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Primary Care Physicians' access to in-house ultrasound examinations across Europe: A questionnaire study.

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Abstract

Objective: The aim of this study was to examine the differences in ultrasound-availability in primary care across Europe.

Design: Cross-sectional study

Setting: Primary care

Participants: Primary Care Physicians (PCPs)

Primary and secondary outcomes: The primary aim was to describe the variation in in-house primary care ultrasonography availability across Europe. We also aimed to describe the association between inhouse ultrasonography availability and the characteristics of PCPs and their clinics.

Results: The proportion of PCPs with access to in-house ultrasonography across Europe varied from 0% to 98% for abdominal ultrasonography and 0% to 31% for pelvic ultrasonography. Overall, less than half of the PCPs surveyed had direct access to in-house diagnostic ultrasonography. We found associations between in-house ultrasonography availability and larger clinics, and clinics with medical doctors specialised in areas, which traditionally use ultrasonography. We also found an association between non-urban clinics and in-house pelvic ultrasound

Conclusions: Across Europe, there is a large variation in PCPs' access to in-house ultrasonography and organizational aspects of primary care seem to determine this variation. If evidence continues to support ultrasonography as a frontline point-of-care test, implementation strategies for increasing its availability in primary care are needed. Future research should focus on facilitators and barriers that may affect the implementation process.

Strengths and limitations

- Primary care physicians were recruited from 20 European countries.
- A protocol defining the outcome measures was written before access to the data was granted.
- A convenience sample chosen by national leads was used, which may not be representative of their nations as a whole.
- This study examines secondary data; the survey questions were not specifically designed for this analysis.

Introduction

Traditionally, ultrasound examinations were performed primarily by trained radiologists using high-end devices. However, the development in technology has made ultrasound devices smaller, better and cheaper, and thereby more accessible to clinicians [1,2]. Today, diagnostic ultrasonography is performed either by an imaging specialist for a full comprehensive description of organ anatomy and pathology, or as a bedside point-of-care test where the clinician uses it in relation to the physical examination to rule in or rule out specific conditions [1,3]. Indeed, ultrasound examinations are increasingly used in both primary and secondary care to improve diagnosis and facilitate patient pathways [4-6].

Whereas the use of ultrasonography in secondary care is well described [1,4,7], literature on the its use in primary care is sparse [5,6,8]. Studies have suggested that point-of-care ultrasonography performed by primary care physicians (PCP) may lead to improved diagnostic accuracy [5,9]. Additionally, General Practitioners (GPs) with access to diagnostic tests have been found to diagnose, treat, and refer patients more appropriately [10]. These findings suggest that in-house availability of ultrasonography in primary care may improve patient care.

Ultrasound examinations in primary care may be performed by both specialists [11] and GPs [12], depending on the varying organisation of health care systems across Europe [13,14]. The availability and use of ultrasound examinations in primary care differs between countries: experts have previously estimated that the proportion of primary care users across Europe varies from less than 1% to 67% [15], and in-house availability of ultrasonography varies from 4% to 58% in the Nordic countries alone [16]. We do not know what determines this variation, or the extent to which PCP and clinic characteristics are associated with the likelihood of inhouse availability of ultrasonography.

The aims of this study were to describe the variation in in-house primary care ultrasonography availability across Europe, and the association between this availability and the characteristics of PCPs and their clinics.

Material and method

Our study was a secondary analysis of data from the Örenäs survey [17]. The Örenäs survey investigated the influence of health system factors on the way that European PCPs manage their patients. As well as collection of demographic data, there was collection of data on PCPs' inhouse access to diagnostic abdominal and pelvic ultrasonography. In the present study, this access is compared with the demographic data. A predefined protocol was developed prior to accessing the data (see supplementary file 1).

The questionnaire was piloted twice by PCPs in 16 Örenäs Research Group centres. Translations of the questionnaire into local languages were made where these were not English. Translation was validated by back-translation to assess semantic and conceptual equivalence and is described elsewhere [18]. The questionnaires were put online using SurveyMonkey (SurveyMonkey, California, USA).

Participants and recruitment

The study was conducted in 25 Örenäs Research Group centres in 20 countries across Europe.

Subjects were eligible for the survey if they were GPs or had specialist training, but worked in the community and could be accessed directly by patients without referral.

Each Örenäs Research Group local lead emailed a survey invitation to the PCPs in their local health district, with the aim of recruiting at least 50 participants. This allowed recruitment of a varied sample with regards to gender, years since graduation, site of practice (urban, rural, remote), and size of practice. Consent was implied by agreeing to take part in the survey.

Data collection:

Access to ultrasonography

Participants were asked if abdominal or pelvic diagnostic ultrasonography was available to them in: 1. Their own practice, 2. At their request outside their practice, or 3. Not directly available to them, or only available via a specialist. We divided this into: *Access to in-house abdominal ultrasonography* (AbdUS) and *No access to in-house AbdUS* (including access at their request outside their practices, not directly available to them, or only available via a specialist) and correspondingly: *Access to in-house pelvic ultrasonography* (*PelUS*) and *No access to in-house*

PelUS. Hence, the variables *In-house access to AbdUS* and *In-house access to PelUS* included direct access to diagnostic ultrasonography in respondents' own practices.

Countries included

The survey was circulated in 20 countries across Europe: Bulgaria, Croatia, Denmark, England, Finland, France, Germany (Essen and Munich), Greece, Israel, Italy, Netherlands, Norway, Poland (Bydgoszcz and Białystok), Portugal, Romania, Scotland, Slovenia, Spain (Barcelona, Galicia, and Mallorca), Sweden and Switzerland.

Characteristics of the PCPs

PCPs were characterised by: *Gender*: male/female, *Level of seniority*: <10 years of experience as a medical doctor and ≥ 10 years (including 10-19, 20-29, 30-39, 40 years or over), and *Speciality of the PCP*: GP/not GP (including specialists in ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics, other).

Characteristics of the clinics

PCPs' clinics were characterised by: *Location:* urban or non-urban (including rural, island, mixed), and clinic size (*Number of PCPs in the clinic*: solo (1 PCP), small (2-5 PCPs), medium (6-9 PCPs), and large (10 or more PCPs)).

In the survey, participants were asked if they had colleagues qualified in different specialties (ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics or other). We assessed the proportion of PCPs with colleagues in their clinic who were qualified in a speciality in which ultrasonography is traditionally used. We estimated this as the *Proportion of PCPs having specialist in internal medicine* in their clinic and the *Proportion of PCPs with an obstetrician/gynaecologist colleague in their own clinic.* Finally, we noted any free-text comments that the PCPs had a *Sonographer/radiologist colleague in the clinic*, elaborated under the reply "other". Free text comments were translated using Google Translate.

Ethics

Ethical approval for the original study was given by the University of Bath Research Ethics

Approval Committee for Health (approval date: 24th November 2014; REACH reference

number: EP 14/15 66). Other countries' study leads either achieved local ethical approval or

gave statements that formal ethical approval was not needed in their jurisdictions (see supplementary file 2).

Patient and public involvement

Patients were not involved in this study

Statistics

We calculated the proportions of PCPs with in-house access to AbdUS or PelUS for each of the characteristics. The between-country differences in proportions of PCPs with access to ultrasonography were tested using Fisher's exact test. A mixed effects logistic regression model was used to test associations between access to in-house ultrasonography and the characteristics of the PCP and clinic. To avoid estimating a large number of parameters, the mixed effects logistic regression model included fixed effects for all variables and random effects for variables depended on country. This model captured the country effect without losing too many degrees of freedom. To identify variables dependent on country, we used multiple logistic regression including main effects and interactions with country between each of the other main effects variables. Backwards model selection was used to eliminate insignificant terms from the model. Missing data were considered completely random and ignored in the analysis. The model was estimated in STATA version 15.0 (StataCorp, Texas, USA). Statistical significance was defined as a P value of ≤0.05.

Results

A total of 2,086 PCPs participated, varying from 59 to 446 PCPs per country. The median response rate per country was 24.8% (range 7.1% to 65.6%). There was a large between-country variation in the variables: 61.7% (range 17.2-88.0%) were female and 38.3% (range 12.0-82.8%) male; 96.9% (range 81.6-100%) were specialised as GPs, and 16.0% (range 1.6-55.9%) had less than 10 years' experience as a medical doctor. The clinics were mainly urban: 59.7% (range 28.6-93.1%); 13.8% (range 0.0-55.2%) were solo practices, 39.0% (range 7.9-67.9%) small, 20.9% (range 3.2-55.5%) medium, and 26.2% (range 0.0-70.1%) large. Between-country variations are shown in Table 1.

Using multiple logistic regression, we identified interactions between country and variables describing the characteristics of the clinics (Location, Clinic size, In-house colleague qualified in

medical a speciality which traditionally uses ultrasonography). There were no interactions between country and variables describing the characteristics of the PCP (Gender, Level of seniority, Speciality of the PCP).

