



PROTECT: The Challenges and Successes

Successes and challenges of collecting data from
consumers as part of a public private consortium

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& Therapeutic Risk Management
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Disclaimer

I am a full-time employee of Quintiles.

Quintiles undertakes work for many pharmaceutical companies but I receive no personal consultancy fees

The views expressed are those of the speaker and should not be taken to represent the views of Quintiles or its related companies

The views expressed should not be taken to represent the views of my former employer: the European Medicines Agency.

“The PROTECT project has received support from the Innovative Medicines Initiative Joint Undertaking (www.imi.europa.eu) under Grant Agreement n° 115004, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.”

WP 4 Active Participants

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Omer de Mol	Genzyme- WPL
Stella Blackburn	Quintiles (WPL 2009-14)
Bina Patel	Amgen- alt. WPL
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Simon Thomas, Luke Richardson, Sally Stephens	University of Newcastle
Rebecca Johnson	IAPO
Shahrul Mt-Isa, Christine Hallgreen, Deborah Ashby	Imperial College
Valerie Hliva	Quintiles
Anna Latos-Bielensca, Anna Jamry	University of Poznan
Jens Peter Balling	Lundbeck (WPL 2009-2013)
Alison Bourke	IMS Cegedim Strategic Data
Pfizer	Financial Support
GSK	Logistics Support

New tools for data collection from consumers

An exploratory study of self-reported medication use in pregnant women and pregnancy outcomes

Objectives

To assess the extent to which data collected directly from pregnant women via the Internet and IVRS provides information on medication use and other potential risk factors throughout pregnancy, and is suitable for research purposes



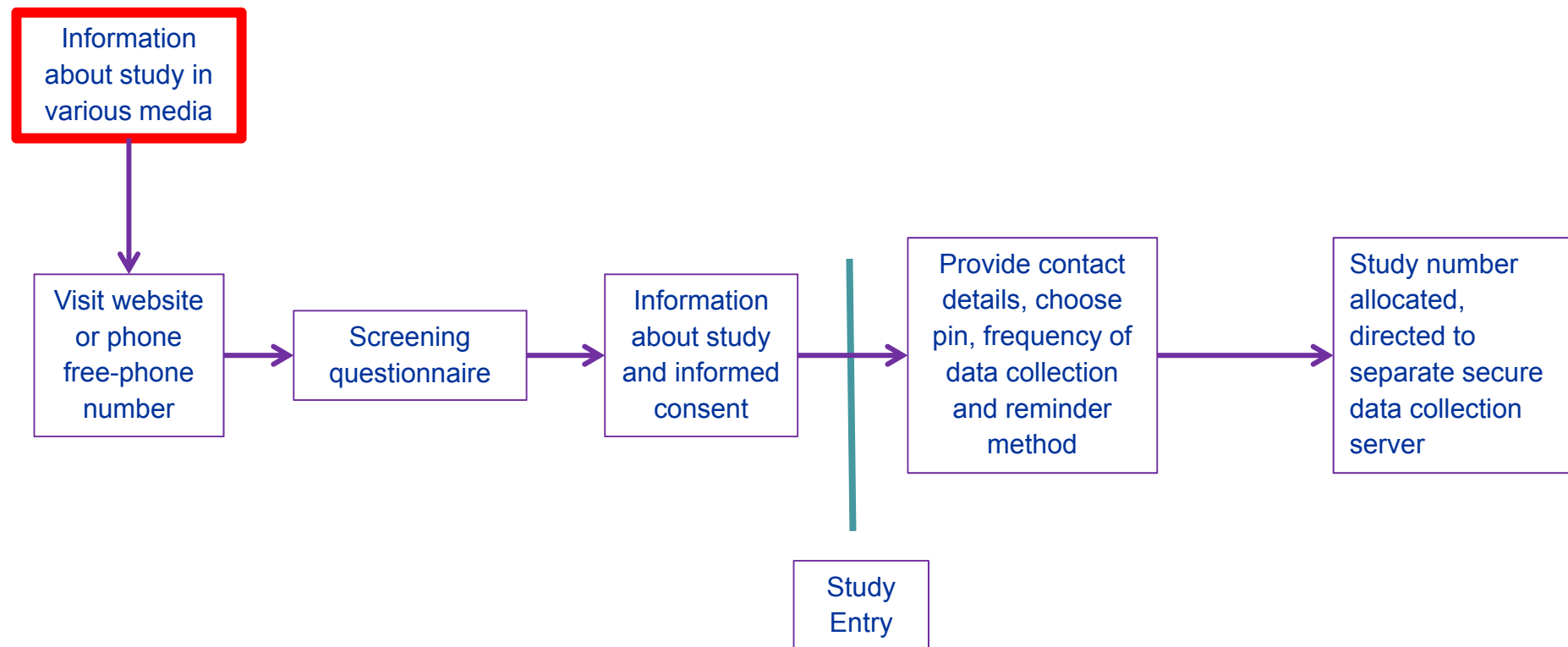
An exploratory study of self-reported medication use in pregnant women and pregnancy outcomes

Questions:

