robles et al. in preparation

Summary



- ❖ Slow process as in any study considered a trial
- ❖ Provisional average to good acceptance
- ❖ Satisfactory clinical process as per personal communication with local teams