Variation in access to in-house ultrasonography between countries and between regions within a country.

The median percentage of PCPs across Europe with access to in-house AbdUS was 15.3% (range 0.0-98.1%) and 12.1% (range 0.0-30.8%) had access to in-house PelUS. However, there was large variation between countries (Table 1 and Figure 1).

(Place Figure 1 here)

In-house access to AbdUS was very common in Germany (98.0%), followed by Slovenia (41.4%) and Switzerland (40.6%). In-house access to AbdUS was least available in England (0%), Croatia (1.5%), and Denmark (1.9%). Compared to AbdUS, in-house access to PelUS was less common, with the highest proportions found in Finland (30.8%), Slovenia (21.5%), and France (20.3%). In contrast, it was uncommon in England (0%), Croatia (1.5%), and Bulgaria (3.4%). The between-country differences in access to in-house ultrasonography were statistically significant (Fisher's exact test: AbdUS: *P*<0.001, PelUS: *P*<0.001).

Additionally, there were large differences in access to in-house AbdUS between the two Polish regions (Bialystok 17.9 and Bydgoszcz 57.9%) and the three Spanish regions (Mallorca 3.8%, Galicia 9.6% and Barcelona 43.7%), whereas there was little difference between the two German regions (Munich 96.3% and Essen 98.7%). There was also a large variation in the proportions of clinics with access to in-house PelUS in Germany (Essen 1.3% and Munich 11.1%), Poland (Bialystok 8.4% and Bydgoszcz 33.3%), and Spain (Galicia 4.8%, Mallorca 6.0% and Barcelona 25.8%).

PCP characteristics and in-house access to ultrasonography.

We found no statistically significant associations between the PCP characteristics and in-house access to AbdUS or PelUS (Table 2)

Clinic characteristics and in-house access to ultrasonography

Larger practices were significantly associated with higher levels of both in-house access to AbdUS (OR=2.5, P=0.008) and PeIUS (OR=1.9, P=<0.001), while we found a negative association

between a small practice size and PelUS (OR=0.6, P=0.01) compared to solo-practices. We also found a negative association between urban location and with higher levels of PelUS (OR 0.5, P=0.028). Having an in-house colleague specialized in a medical field which traditionally uses ultrasonography, was found to be positively associated with having access to in-house AbdUS (OR 2.1, P=0.016) and PelUS (OR 3.0, P<0.001); 36.1% of PCPs with in-house AbdUS had an internal medicine colleague in their clinics, and 29.7% of PCPs having in-house access to PelUS had a specialist in obstetrics/gynaecology in their clinics. Nine PCPs (Croatia: 1, Finland: 1, Greece: 2, Romania: 1, Scotland: 1, and Slovenia: 3) stated that they had a radiologist or a sonographer in their practices.

Discussion

Principal findings

We found large variations across Europe in primary care access to in-house ultrasonography. The majority of PCPs do not have diagnostic ultrasonography available in their own clinics. We found some associations between characteristics of the clinic and the likelihood of having inhouse ultrasonography, including a significant association between increased likelihood and clinics with more than 10 PCPs, and with clinics with colleagues specialised in internal medicine or gynaecology/obstetrics. We also found an association between increased likelihood of having in-house access to PelUS and non-urban clinics. Solo-clinics were more likely to have in-house PelUS than other small clinics.

Strengths and limitations

A strength of this study is the large number of participating countries, with a response rate higher than previous studies [19,20]. We used a predefined protocol, and the survey recruitment strategy was not biased by access to in-house ultrasonography, since the overall aim of the survey was to explore PCPs' decision-making with regard to referring patients who may have cancer for further investigation.

However, selection bias may have been introduced by both the recruitment methods and the survey distribution, and the participants may not be representative of the whole population of PCPs in each country. In most of the countries involved, the survey was only circulated in one specific region, and in those countries where regional data was available, we found inter-

regional variation in ultrasonography access. This means that regional differences may have influenced our results.

Using secondary data may introduce information bias. In our study we explored whether having access to in-house ultrasonography was associated with having a colleague specialised in a medical field that traditionally uses ultrasonography. We did not explore whether this colleague was actually performing ultrasound examinations in respondents' clinics. Furthermore, a statement that the respondent had a sonographer or radiologist colleague in the clinic depended on the participant's free text answers, and the frequency of this may therefore be underestimated.

We collected data on the GPs (gender, level of seniority and speciality) and the clinics (location and size); other background characteristics may influence the PCP's access to ultrasonography. Thus, residual confounding may exist.

Comparison with existing literature

In a survey from 2016 [15], ultrasound experts estimated the proportion of GPs using ultrasonography to vary from less than 1% in Austria, Catalonia, Denmark and Sweden, to 45% in Germany. Our study confirmed significant variation, although our proportions were higher (Figure 1). This may be caused by the difference between estimations by experts and measured proportions. Furthermore, the previous study estimated PCPs' use of ultrasonography, while our study measured PCPs' actual access to in-house ultrasonography. Access to ultrasonography in the Scandinavian countries was explored using QUALICOPC data from 2012 [16]. This found higher levels of access than our study (Denmark 11.3%, Finland 57.7%, Norway 16.7%, Sweden 4.1%). This may be because the QUALICOPC study asked about access to any type of ultrasound, not specifically diagnostic abdominal or pelvic ultrasonography; hence, therapeutic ultrasound used for musculoskeletal conditions and A-mode ultrasound may have been included in those data.

European between-country variations have also been described for other diagnostic tests in primary care [14], thus variations in access to in-house ultrasound may be caused by national differences in the organization of primary care. For example, the high proportion in Finland may be explained by larger health care centres with more advanced equipment [16], whereas in

Germany PCPs are taught how to use ultrasonography for abdominal examinations [21]. Whether the gate-keeper function that PCPs have in some countries [13] or the waiting time to see a specialist is important is unclear, since we did not collect data on these issues.

Financial aspects may also be important. In countries where PCPs are largely self-employed [22] they need to pay for ultrasound equipment themselves. Additionally, ultrasonography is a time-consuming examination, and differences in remuneration for performing ultrasonography may be of particular importance [13,15,23]. Workload for the PCP may also be an important factor, since research has shown considerable variation in the number of consultations per day [23] and the consultation length [24].

Distance from the secondary care provider has previously been found to be of importance for in-house PelUS [25-27], and our study also found an association between in-house PelUS availability and non-urban practices. Associations between technology and larger clinics have previously been described [23]. However, the association between larger clinics and access to ultrasonography may also be explained by the multidisciplinary nature of some larger clinics. Some countries, for example Finland, Spain, Sweden and England, have multidisciplinary teams working in primary care, while others, e.g. Switzerland, Romania, Norway, Germany, Denmark and Bulgaria, tend to have less staff [28,29]. In our study we found an association between inhouse ultrasonography availability and having a colleague in the clinic who was qualified in a medical specialty which traditionally uses ultrasonography. However, we do not know if these colleagues were performing ultrasonography examinations, and most PCPs did not have such colleagues.

Implications

Several factors may influence the availability of ultrasonography in primary care across Europe, including who performs the examinations. As ultrasonography is disseminating into primary care, knowledge about the influence that these factors have are important to guide the implementation process and to secure appropriate use of the technology.

Conclusions

PCPs' access to in-house ultrasonography in primary care across Europe varied from 0% to 98% for AbdUS, and 0% to 31% for PelUS. While in-house ultrasonography might be an important tool to ensure faster and more correct diagnosis in primary care, in every country except Germany it was available to less than half of our PCP respondents. As evidence continues to support point-of-care ultrasonography as a frontline test, implementation strategies for the increased availability of the technology in primary care are needed. Several factors might influence PCPs' access to in-house diagnostic ultrasonography, and future research should focus on exploring these factors further.

List of abbreviations

AbdUS Abdominal Ultrasonography

PelUS Pelvic Ultrasonography

GPs General Practitioners

PCPs Primary Care Physicians

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The authors declare that they have no competing interests.

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Author contributions

CAA, MH, BST, PV and MBJ all participated in designing the study. CAA performed the analysis and wrote the first draft of the article in collaboration with MH and MBJ. All authors participated in the review process and made significant contributions to the final version of the article.