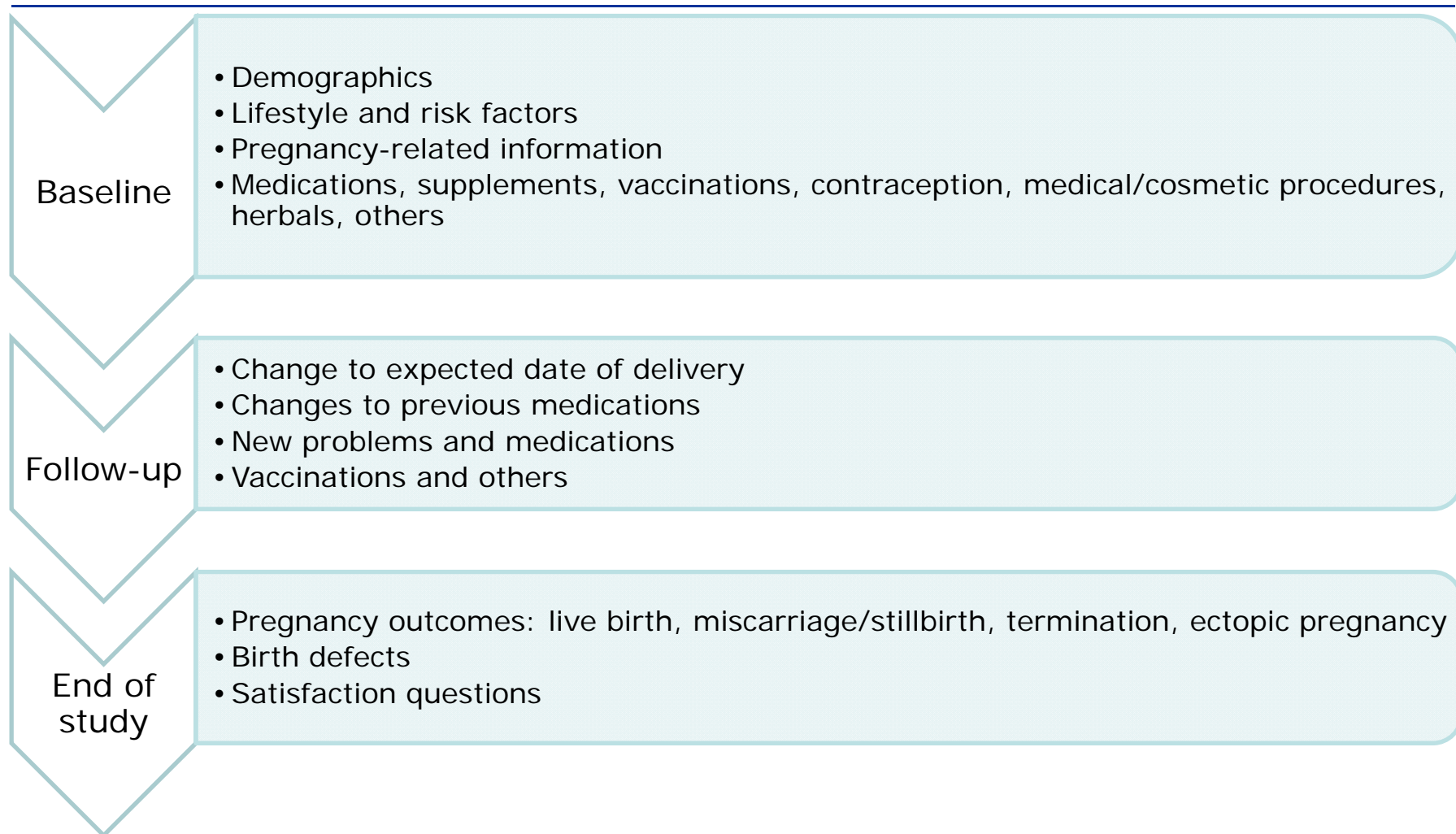
- Can we get data earlier in pregnancy than traditional routes?
- How consistently and for how long will women provide the data requested?
- How representative are the women?
- How important are data *not* captured by EHR or pharmacy databases?
- Is the information of sufficient quality to be used for pharmacovigilance?



Study entry process

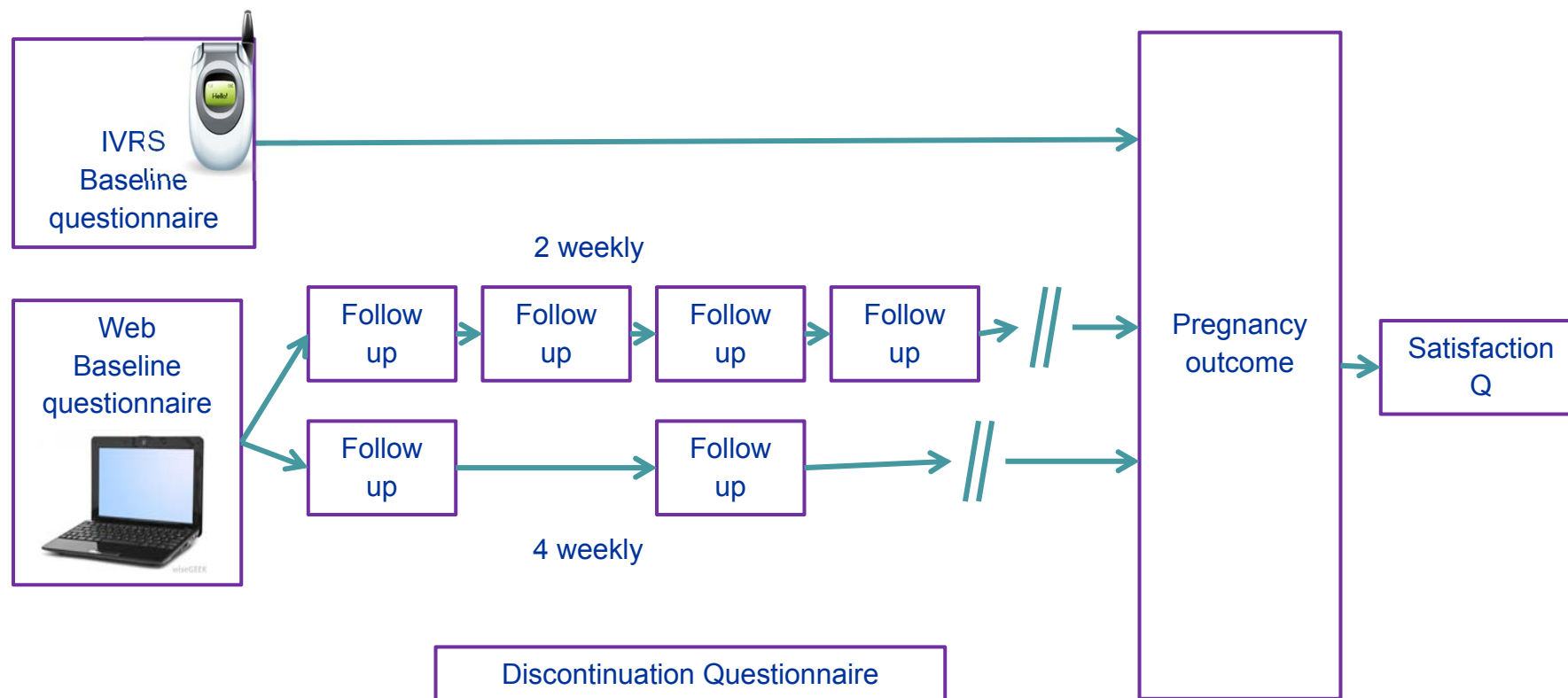


Data collected





Technology



Four languages



Welcome

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium



PROTECT Pregnancy study

Click on this flag if you live in the UK and you would like to learn more about our study.