The following Örenäs Research Group members participated in designing and/or piloting the study, and are non-author collaborators: Isabelle Aubin-Auger, Université Paris Diderot, France; Joseph Azuri, Tel Aviv University, Israel; Matte Brekke, University of Oslo, Norway; Krzysztof Buczkowski, Nicolaus Copernicus University, Poland; Nicola Buono, National Society of Medical Education in General Practice (SNaMID), Italy; Emiliana Costiug, Iuliu Hatieganu University of Medicine and Pharmacy, Romania; Geert-Jan Dinant, Maastricht University, Netherlands; Magdalena Esteva, Majorca Primary Health Care Department, Palma Mallorca, Spain; Gergana Foreva, Medical Center BROD, Bulgaria; Svjetlana Gašparović Babić, The Teaching Institute of Public Health of Primorsko-goranska County, Croatia; Robert Hoffman, Tel Aviv University, Israel; Eva Jakob, Centro de Saúde Sarria, Spain; Tuomas Koskela, University of Tampere, Finland; Mercè Marzo-Castillejo, Institut Català de la Salut, Barcelona, Spain; Peter Murchie, University of Aberdeen, Scotland; Ana Luísa Neves, Imperial College, UK and University of Porto, Portugal; Davorina Petek and Marija Petek Ster, University of Ljubljana, Slovenia; Jolanta Sawicka-Powierza, Medical University of Bialystok, Poland; Antonius Schneider, Technische Universität München, Germany; Emmanouil Smyrnakis, Aristotle University of Thessaloniki, Greece; Sven Streit, University of Bern, Switzerland; Hans Thulesius, Lund University, Sweden; Birgitta Weltermann, University of Bonn, Germany.

Data availability statement

Data including statistical logfiles and the original questionnaire are available upon request to the corresponding author.

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Table 1. Description of participating Primary Care Physicians (PCPs) and their practices

Country	ntry n PCP characteristics n (%) Clinic characteristics n (%)						Access	Access							
	(%)												AbdUS	PelUS	
		Gen Female	ider Male		ority	Special GP	lization Not GP		Location Clinic size Urban Not Solo Small Medium Large			- (0/)	n (0/)		
		remale	iviale	< 10 years	≥ 10 years	GP	NOT GP	Orban	urban	3010	Sman	Medium	Large	n (%)	n (%)
Bulgaria	59	44	13	8	50	52	2	44	14	32	17	2	7	8	2
	(65.6)	(77.2)	(22.8)	(13.8)	(86.2)	(96.3)	(3.7)	(75.9)	(24.1)	(55.2)	(29.3)	(3.5)	(12.1)	(13.6)	(3.4)
Croatia	67	54	12	11	54	52	2	31	36	33	21	11	2	1	1
	(22.9)	(81.8)	(18.2)	(16.9)	(83.1)	(96.3)	(3.7)	(46.3)	(53.7)	(49.3)	(31.3)	(16.4)	(3.0)	(1.5)	(1.5)
Denmark	107	59	43	6	96	85	0	68	34	18	62	19	3	2	4
	(26.8)	(57.8)	(42.2)	(5.9)	(94.1)	100.0)	(0.0)	(66.7)	(33.3)	(17.6)	(60.8)	(18.6)	(2.9)	(1.9)	(3.4)
England	65 (21.7)	46 (70.8)	19 (29.2)	12 (18.8)	52 (81.3)	65 (100.0)	0 (0.0)	28 (43.1)	37 (56.9)	0 (0.0)	19 (29.2)	35 (53.9)	11 (16.9)	0 (0.0)	0 (0.0)
Finland	65 (36.5)	45 (69.2)	20 (30.8)	29 (44.6)	36 (55.4)	51 (98.1)	1 (1.9)	56 (86.2)	9 (13.9)	2 (3.2)	5 (7.9)	21 (33.3)	35 (55.6)	23 (35.38)	20 (30.77)
France	59	32	27	33	26	59	0	54	4	6	36	8	9	9	12
	(10.7)	(54.2)	(45.8)	(55.9)	(44.1)	(100.0)	(0.0)	(93.1)	(6.9)	(10.2)	(61.0)	(13.6)	(15.3)	(15.25)	(20.34)
Germany	103	30	73	3	99	84	19	61	42	26	74	3	0	101	4
	(42.6)	(29.1)	(70.9)	(2.9)	(97.1)	(81.6)	(18.5)	(59.2)	(40.8)	(25.2)	(71.8)	(2.9)	(0.0)	(98.06)	(3.88)
Greece	68	34	34	0	68	67	1	20	48	24	22	7	13	11	9
	(21.4)	(50.0)	(50.0)	(0.0)	(100)	(98.5)	(1.5)	(29.4)	(706)	(36.4)	(33.3)	(10.6)	(19.7)	(16.18)	(13.24)
Israel	75	38	37	17	57	71	2	66	9	7	43	18	7	6	9
	(22.1)	(50.7)	(49.3)	(23.0)	(77.0)	(97.3)	(2.7)	(88.0)	(12.0)	(9.3)	(57.3)	(24.0)	(9.3)	(8.0)	(12.0)
Italy	63	20	40	4	58	36	7	31	32	22	22	10	9	12	8
	(31.5)	(33.3)	(66.7)	(6.5)	(93.5)	(83.7)	(16.3)	(49.2)	(50.8)	(34.9)	(34.9)	(15.8)	(14.3)	(19.05)	(12.7)
Netherlands	113 (7.1)	51 (46.4)	59 (53.6)	17 (15.3)	94 (84.7)	32 (91.4)	(8.6)	55 (49.1)	57 (50.9)	5 (4.5)	76 (67.9)	29 (25.9)	2 (1.8)	13 (11.5)	10 (8.85)
Norway	90	40	50	20	70	73	0	50	40	3	58	26	3	12	11
	(18.0)	(44.4)	(55.6)	(22.2)	(77.8)	(100.0)	(0.0)	(55.6)	(44.4)	(3.3)	(64.4)	(28.9)	(3.3)	(13.33)	(12.22)
Poland	152	110	40	52	99	145	6	108	44	9	84	41	18	50	27
	(36.0)	(73.3)	(26.7)	(34.4)	(65.6)	(96.0)	(4.0)	(71.1)	(29.0)	(5.9)	(55.3)	(27.0)	(11.8)	(32.89)	(17.76)
Portugal	65	48	17	39	26	65	0	44	21	2	14	36	13	2	2
	(28.6)	(73.9)	(26.2)	(60)	(40)	(100.0)	(0.0)	(67.7)	(32.3)	(3.1)	(21.5)	(55.4)	(20.0)	(3.08)	(3.08)
Romania	177	154	21	8	167	174	2	108	67	64	70	14	22	56	38
	(-)	(88.0)	(12.0)	(4.6)	(95.4)	(98.9)	(1.1)	(61.7)	(38.3)	(37.7)	(41.2)	(8.2)	(12.9)	(31.64)	(21.47)
Scotland	65 (18.6)	31 (47.7)	34 (52.3)	5 (7.8)	59 (92.2)	63 (98.4)	1 (1.6)	21 (32.3)	44 (67.7)	0 (0.0)	18 (27.7)	18 (27.7)	29 (44.6)	10 (15.38)	10 (15.38)
Slovenia	104 (29.5)	78 (75.7)	25 (24.3)	17 (16.4)	87 (83.7)	102 (99.0)	1 (1.0)	44 (42.3)	60 (57.7)	(6.7)	(32.7)	(26.0)	36 (34.6)	43 (41.35)	31 (29.81)
Spain	446	312	131	29	417	438	5	302	143	5	59	69	312	133	81
	(-)	(70.4)	(29.6)	(6.5)	(93.5)	(98.9)	(1.1)	(67.9)	(32.1)	(1.1)	(13.3)	(55.5)	(70.1)	(29.82)	(18.16)
Sweden	79 (19.8)	37 (46.8)	42 (53.2)	20 (25.3)	59 (74.7)	66 (95.7)	3 (4.4)	29 (36.7)	50 (63.3)	0 (0.0)	34 (43.6)	35 (44.9)	9 (11.5)	3 (3.8)	5 (6.33)
Switzerland	64	11	53	1	63	61	3	18	45	21	38	2	2	26	7
	(64.0)	(17.2)	(82.8)	(1.6)	(98.4)	(95.3)	(4.7)	(28.6)	(71.4)	(33.3)	(60.3)	(3.2)	(3.2)	(40.63)	(10.94)
Totals *	2086	1274	790	331	1737	1841	58	1238	836	286	806	431	542	521	291
Median percentages [IQR]**		56.0 [46.7- 73.5]	44.0 [26.5- 53.3]	15.9 [6.4- 23.6]	84.2 [76.4- 93.7]	98.2 [95.9- 99.3]	1.8 [0.8- 4.1]	57.4 [42.9- 68.7]	42.6 [31.3- 57.1]	8.0 [3.2- 33.7]	38.0 [29.3- 60.4]	25.0 [12.9- 30.0]	12.5 [3.3- 19.8]	15.3 [7.0- 32.0]	12.1 [3.8- 17.9]

N (%) = number of participants in each county (response rate), n = absolute value in each variable, PCP = primary care physician, GP= general practitioner, AbdUS = abdominal ultrasonography, PelUS= pelvic ultrasonography *Absolute numbers given in each variable (n) do not add up to the total number of participants in each country (N) due to missing values.

^{**} IQR = interquartile range

Table 2 Associations between in-house access to ultrasonography and characteristics of Primary Care Physicians and clinics.

	AbdUS n (%)	OR (95% CI)*	P value**	PelUS n (%)	OR (95% CI)*	P value**
Characteristics of the PCP						
Male	233 (29.5)	1.1 (1.0-1.3)	0.101	116 (14.7)	1.0 (0.9-1.2)	0.888
	<u>"</u>	1.1 (1.0-1.3)	0.101	` '	1.0 (0.9-1.2)	0.888
Female	285 (22.4)	-	-	175 (13.7)	-	-
< 10 years of experience	65 (19.6)	1.0 (0.8-1.2)	0.944	46 (13.9)	1.0 (0.8-1.2)	0.798
≥ 10 years of experience	453 (26.1)	-	-	244 (14.1)	-	-
General practitioner	468 (25.4)	0.9 (0.5-1.5)	0.657	271 (14.7)	1.4 (0.8-2.4)	0.304
Not general practitioner	53 (21.6)	-	-	20 (8.2)	-	-
Characteristics of the clinic						
Urban location	350 (28.3)	0.7 (0.4-1.2)	0.247	195 (15.8)	0.5 (0.2-0.9)	0.028
Not urban location	170 (20.3)	-	-	96 (11.5)	-	-
Large practice	212 (39.1)	2.5 (1.2-4.9)	0.008	144 (26.6)	1.9 (1.3-2.7)	<0.001
Medium practice	78 (18.1)	1.1 (0.5-2.5)	0.765	57 (13.2)	0.8 (0.4-1.3)	0.324
Small practice	182 (22.6)	0.6 (0.3-1.2)	0.130	78 (9.7)	0.6 (0.4-0.9)	0.011
Solo practice	47 (16.4)	-	-	12 (4.2)	-	-
In-house colleague qualified in	90 (36.1)	2.1 (1.1-3.8)	0.016	99 (29.7)	3.0 (1.8-5.1)	<0.001
medical a speciality which						
traditionally uses						
ultrasonography***						

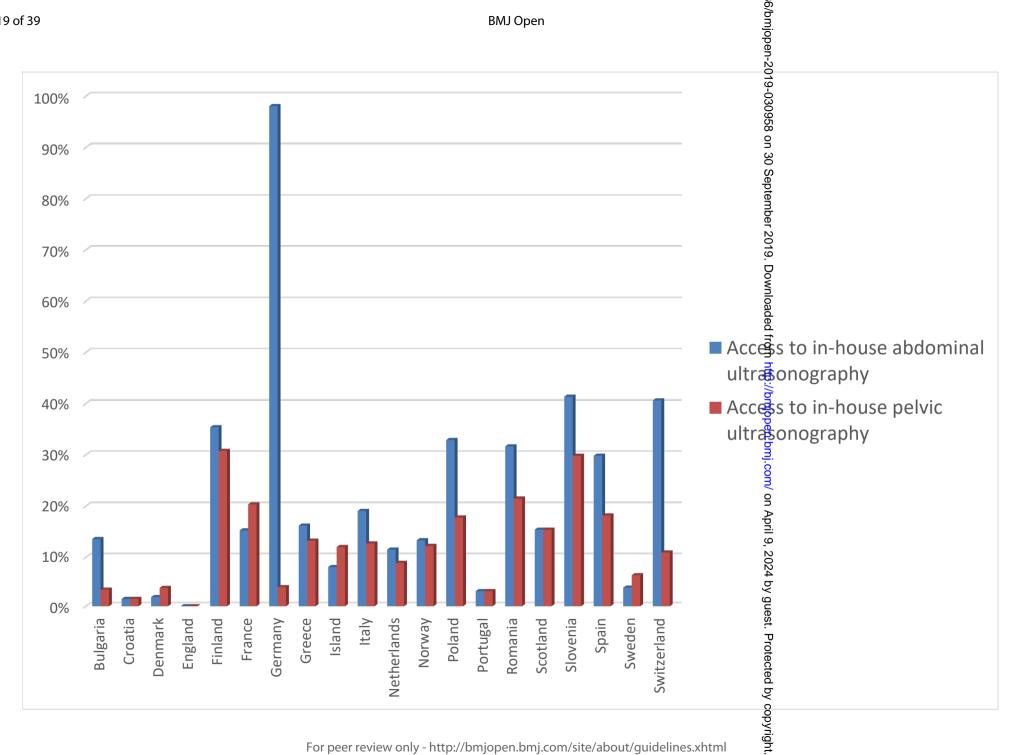
AbdUS = Access to in-house abdominal ultrasonography, PelUS = Access to in-house pelvic ultrasonography. PCP= primary care physician

- n (%) = Absolute number and percentage of dependent variable for each independent variable.
- * Odds ratios with 95% confidence interval calculated using a mixed effects logistic regression model including fixed effects for all variables and random effects variables interacting with country.
- ** P values for adjusted odds ratio
- *** An in-house colleague who had specialized in internal medicine (for AbdUS) or gynaecology or obstetrics (for PelUS) was considered to have qualified in a medical speciality that traditionally uses ultrasonography.

Figure 1.

[Attached in a separate file]

Figure legend: Between-country differences in access to in-house diagnostic ultrasonography



Supplementary file 1. Predefined protocol for Örenäs ultrasound study

Primary Care Physicians' access to Ultrasound Examinations across Europe

Version 14.0

Date: 17.09.2017

Signed final protocol version: 17-09-2017, Amendment: 19-10-2017

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On behalf of the Örenäs Research Group.

1 Background and Rationale

Ultrasound (US) imaging is increasingly used by clinicians to facilitate diagnosis and guide processes. [Morris 2015] Traditionally US required large expensive devices and was performed by highly trained specialists to provide a full anatomical description of an organ or pathological findings, but as the development in technology has made US devices smaller, cheaper, and better, the use of US has become intergraded in most medical areas as point-of-care ultrasound (POC-US)[Moore, Dietrich]

POC-US is a focused US scan for a predefined condition and it is performed by healthcare professionals trained to use POC-US to answer simple clinical question, typically with yesno answers e.g., "is there a gallbladder stone?" Thus POC-US is an extension of the physical examination of the patient, where positive and negative findings are evaluated in context with the patient's signs and symptoms and the result is noted in the patient's record similar to how we record auscultation findings when using the stethoscope. [Moore] POC-US is typically performed "bed-side" by the clinician, in patients, who would otherwise be referred to the specialist for a more comprehensive examination and POC-US only replaces the specialist US if the clinical question has been adequately answered [Dietrich]

Potentially there are great advantages of using POC-US: It may improve success in US guided procedures e.g. vascular access [Brandt], it may lead to more correct diagnoses

[Laursen], and supplement or replace more advanced imaging [Colli]. It may also facilitate screening e.g. of abdominal aorta aneurism[Blois] in high risk patients. In a small Canadian study [Siu] 78% of PCPs had previous experience with US. While none of these PCPs were using US in their offices, 78% felt sure that US would change their clinical decisions and 72% that US would improve patient care.

However, an increased use of US imaging may lead to overdiagnosing [Shabanzadeh], spurious findings or diagnosing of clinically unimportant conditions [Zülke].

US is a user-dependent examination that requires appropriate training and quality assurance [Moore, Morris]. Misinterpretations may lead to flawed diagnoses that could raise an unnecessary concern in patients; and even worse, it could delay proper treatment if a serious condition is overlooked and the scanning health care professional and patient feel confident that everything is fine [Wittenberg].

A recent systematic review [Andersen] showed that there are only few studies describing the use of US in primary care. There are no randomized trials and most of the studies are only descriptive reports with only a few scanning Primary Care Physicians (PCP)s. The review showed that POC-US was mainly used for abdominal and pelvic examinations.

Since there is no sufficient registration of POC-US in general practice [Wittenberg] we do not know how disseminated ultrasound is among PCPs. Three studies explored this: A French study [Maurin] with military general practitioners showed that 20% used US regularly. Another study [Heidemann] showed that 70 % of PCPs in Germany had access to an US device. Finally a questionnaire send to experts in ultrasound, in 12 European countries, showed a variation in the estimated proportion of users of ultrasound in general practice from less than 1% to 67 % [Mengel-Jørgensen]. We do not know what determines this variation.

In this study we intend to explore the variation in the proportions of in-house ultrasound availability in general practice across 20 European countries as well as the associations between in-house ultrasound availability and PCP and clinic characteristics.

2 Research objectives

We aim to:

- Describe the difference in the proportion of in-house abdominal and pelvic ultrasound in primary care across 20 European countries.
- Describe how access to in-house abdominal and pelvic ultrasound in primary care is associated with PCP characteristics. (gender, speciality, experience as a PCP)
- Describe how access to in-house abdominal and pelvic ultrasound in primary care is associated with characteristics of PCP clinics. (number of PCPs, location)

3 Design

Cross-sectional survey

4 Study Setting

The study uses data from the Örenäs-EGPRN survey, which was conducted in 2016 among PCPs in 20 European countries (Belgium, Bulgaria, Croatia, Denmark, England, France, Germany, Greece, Israel, Italy, Netherlands, Norway, Poland, Portugal, Romania, Scotland, Slovenia, Spain, Sweden, and Switzerland). The survey set out to explore factors that may affect a PCPs' decisions to refer patients for further investigation.