PROTECT Zwangerschap studie

Klik op deze vlag indien u in Nederland woont en meer te weten wilt komen over onze studie.



PROTECT Graviditetsstudie

Klik på dette flag hvis du bor i Danmark og gerne vil vide mere om studiet



PROTECT Projekt badawczy dla kobiet w ciąży

Jeśli mieszka Pani w Polsce i chciałaby otrzymywać dodatkowe informacje na temat projektu proszę kliknąć na flagę.







The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking (www.imi.europa.eu) under grant agreement n° 115004, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

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Country specific protocol differences

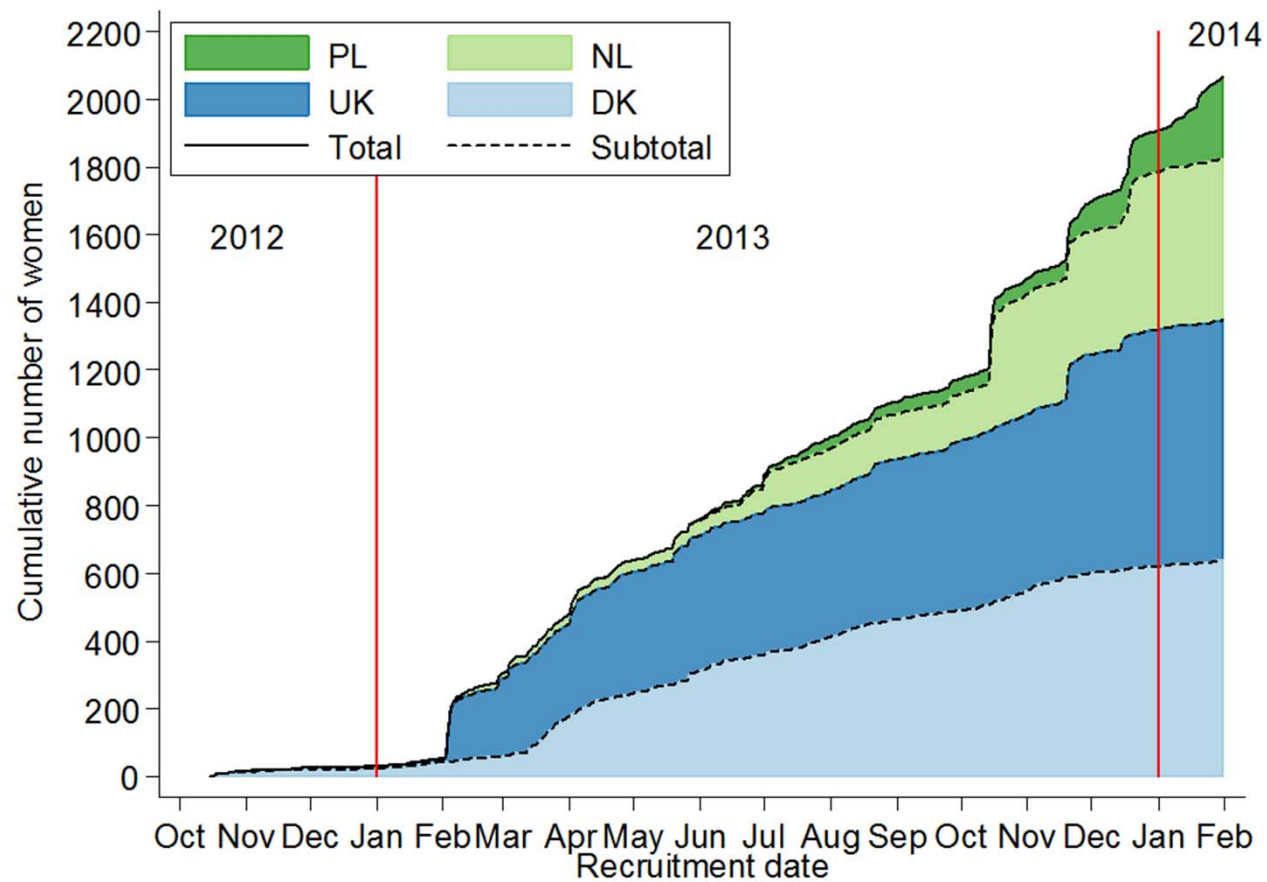
	Denmark	The Netherlands	Poland	United Kingdom
Country Lead	Statens Serum Institute	University of Groningen	Poznan University of Medical Sciences	University of Newcastle
Minimum age	18	18	18	16
Informed Consent	Electronic only	Both internet and IVRS	Written informed consent	Both internet and IVRS
Ethical Approval	Not required	Waiver (certificate of non objection)	1 week	3 weeks

Data protection

Denmark	The Netherlands	Poland	United Kingdom	EMA
3 months	1 day	9 months	2 weeks	3 months opinion, 5 months prior check