In this survey, the PCPs were asked whether they had abdominal diagnostic ultrasound and (b) pelvic diagnostic ultrasound available to them (i) in their own practices, (ii) at their request outside their practices, or (iii) not directly available to them or only available via a specialist.

Developing the Örenäs survey:

The Örenäs survey was developed by the Örenäs Research Group, which is a pan-European group of primary care researchers (Appendix A). This group was formed in 2013 to study potential factors influencing national variations in the early diagnosis of cancer in primary care.

At a research symposium, the Örenäs-EGPRN group identified a large variety of non-clinical factors that are likely to have a significant impact on referral decisions (Harris et al. 2015). These include levels of gatekeeping responsibility, funding systems, access to special investigations, fear of litigation, and relationships with specialist colleagues. The Örenäs survey was conducted to investigate how these system factors influence the thinking of individual PCPs when faced with patients who may have cancer, and how that compares across European countries with varying cancer survival rates.

A preliminary questionnaire containing five clinical vignettes (adapted from ICBP vignettes), and the 45 identified decision-making factors, was piloted by the Örenäs-EGPRN investigators in January 2015 to check validity. One of the vignettes and six of the factors were found to be unhelpful and were removed.

A questionnaire with only the remaining 39 decision-making statements was circulated to all Örenäs Research Group members in July 2015 to identify the statements on which there was little or no difference in responses between countries. These 19 statements have been removed from the final questionnaire, leaving 20 statements.

The final questionnaire then contained demographic questions, four patient cases with a question asking for the PCP's most likely immediate investigation/referral action and a list of 20 system factors that may have affected the PCP's referral decision in these cases, requesting an answer on a 5-point Likert scale ranging from 'Strongly agree' to 'Strongly disagree' for each.

The questionnaire was then forwards- and backwards-translated by two separate researchers in each participating country (Appendix 2). The validation and cultural adaption was lead by Michael Harris in collaboration with the national researchers.

5 Participants

Local PCPs including doctors and general practitioners, who have had specialist training, work in the community and can be accessed directly by patients without referral.

6 Recruitment

This was a convenience sample. Each national researcher was asked to recruit at least 50 local PCPs. The national researcher will be asked to declare how they recruited participants.

7 Data

We will extract the following data from the Örenäs survey.

Access to abdominal and pelvic ultrasound

Will be explored through part of question 6 in the Örenäs survey.

Access in your own practice: Abdominal diagnostic ultrasound (Yes/No), Pelvic diagnostic ultrasound (Yes/No)

No access in your own clinic (including Direct access outside your practice and Indirect access through a specialist): Abdominal diagnostic ultrasound (Yes/No), Pelvic diagnostic ultrasound (Yes/No)

Country of origin

From the online server "SurveyMonkey" we are able to extract data on the country of origin for each questionnaire (Belgium, Bulgaria, Croatia, Denmark, England, France, Germany, Greece, Israel, Italy, Netherlands, Norway, Poland, Portugal, Romania, Scotland, Slovenia, Spain, Sweden, and Switzerland).

The PCPs' characteristics

Will be measured through questions 1-3 in the Örenäs survey:

Years since graduation as a doctor: <=20 years, >20 years

Gender: female, male

Speciality: general practitioner, another speciality

The characteristics of the PCPs' clinics

Will be measured through questions 4-5 in the Örenäs survey:

Location: Urban, not urban (incl. rural, island, mixed)

Number of PCPs in the clinic: 1, 2-5 (including 2, 3, 4-5), 6-9 (including 6-7, 8-9), 10 or more.

Outcome measures:

We will describe the difference between European PCPs access to abdominal and pelvic ultrasound in their own clinics in relative frequencies. For each country we will describe the proportion of PCPs, who have direct access in their own clinic and those who do not have direct access in their own clinic (including those who have direct access through referral and those who have access through a specialist).

	Proportion in each country
Abdominal US	
Access in your own practice	
No access in your own practice	
Pelvis US	
Access in your own practice	
No access in your own practice	

In order to describe, how access to abdominal and pelvic ultrasound is associated with PCPs, we will compare relative frequencies of the PCPs characteristics (experience as a medical doctor, gender, and speciality) with access to ultrasound.

		Access to pelvic ultrasound in		
in your own practice		your own practice		
Yes	No	Yes	No	
	1/2			
	in your own pra	Access to abdominal ultrasound in your own practice Yes No No I STATE OF THE PROPERTY OF TH	in your own practice your own practi	

In order to describe, how access to abdominal and pelvic ultrasound is associated to the PCPs clinics, we will compare relative frequencies of the characteristics of the PCP clinics with access to ultrasound.

	Access to abdon in your own pra		Access to pelvic ultrasound in your own practice		
	Yes	No	Yes	No	
Type of Practice					
Urban					
Not urban					

Number of PCP in the clinic		
1		
2-5		
6-9		
10 or more		

8 Data management

All data has been collected in the online server "SurveyMonkey" by the Örenäs research group. Information relating to individual PCPs are anonymised. The data can only be accessed by Michael Harris. Appendix 3 lists the data management plan for the Örenäs study.

Data extraction for this study will follow the approval of the study protocol.

The data extraction will be safely stored at a secure server at CAM-AAU Aalborg University, Fyrkildevej 7 1.sal lejl. 3, 9220 Aalborg Øst, Denmark. Only Martin Bach Jensen and Camilla Aakjær Andersen will have access to the data. Data management agreements have been made between the Research Unit for General Practice in Aalborg and Aalborg University. Data will be saved for five years.

9 Statistical analysis

All categorical variables will be collected on nominal scale and the results will be reported as relative frequencies expressed in proportions with 95 % confidence intervals.

We will use odds ratios to measure associations.

10 Ethical considerations

Consent by the participating PCDs was implied by agreeing to take part in the survey.

Ethical approval for the study has been given by the University of Bath Research Ethics Approval Committee for Health (approval date: 24th November 2014; REACH reference number: EP 14/15 66; UK National Health Service ethical approval is not required).

Approval by the he Danish Data Protection Agency or Ethical approval is not needed. The Danish Committee of Multipractice Studies in General Practice has approved the Örenäs study on July 26th 2016 (MPU 21-2016)

11 Funding

The study on the GPs access to ultrasound examinations has received no external funding.

12 Dissemination policy

The results of this study will be submitted for publication in an international peer reviewed journal. The knowledge of this study will also be disseminated through conferences and research networks.

13 Protocol amendment

After receiving the data on the included variables in September 2017, we decided to include colleagues qualified in different specialties (ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics or other) as a variable describing the clinic characteristics. We received data on this variable in October 2017. We aimed to assess the proportion of PCPs with colleagues in their clinic who were qualified in a speciality in which ultrasonography is traditionally used. We estimated this as the *Proportion of PCPs having specialist in internal medicine* in their clinic and the *Proportion of PCPs with an obstetrician/gynaecologist colleague in their own clinic.* Finally, we included free-text comments with *Sonographer/radiologist colleague in the clinic*, elaborated under the reply "other". Free text comments were translated using Google Translate.

Appendix A. List of Örenäs-EGPRN investigators

These investigators were jointly responsible for the study design:

Davorina Petek, University of Ljubljana, Slovenia

Hans Thulesius, Lund University, Sweden

Magdalena Esteva, Gerencia Atenció Primaria Mallorca, Spain

Marija Petek Ster, University of Ljubljana, Slovenia

Mercè Marzo-Castillejo, IDIAP Jordi Gol, Institut Català de la Salut, Spain

Peter Frey, Berner Institut für Hausarztmedizin, Switzerland

Svjetlana Gašparović-Babić, Teaching Institute of Public Health of Primorsko-Goranska, Croatia

Michael Harris, University of Bath, England (Principal Investigator)

Appendix B. Protocol for translation and back-translation of questionnaire

Adapted from Prof Gergana Foreva's original protocol.

- 1) One "forward" translation (preferably by a bilingual native speaker).
- 2) One blind "backward" translation (i.e. by someone who was not involved in the forward translation stage; if possible a bilingual native English speaker).
- 3) Review of back translations by Örenäs-EGPRN group and adjustment as necessary (to check linguistic equivalence).
- 4) Test corrected version on small sample of (preferably monolingual) local GPs to evaluate the instructions, response format and the items of the instrument for clarity, and to check cultural equivalence; each participant is asked to rate the instructions and items as "clear" or "unclear"; if rated as "unclear", asked to provide suggestions as to how to rewrite the statements to make the language clearer.
- 5) Further improvement of questionnaire as needed, after discussion between local lead and Örenäs-EGPRN group.

Appendix C. Data Management Plan

What data will be collected or created?

Each Örenäs national lead that agrees to take part in the project will aim to recruit at least 50 primary care doctors to complete an on-line survey.

How will the data be collected or created?

The survey and responses will be on a single on-line questionnaire platform.

What documentation and metadata will accompany the data?

Dates of completion and IP address will be captured by the on-line survey platform.

Respondents will be asked for demographic data.

Data will be downloaded in Excel format.

How will any ethical issues be managed?

Respondents will be sent a Participant Information Sheet (PIS) along with their invitation to complete the survey.

Consent will be implicit by agreeing to take the survey.

The PIS and survey will be in participants' own languages. The survey will be validated by back-translation.

No information that may result in participant identification will be requested.

Data will be stored on password-protected systems.

How will copyright and Intellectual Property Rights (IPR) issues be managed?

The University of Bath will own the copyright and IPR of any data that is collected or created, along with the licence(s) for its use and reuse.

How will the data be stored and backed up during the research?

Data will be stored by the on-line questionnaire platform and on a password-protected computer.

There will be automated hourly backup to a remote hard disk.

How will access and security be managed?

Access will be controlled by the Principal Investigator. Any dissemination to collaborators will be by password-controlled file transfer.

Which data are of long-term value and should be retained, shared, and/or preserved?

Data will be retained for at least three years so that they can be accessed for use for scientific papers and preparation for new studies.

What is the long-term preservation plan for the dataset?

Data will be held on password-protected personal computer and hard-disk backup.

There are no significant time or equipment costs.

How will the data be shared?

Data will be shared with co-investigators. Data requests will be handled directly.

Are any restrictions on data sharing required?

Any personally identifiable information will be withheld.

Who will be responsible for data management?

Dr Michael Harris, Principal Investigator.

What resources will be required to deliver the plan?

No additional specialist expertise is needed.

Data analysis software may be needed but is expected to be covered by existing institutional provision.

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Supplementary file 2. Ethical and other approvals obtained in each Örenäs Research Group participating jurisdiction

	Date of Ethics Approval	Approvals obtained	Reference
Bulgaria	29 October 2015	Medical University Plovdiv Ethical Commission	P-7820
Croatia	16 December 2016	Nastavni Zovod Za Javno Zdravstvo	08-820-61/31-15
Denmark	7 May 2016	Danish Data Protection Agency; according to Danish law and the Central Denmark Region Committees on Health Research Ethics, approval by the National Committee on Health Research Ethics was not required as no biomedical intervention was performed.	2009-41-3471
Finland	16 November 2016	Academic Ethics Committee of the Tampere Region	16 November 2016
France	N/A	In France, research ethics approval was not required as no biomedical intervention was performed.	
Germany	15 January 2016	Ethik-Kommission Universität Duisberg-Essen	16-6747-B0
Greece	N/A	In Greece, research ethics approval was not required as no biomedical intervention was performed.	
Israel	N/A	In Israel, research ethics approval was not required as no biomedical intervention was performed.	
Italy	N/A	In Italy the approval of the ethical committee is not required when a study is neither an interventional nor an observational study on pharmacological treatment.	Decreto Legislativo n. 211 (24 giugno 2003)<2001/20/EC
Netherlands	27 June 2016	medisch- ethischetoetsingscommissie (METC) azM/UM Maastricht UMC+	METC 16-4-113
Norway	N/A	In Norway, research ethics approval was not required as no biomedical intervention was performed.	
Poland	28 January 2016	Komisja Bioetyczena Uniwersytetu Medycznego w Bialymstoku	R_I_022/10/2016

	1		T
Portugal	N/A	In Portugal, research ethics approval was not required as no biomedical intervention was performed.	
Romania	N/A	In Romania, research ethics approval was not required as no biomedical intervention was performed.	
Slovenia	8 December 2014	Komisija Republike Slovenije Medicinsko Etiko	KME 113/08/14
Spain	25 October 2015	Comissio d'Investigacio Govern de les Illes Balears	Palma 27oct15
	23 Decmber 2015	Informe del Comite Etic d'Investigacio Clinica	P15/159
Sweden	N/A	In Sweden, research ethics approval was not required as no biomedical intervention was performed. It does not fall under the law of research on human subjects to ask professionals about their work and how they perceive it.	
Switzerland	N/A	Swiss law on human research (Humanforschungsgesetz, HFG) does not require that an ethics committee approve collection and analysis of non-medical and anonymous data.	
United Kingdom	24 November 2014	Research Ethics Approval Committee for Health, University of Bath	EP 14/15 66

		BMJ Open Pen-2019	Page
	ST	ROBE 2007 (v4) Statement—Checklist of items that should be included in reports of <i>cross-</i> ജ് ctional studies	
Section/Topic	#	Recommendation 8	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1 and 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction		er 201	
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods	•	nioac	
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5 and 6
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	5 and 6
measurement		comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	7
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results		(e) Describe any sensitivity analyses	

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examine or eligibility,	7 and Table 1
		confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	7 and Table 1
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	7 and Table 1
Outcome data	15*	Report numbers of outcome events or summary measures	8 and Table 1
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision teg, 95% confidence	8 and Table 2
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time eriod	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion		http	
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9 and 10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9 and 10
Other information		Apri	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	12
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in case and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published exambles of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.grg/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.spobe-statement.org.

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Primary Care Physicians' access to in-house ultrasound examinations across Europe: A questionnaire study.

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Primary Care Physicians' access to in-house ultrasound examinations across Europe: A questionnaire study.

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Abstract

Objective: The overall objective of this study was to examine the differences in ultrasound-availability in primary care across Europe.

Design: Cross-sectional study

Setting: Primary care

Participants: Primary Care Physicians (PCPs)

Primary and secondary outcomes measures: The primary aim was to describe the variation in in-house primary care ultrasonography availability across Europe using descriptive statistics. The secondary aim was to explore associations between in-house ultrasonography availability and the characteristics of PCPs and their clinics using a mixed effects logistic regression model.

Results: We collected data from 20 European countries. A total of 2,086 PCPs participated, varying from 59 to 446 PCPs per country. The median response rate per country was 24.8%.

The median (minimum - maximum) percentage of PCPs across Europe with access to in-house abdominal ultrasonography was 15.3% (0.0-98.1%) and 12.1% (0.0-30.8%) had access to in-house pelvic ultrasonography with large variations between countries. We found associations between in-house abdominal ultrasonography availability and larger clinics (OR 2.5, 95% CI: 1.2-4.9) and clinics with medical doctors specialised in areas, which traditionally use ultrasonography (OR 2.1, 95% CI: 1.1-3.8). Corresponding associations were found between in-house pelvic ultrasonography availability and larger clinics (OR 1.9, 95% CI: 1.3-2.7) and clinics with medical doctors specialised in areas, which traditionally use ultrasonography (OR 3.0, 95% CI: 1.8-5.1). Additionally, we found a negative association between urban clinics and in-house pelvic ultrasound availability (OR 0.5, 95% CI: 0.2-0.9).

Conclusions: Across Europe, there is a large variation in PCPs' access to in-house ultrasonography and organizational aspects of primary care seem to determine this variation. If evidence continues to support ultrasonography as a frontline point-of-care test, implementation strategies for increasing its availability in primary care are needed. Future research should focus on facilitators and barriers that may affect the implementation process.

Strengths and limitations

- Primary care physicians were recruited from 20 European countries.
- A convenience sample chosen by national leads was used, which may not be representative of their nations as a whole.
- This study examines secondary data; the survey questions were not specifically designed for this analysis.



Introduction

Traditionally, ultrasound examinations were performed primarily by trained radiologists using high-end devices. However, the development in technology has made ultrasound devices smaller, better and cheaper, and thereby more accessible to clinicians [1,2]. Today, diagnostic ultrasonography is performed either by an imaging specialist for a full comprehensive description of organ anatomy and pathology, or as a bedside point-of-care test where the clinician uses it in relation to the physical examination to rule in or rule out specific conditions [1,3]. Indeed, ultrasound examinations are increasingly used in both primary and secondary care to improve diagnosis and facilitate patient pathways [4-6].

Whereas the use of ultrasonography in secondary care is well described [1,4,7], literature on the its use in primary care is sparse [5,6,8]. Studies have suggested that point-of-care ultrasonography performed by primary care physicians (PCP) may lead to improved diagnostic accuracy [5,9]. However, ultrasonography is an operator-dependent examination and sufficient training of PCPs performing ultrasonography is paramount, especially if the frequency of performed ultrasound examinations is low. Today, Ultrasound examinations in primary care may be performed by both specialists [10] and GPs [11], depending on how the health care systems across Europe are organised [12,13]. General Practitioners (GPs) with access to diagnostic tests have been found to diagnose, treat, and refer patients more appropriately [14]. Hence, in-house availability of ultrasonography in primary care may improve patient care.