BUT

Slow recruitment

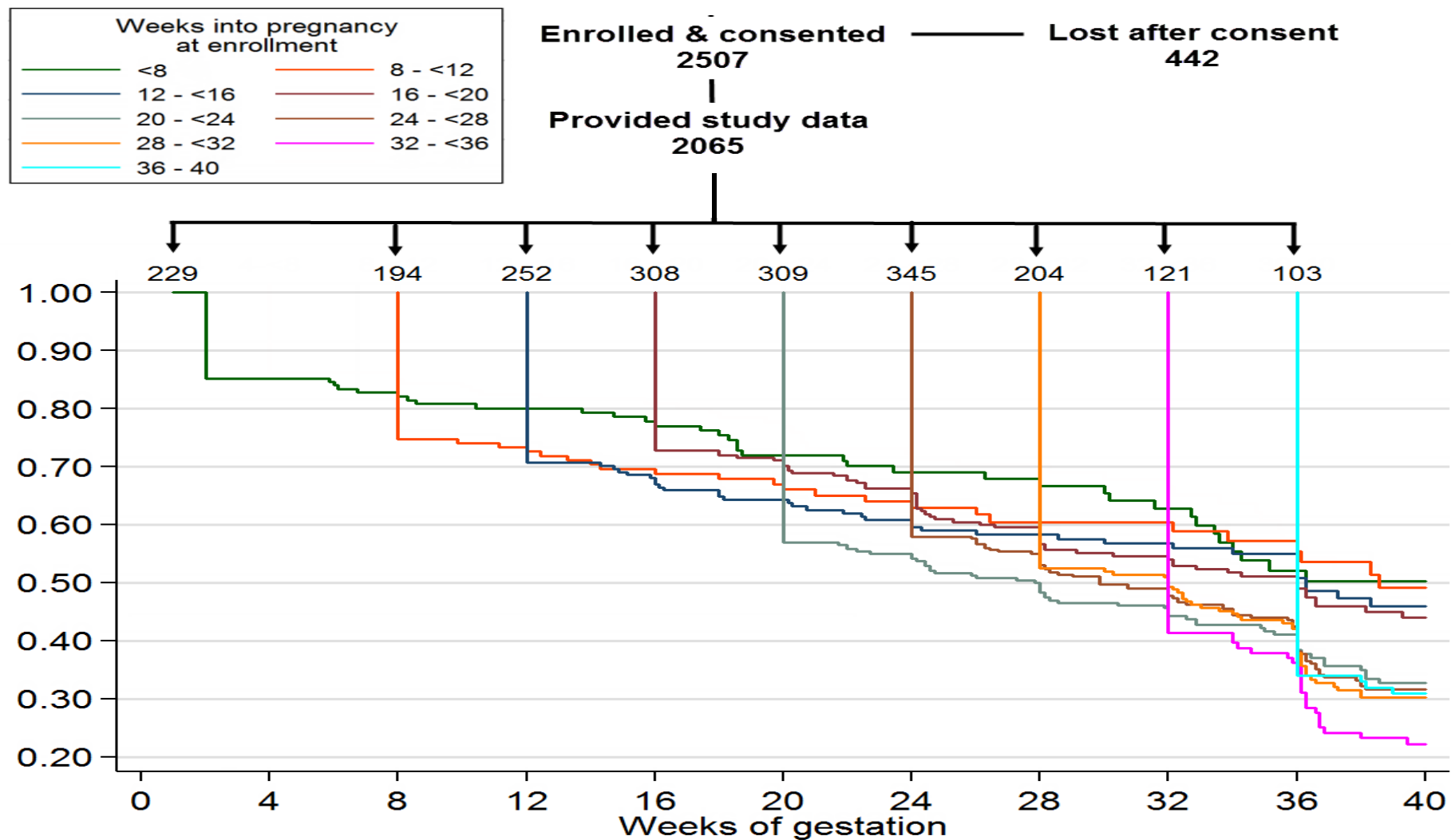


PROTECT

Examples of the media used to advertise the study