The availability and use of ultrasound examinations in primary care differs between countries: experts have previously estimated that the proportion of primary care users across Europe varies from less than 1% to 67% [15], and in-house availability of ultrasonography varies from 4% to 58% in the Nordic countries alone [16]. We do not know what determines this variation, or the extent to which PCP and clinic characteristics are associated with the likelihood of inhouse availability of ultrasonography.

The aims of this study were to describe the variation in in-house primary care ultrasonography availability across Europe, and the association between this availability and the characteristics of PCPs and their clinics.

Material and method

Our study was a secondary analysis of data from the Örenäs survey [17]. The Örenäs survey investigated the influence of health system factors on the way that European PCPs manage their patients. As well as collection of demographic data, there was collection of data on PCPs' inhouse access to diagnostic abdominal and pelvic ultrasonography. In the present study, this access is compared with the demographic data. A predefined protocol was developed prior to accessing the data (see supplementary file 1).

The questionnaire was piloted twice by PCPs in 16 Örenäs Research Group centres. Translations of the questionnaire into local languages were made where these languages were not English. Translation was validated by back-translation to assess semantic and conceptual equivalence and is described elsewhere [18]. The questionnaires were put online using SurveyMonkey (SurveyMonkey, California, USA).

Participants and recruitment

The study was conducted in 25 Örenäs Research Group centres in 20 countries across Europe. In some countries, more than one Örenäs Research Group was keen to collect data for this study. In those countries, each group recruited participants on a regional basis, so there was no risk of geographical overlap.

Subjects were eligible for the survey if they were GPs or had specialist training, but worked in the community and could be accessed directly by patients without referral.

Each Örenäs Research Group local lead emailed a survey invitation to the PCPs in their local health district, with the aim of recruiting at least 50 participants. The Örenäs Research Group local leads were asked to recruit a varied sample with regards to gender, years since graduation, site of practice (urban, rural, remote), and size of practice. Consent was implied by agreeing to take part in the survey.

Data collection:

Access to ultrasonography

Participants were asked if abdominal or pelvic diagnostic ultrasonography was available to them in: 1. Their own practice, 2. At their request outside their practice, or 3. Not directly available to

them, or only available via a specialist. We divided this into: Access to in-house abdominal ultrasonography (AbdUS) and No access to in-house AbdUS (including access at their request outside their practices, not directly available to them, or only available via a specialist) and correspondingly: Access to in-house pelvic ultrasonography (PelUS) and No access to in-house PelUS. Hence, the variables In-house access to AbdUS and In-house access to PelUS included direct access to diagnostic ultrasonography in respondents' own practices.

Countries included

The survey was circulated in 20 countries across Europe: Bulgaria, Croatia, Denmark, England, Finland, France, Germany (Essen and Munich), Greece, Israel, Italy, Netherlands, Norway, Poland (Bydgoszcz and Białystok), Portugal, Romania, Scotland, Slovenia, Spain (Barcelona, Galicia, and Mallorca), Sweden and Switzerland.

Characteristics of the PCPs

PCPs were characterised by: *Gender*: male/female, *Level of seniority*: <10 years of experience as a medical doctor and ≥ 10 years (including 10-19, 20-29, 30-39, 40 years or over), and *Speciality* of the PCP: GP/not GP (including specialists in ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics, other).

Characteristics of the clinics

PCPs' clinics were characterised by: Location (*self-defined by participants*): urban or non-urban (including rural, island, mixed), and clinic size (*Number of PCPs in the clinic*: solo (1 PCP), small (2-5 PCPs), medium (6-9 PCPs), and large (10 or more PCPs)).

In the survey, participants were asked if they had colleagues qualified in different specialties (ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics or other). We assessed the proportion of PCPs with colleagues in their clinic who were qualified in a speciality in which ultrasonography is traditionally used (where clinical guidelines for use and educational programmes exist for the speciality). We estimated this as the *Proportion of PCPs having specialist in internal medicine* in their clinic and the *Proportion of PCPs with an obstetrician/gynaecologist colleague in their own clinic.* Finally, we noted any free-text comments that the PCPs had a *Sonographer/radiologist colleague in the clinic*, elaborated under the reply "other". Free text comments were translated using Google Translate.

Ethics

Ethical approval for the original study was given by the University of Bath Research Ethics Approval Committee for Health (approval date: 24th November 2014; REACH reference number: EP 14/15 66). Other countries' study leads either achieved local ethical approval or gave statements that formal ethical approval was not needed in their jurisdictions (see supplementary file 2).

Patient and public involvement

Patients were not involved in this study

Statistics

We calculated the proportions of PCPs with in-house access to AbdUS or PelUS for each of the characteristics. A mixed effects logistic regression model was used to test associations between access to in-house ultrasonography and the characteristics of the PCP and clinic. To avoid estimating a large number of parameters, the mixed effects logistic regression model included fixed effects for all variables and random effects for variables depended on country. This model allowed us to look across countries and captured the country effect without losing too many degrees of freedom. To identify variables dependent on country, we used multiple logistic regression including main effects and interactions with country between each of the other main effects variables. Backwards model selection was used to eliminate insignificant terms from the model. Missing data were considered completely random and ignored in the analysis. The model was estimated in STATA version 15.0 (StataCorp, Texas, USA). Statistical significance was defined as a P value of ≤0.05.

Results

A total of 2,086 PCPs participated, varying from 59 to 446 PCPs per country. The median response rate per country was 24.8% (range 7.1% to 65.6%). There was a large between-country variation in the variables: 61.7% (range 17.2-88.0%) were female and 38.3% (range 12.0-82.8%) male; 96.9% (range 81.6-100%) were specialised as GPs, and 16.0% (range 1.6-55.9%) had less than 10 years' experience as a medical doctor. The clinics were mainly urban: 59.7% (range 28.6-93.1%); 13.8% (range 0.0-55.2%) were solo practices, 39.0% (range 7.9-67.9%) small, 20.9%

(range 3.2-55.5%) medium, and 26.2% (range 0.0-70.1%) large. Between-country variations are shown in Table 1.

Using multiple logistic regression, we identified interactions between country and variables describing the characteristics of the clinics (Location, Clinic size, In-house colleague qualified in medical a speciality which traditionally uses ultrasonography). There were no interactions between country and variables describing the characteristics of the PCP (Gender, Level of seniority, Speciality of the PCP). As a result, we applied a mixed effects logistic regression model that included fixed effects for all variables and random effects for variables describing the characteristics of the clinics. Visual inspection of the country-specific random effects showed concordance between AbdUS and PelUS, indicating comparable parameter estimates and that the country effects were modelled appropriately. Hence, we applied the same model structure to both AbdUS and PelUS.

Twenty-one observations from nine different countries were excluded due to an unreported number of PCPs working in the clinic. We chose to consider these missing data random, as we believed that the likelihood of the PCP answering the question about the number of PCPs working in the clinic was independent from the PCP's access to in-house AbdUS or PelUS.

Variation in access to in-house ultrasonography between countries and between regions within a country.

The median percentage of PCPs across Europe with access to in-house AbdUS was 15.3% (range 0.0-98.1%) and 12.1% (range 0.0-30.8%) had access to in-house PelUS. However, there was large variation between countries (Table 1 and Figure 1).

(Place Figure 1 here)

In-house access to AbdUS was very common in Germany (98.0%), followed by Slovenia (41.4%) and Switzerland (40.6%). In-house access to AbdUS was least available in England (0%), Croatia (1.5%), and Denmark (1.9%). Compared to AbdUS, in-house access to PelUS was less common, with the highest proportions found in Finland (30.8%), Slovenia (21.5%), and France (20.3%). In contrast, it was uncommon in England (0%), Croatia (1.5%), and Bulgaria (3.4%).

Additionally, there were large differences in access to in-house AbdUS between the two Polish regions (Bialystok 17.9 and Bydgoszcz 57.9%) and the three Spanish regions (Mallorca 3.8%, Galicia 9.6% and Barcelona 43.7%), whereas there was little difference between the two German regions (Munich 96.3% and Essen 98.7%). There was also a large variation in the proportions of clinics with access to in-house PelUS in Germany (Essen 1.3% and Munich 11.1%), Poland (Bialystok 8.4% and Bydgoszcz 33.3%), and Spain (Galicia 4.8%, Mallorca 6.0% and Barcelona 25.8%).

PCP characteristics and in-house access to ultrasonography.

We found no statistically significant associations between the PCP characteristics and in-house access to AbdUS or PelUS (Table 2)

Clinic characteristics and in-house access to ultrasonography

Larger practices were significantly associated with higher levels of both in-house access to AbdUS (OR=2.5, 95% CI: 1.2-4.9) and PelUS (OR= 1.9, 95% CI: 1.3-2.7), while we found a negative association between a small practice size and PelUS (OR=0.6, 95% CI: 0.4-0.9) compared to solopractices. We also found a negative association between urban location and with higher levels of PelUS (OR 0.5, 95% CI: 0.2-0.9). Having an in-house colleague specialized in a medical field which traditionally uses ultrasonography, was found to be positively associated with having access to in-house AbdUS (OR 2.1, 95% CI: 1.1-3.8) and PelUS (OR 3.0, 95% CI: 1.8-5.1); 36.1% of PCPs with in-house AbdUS had an internal medicine colleague in their clinics, and 29.7% of PCPs having in-house access to PelUS had a specialist in obstetrics/gynaecology in their clinics. Nine PCPs (Croatia: 1, Finland: 1, Greece: 2, Romania: 1, Scotland: 1, and Slovenia: 3) stated that they had a radiologist or a sonographer in their practices.