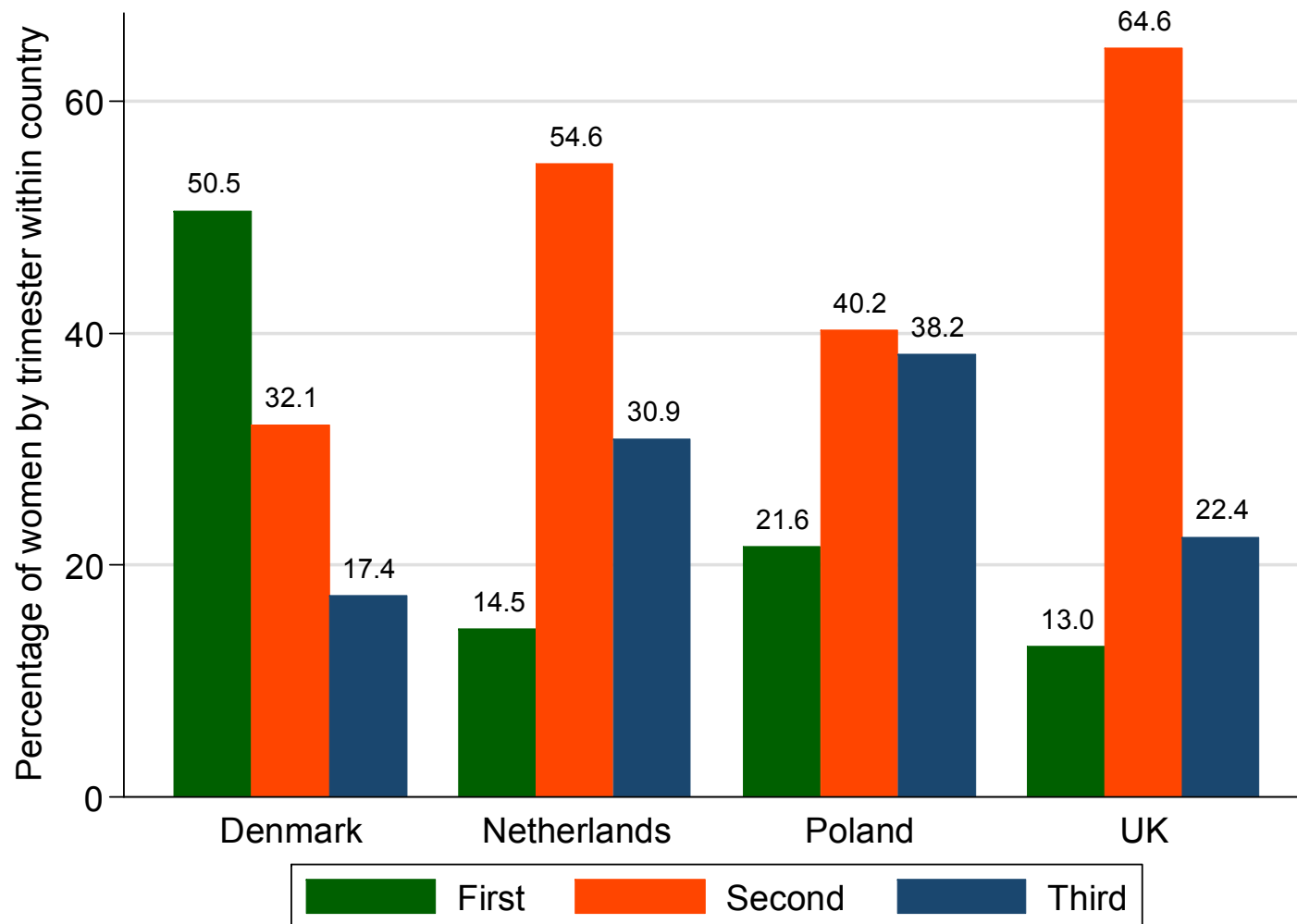
Attrition



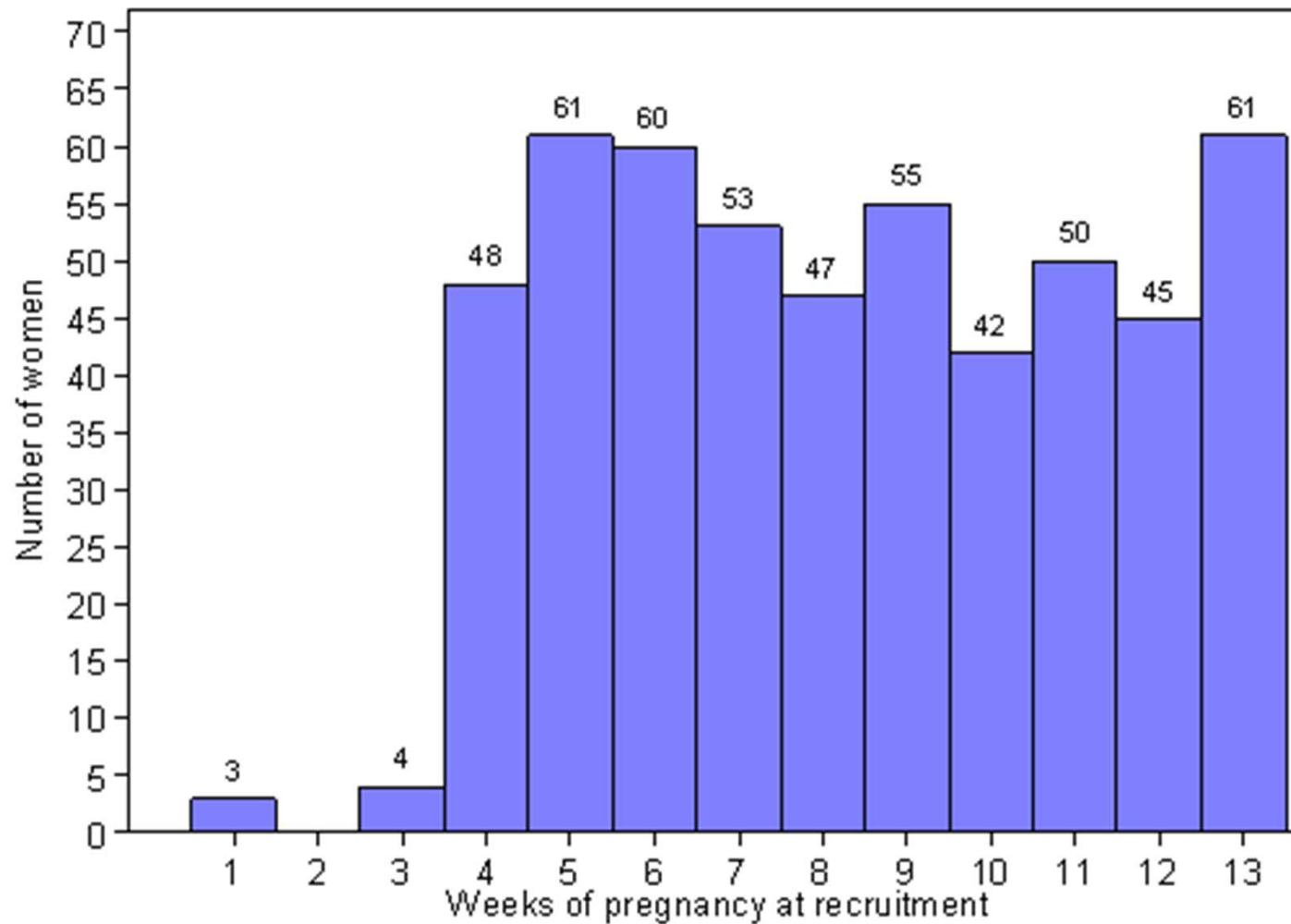


2065

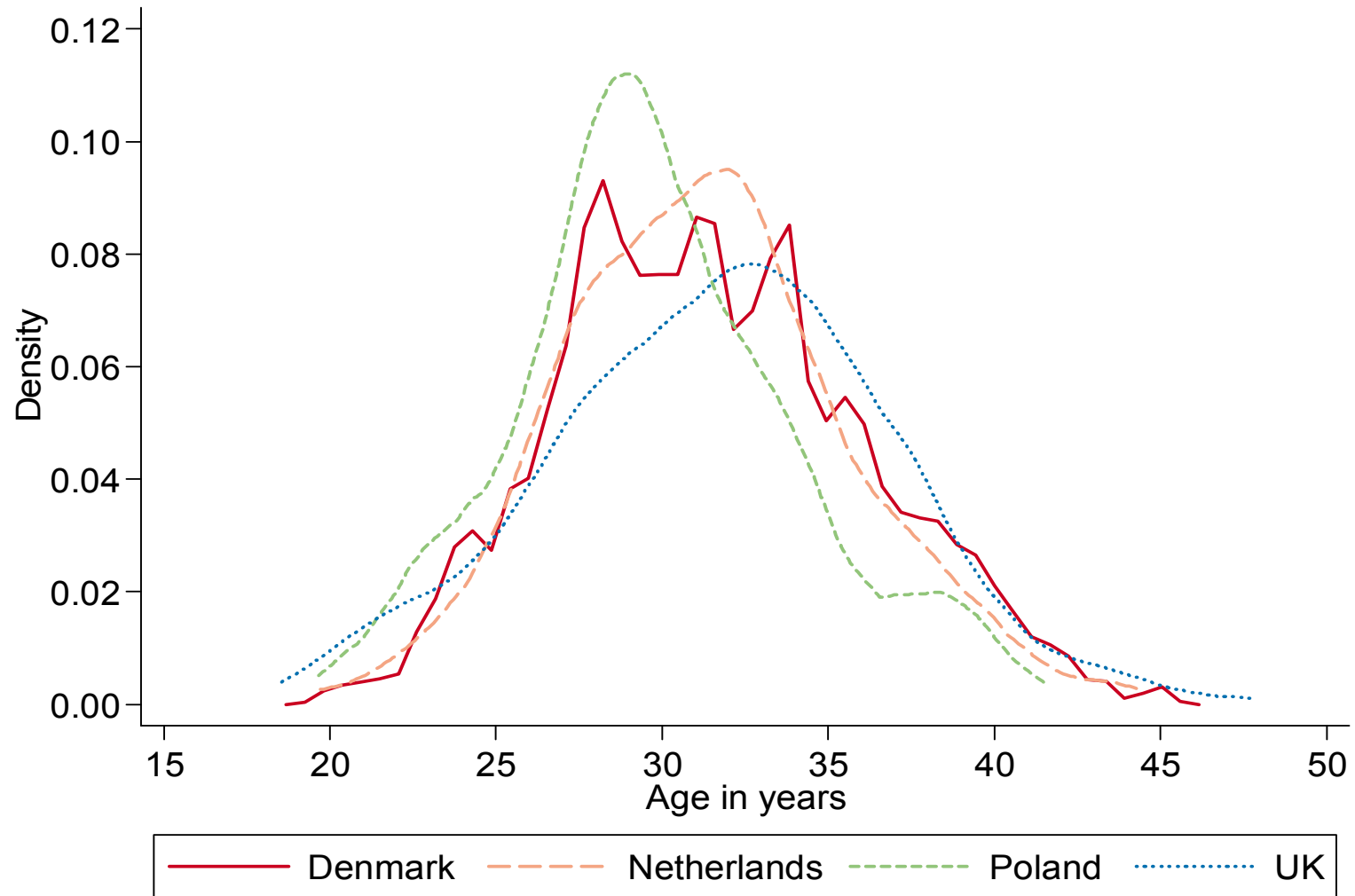
Enrollment by trimester (N=2065)



Enrollment during first trimester (N=529)



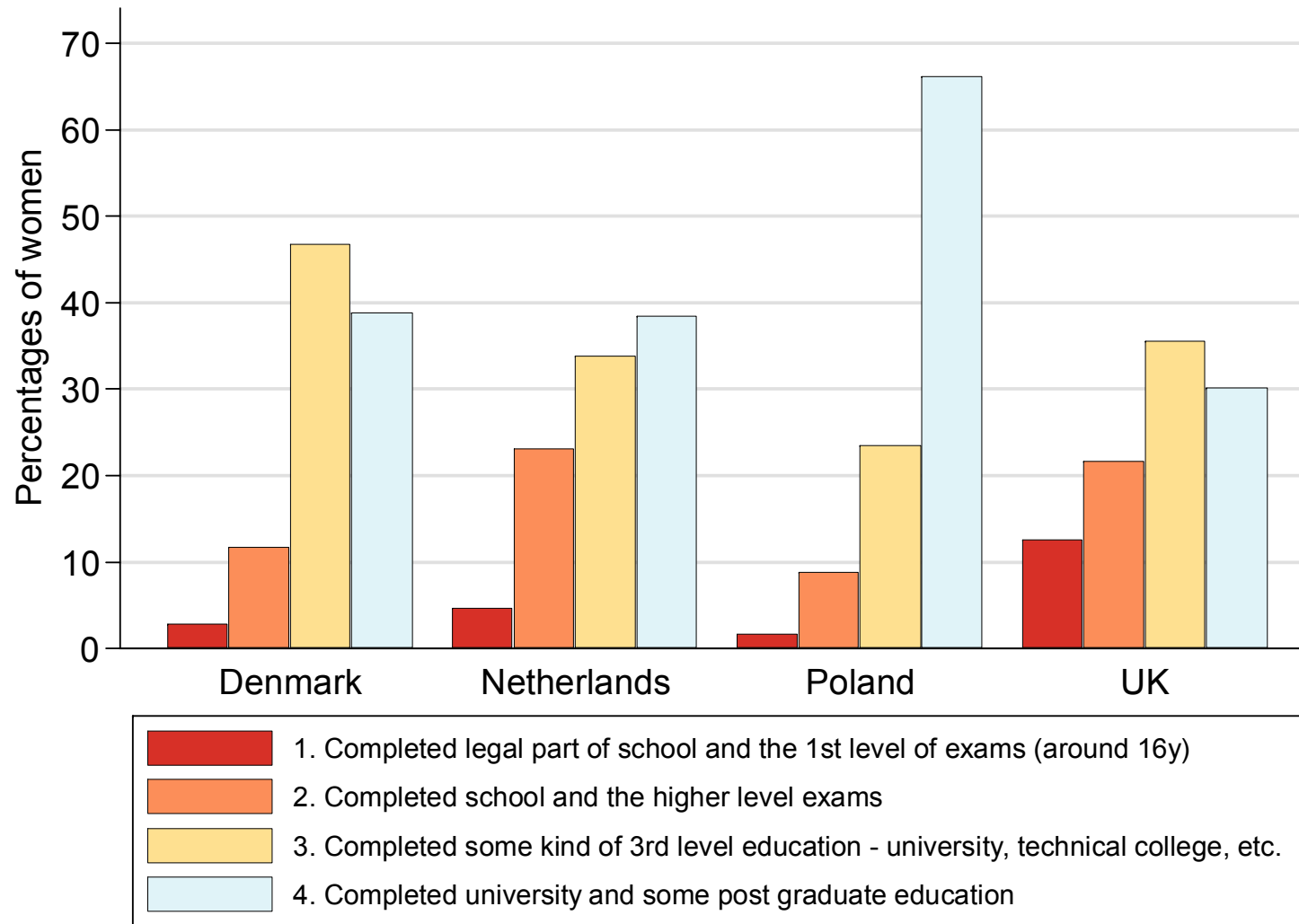
Age at end of pregnancy



Height, weight and BMI

	DK	NL	PL	UK
Weight before pregnancy, mean (SD) kg	70.1 (14.6)	70.7 (12.9)	62.6 (11.7)	71.6 (17.6)
Height, mean (SD) cm	169.3 (6.7)	170.6 (9.2)	166.6 (6.2)	164.8 (13.7)
BMI, mean (SD)	24.4 (4.7)	24.6 (9.1)	22.5 (3.6)	27.4 (13.2)
BMI	%, (no.)	%, (no.)	%, (no.)	%, (no.)
<18	2.2 (14)	0.4 (2)	4.6 (11)	2.0 (14)
18 - <25	62.9 (402)	63.9 (304)	75.5 (182)	50.8 (360)
25 - <30	22.8 (146)	27.1 (129)	12.4 (30)	23.3 (165)
30 - <35	8.5 (54)	6.9 (33)	2.9 (7)	12.6 (89)
≥35	3.6 (23)	1.7 (8)	1.2 (3)	9.9 (70)
Missing	0.0 (0)	0.0 (0)	3.3 (8)	1.6 (11)

Education by Country



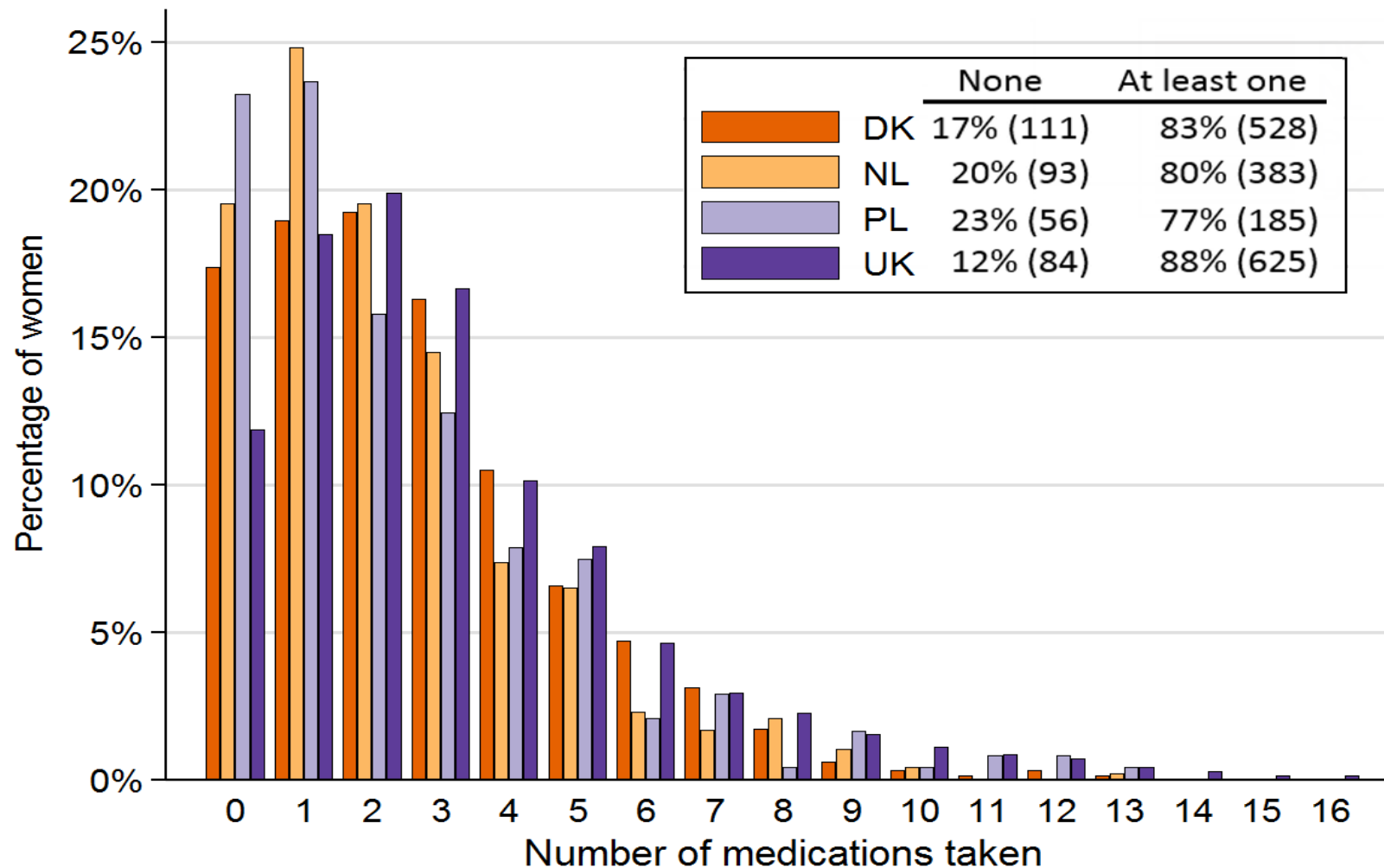
Current pregnancy and gravidity

	DK	NL	PL	UK
First pregnancy	38.3% (245)	47.3% (225)	50.6% (122)	41.6% (295)

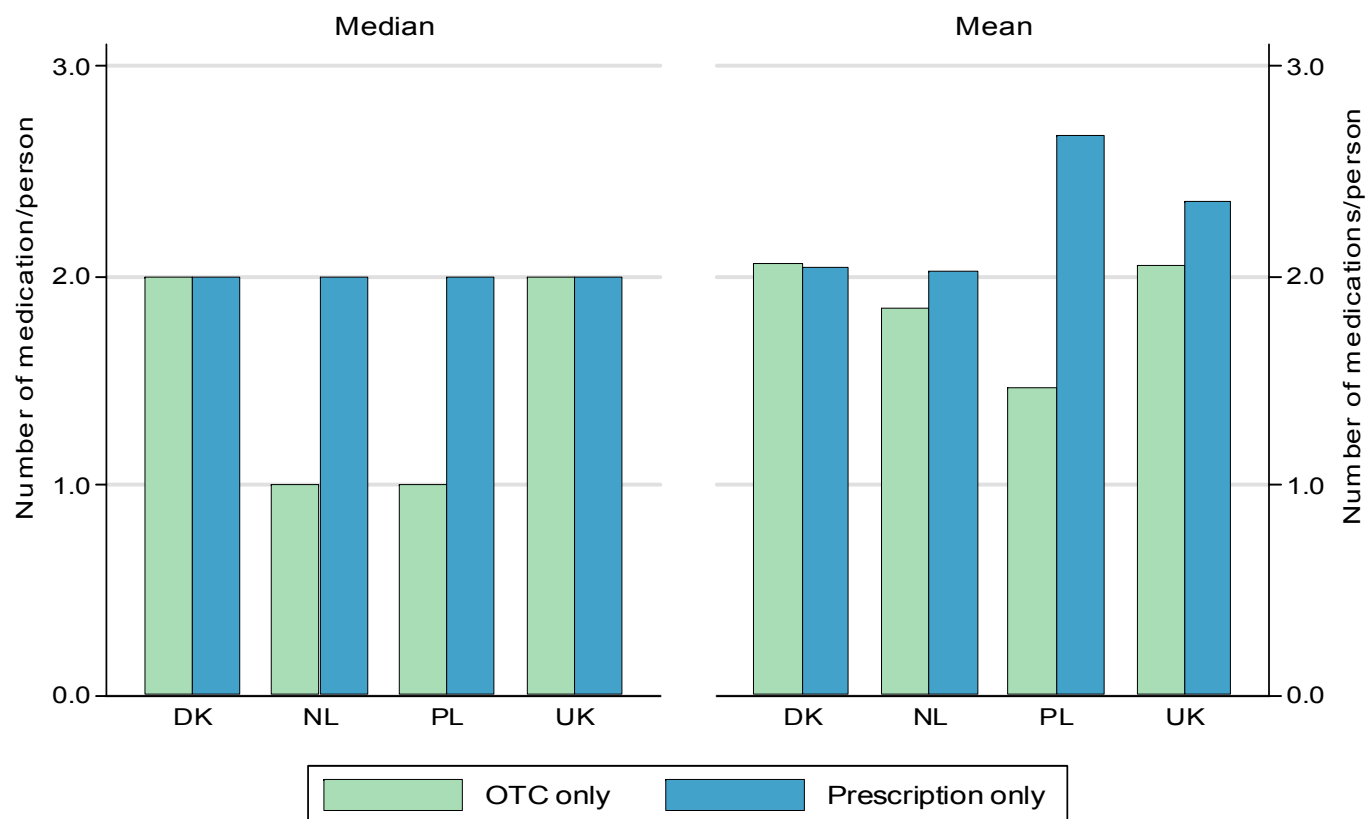
Outcomes: median (range) from previous pregnancies

	DK	NL	PL	UK
Number of previous pregnancies	1 (1 - 12)	1 (1 - 13)	1 (1 - 5)	2 (1 - 12)
Live birth	1 (0 - 5)	1 (0 - 4)	1 (0 - 3)	1 (0 - 9)
Miscarriage	1 (0 - 10)	1 (0 - 13)	1 (0 - 3)	1 (0 - 11)
Elective termination	1 (0 - 4)	1 (0 - 2)	1 (0 - 1)	1 (0 - 3)
Stillbirth	1 (0 - 1)	1 (0 - 1)	1 (0 - 1)	1 (0 - 1)
Ectopic	1 (0 - 1)	1 (0 - 1)	1 (0 - 1)	1 (0 - 1)

Number of medications



No. of OTC and Prescription medicines



Life style factors

	DK (%)	NL (%)	PL (%)	UK (%)
Pregnant while using contraception	3.3	3.2	2.5	6.1
Took “morning after pill”	0.3	2.1	0.8	1.3
Smoker before pregnancy	16.6	14.3	18.7	16.1
Smoker during pregnancy	4.1	4.2	4.6	4.8
Alcohol				
2-3 times / week	0.3	0.2	0.0	0.6
2-4 times/month	6.1	0.6	0.0	10.7
≤ 1 per month	20.7	6.1	11.6	21.4
Never	72.6	92.6	87.6	66.6
Unknown	0.3	0.4	0.8	0.6
<i>Recreational drug use</i>	<i>0.9</i>	<i>0.4</i>	<i>0.4</i>	<i>1.1</i>
<i>Undisclosed recreational drug use</i>	<i>0.6</i>	<i>0.2</i>	<i>2.9</i>	<i>0.4</i>

Other medication use & risk factors

	DK (%)	NL (%)	PL (%)	UK (%)
Decided not to take a prescribed medicine	4.9	4.0	4.6	5.5
Took prescribed medicine from friend or family	0.3	0.6	0.4	0.7
Anaesthetics	4.9	8.8	11.6	7.1
General	0.6	1.1	0.4	0.6
Spinal	0	0	0	0.3
Local	4.1	7.6	10.0	5.9
Did not know type	0.2	0.2	1.2	0.3
X rays	6.9	4.6	3.7	4.9
Herbal medicines	4.3	7.8	0	6.6
OTC medications*	68.5	65.1	47.3	76.4

* Includes those available through both prescription and OTC

Conclusions

- It is possible to recruit women early in pregnancy before they may have consulted HCPs
- Direct to consumer studies offer important benefits in collecting certain data not found in EHR
- Data protection and informed consent can be challenging
- It is important to budget for recruitment costs
- More thought needs to be given to how to retain women in the study.