Discussion

Principal findings

We found large variations across Europe in primary care access to in-house ultrasonography.

The majority of PCPs do not have diagnostic ultrasonography available in their own clinics. We found some associations between characteristics of the clinic and the likelihood of having inhouse ultrasonography, including a significant association between increased likelihood and

clinics with more than 10 PCPs, and with clinics with colleagues specialised in internal medicine or gynaecology/obstetrics. We also found an association between increased likelihood of having in-house access to PelUS and non-urban clinics. Solo-clinics were more likely to have in-house PelUS than other small clinics.

Strengths and limitations

A strength of this study is the large number of participating countries, with a response rate higher than previous studies [19,20]. Moreover, the survey recruitment strategy was not biased by access to in-house ultrasonography, since the overall aim of the survey was to explore PCPs' decision-making with regard to referring patients who may have cancer for further investigation.

However, selection bias may have been introduced by both the recruitment methods and the survey distribution, and the participants may not be representative of the whole population of PCPs in each country. In most of the countries involved, the survey was only circulated in one specific region, and in those countries where regional data was available, we found interregional variation in ultrasonography access. This means that regional differences may have influenced our results.

Using secondary data may introduce information bias. In our study, we explored whether having access to in-house ultrasonography was associated with having a colleague specialised in a medical field that traditionally uses ultrasonography. We did not explore whether this colleague was actually performing ultrasound examinations in respondents' clinics. Furthermore, a statement that the respondent had a sonographer or radiologist colleague in the clinic depended on the participant's free text answers, and the frequency of this may therefore be underestimated.

We collected data on the GPs (gender, level of seniority and speciality) and the clinics (location and size); other background characteristics may influence the PCP's access to ultrasonography. Thus, residual confounding may exist.

This study used an exploratory approach for the secondary outcomes and the statistical model included all possible associations between the measured variables. However, the nature of our sample may have caused limitations as some associations may have been missed due to lack of

power, and some variables may have been eliminated during the fitting of the model due to lack of power. However, the aim of this study was a preliminary assessment and more research is needed to determine the importance of different factors in relation to in-house ultrasonography access.

Comparison with existing literature

In a survey from 2016 [15], ultrasound experts estimated the proportion of GPs using ultrasonography to vary from less than 1% in Austria, Catalonia, Denmark and Sweden, to 45% in Germany. Our study confirmed significant variation, although our proportions were higher (Figure 1). This may be caused by selection bias or by the difference between estimations by experts and measured proportions. Furthermore, the previous study estimated PCPs' use of ultrasonography, while our study measured PCPs' actual access to in-house ultrasonography. Access to ultrasonography in the Scandinavian countries was explored using QUALICOPC data from 2012 [16]. This found higher levels of access than our study (Denmark 11.3%, Finland 57.7%, Norway 16.7%, Sweden 4.1%). This may be because the QUALICOPC study asked about access to any type of ultrasound, not specifically diagnostic abdominal or pelvic ultrasonography; hence, therapeutic ultrasound used for musculoskeletal conditions and Amode ultrasound may have been included in those data.

European between-country variations have also been described for other diagnostic tests in primary care [13], thus variations in access to in-house ultrasound may be caused by national differences in the organization of primary care. For example, the high proportion in Finland may be explained by larger health care centres with more advanced equipment [16], whereas in Germany PCPs are taught how to use ultrasonography for abdominal examinations [21]. Whether the gate-keeper function that PCPs have in some countries [12], the speciality training system for PCPs, the PCP's ultrasound training, or the waiting time to see a specialist is important is unclear, since we did not collect data on these issues.

Financial aspects may also be important. In countries where PCPs are largely self-employed [22] they need to pay for ultrasound equipment themselves. Additionally, ultrasonography is a time-consuming examination, and differences in remuneration for performing ultrasonography may be of particular importance [12,15,23]. Workload for the PCP may also be an important factor,

since research has shown considerable variation in the number of consultations per day [23] and the consultation length [24].

Distance from the secondary care provider has previously been found to be of importance for in-house PelUS [25-27], and our study also found an association between in-house PelUS availability and non-urban practices. Associations between technology and larger clinics have previously been described [23]. However, the association between larger clinics and access to ultrasonography may also be explained by the multidisciplinary nature of some larger clinics. Some countries, for example Finland, Spain, Sweden and England, have multidisciplinary teams working in primary care, while others, e.g. Switzerland, Romania, Norway, Germany, Denmark and Bulgaria, tend to have less staff [28,29]. In our study we found an association between inhouse ultrasonography availability and having a colleague in the clinic who was qualified in a medical specialty which traditionally uses ultrasonography. However, we do not know if these colleagues were performing ultrasonography examinations, and most PCPs did not have such colleagues. As AbdUS and PelUS can be performed by PCPs with different educational backgrounds and correspondingly different levels of ultrasound training, quality assurance of ultrasound examinations performed in primary care is important.

Implications

Several factors may influence the availability of ultrasonography in primary care across Europe, including who performs the examinations and the organisation of healthcare systems. This study may generate hypotheses for future studies that further explore national factors. As ultrasonography is disseminating into primary care, knowledge about the influence that these factors have are important to guide the implementation process and to secure appropriate use of the technology.

Conclusions

PCPs' access to in-house ultrasonography in primary care across Europe varied from 0% to 98% for AbdUS, and 0% to 31% for PelUS. While in-house ultrasonography might be an important tool to ensure faster and more correct diagnosis in primary care, in every country except Germany it was available to less than half of our PCP respondents. As evidence continues to

support point-of-care ultrasonography as a frontline test, implementation strategies for the increased availability of the technology in primary care are needed. Several factors might influence PCPs' access to in-house diagnostic ultrasonography, and future research should focus on exploring these factors further.

List of abbreviations

AbdUS Abdominal Ultrasonography

PelUS Pelvic Ultrasonography

GPs General Practitioners

PCPs Primary Care Physicians

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The authors declare that they have no competing interests.

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Author contributions

CAA, MH, BST, PV and MBJ all participated in designing the study. CAA performed the analysis and wrote the first draft of the article in collaboration with MH and MBJ. All authors participated in the review process and made significant contributions to the final version of the article.

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Data availability statement

Data including statistical logfiles and the original questionnaire are available upon request to the corresponding author.

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To be contained only

Table 1. Description of participating Primary Care Physicians (PCPs) and their practices

Country	n (%)	PCP characteristics n (%)			Clinic characteristics n (%)					Access AbdUS	Access PelUS				
	(%)	Gen	ıder	Seni	ority	Specia	lization	Loca	ation		Clin	ic size		Abdus	Pelus
		Female	Male	< 10 years	≥10 years	GP	Not GP	Urban	Not urban	Solo	Small	Medium	Large	n (%)	n (%)
Bulgaria	59	44	13	8	50	52	2	44	14	32	17	2	7	8 (12.6)	2
Croatia	(65.6) 67	(77.2) 54	(22.8)	(13.8)	(86.2)	(96.3)	(3.7)	(75.9) 31	(24.1)	(55.2)	(29.3)	(3.5)	(12.1)	(13.6)	(3.4)
Cioatia	(22.9)	(81.8)	(18.2)	(16.9)	(83.1)	(96.3)	(3.7)	(46.3)	(53.7)	(49.3)	(31.3)	(16.4)	(3.0)	(1.5)	(1.5)
Denmark	107 (26.8)	59 (57.8)	43 (42.2)	6 (5.9)	96 (94.1)	85 100.0)	0 (0.0)	68 (66.7)	34 (33.3)	18 (17.6)	62 (60.8)	19 (18.6)	3 (2.9)	2 (1.9)	4 (3.4)
England	65 (21.7)	46 (70.8)	19 (29.2)	12 (18.8)	52 (81.3)	65 (100.0)	0 (0.0)	28 (43.1)	37 (56.9)	0 (0.0)	19 (29.2)	35 (53.9)	11 (16.9)	0 (0.0)	0 (0.0)
Finland	65 (36.5)	45 (69.2)	20 (30.8)	29 (44.6)	36 (55.4)	51 (98.1)	1 (1.9)	56 (86.2)	9 (13.9)	2 (3.2)	5 (7.9)	21 (33.3)	35 (55.6)	23 (35.38)	20 (30.77)
France	59 (10.7)	32 (54.2)	27 (45.8)	33 (55.9)	26 (44.1)	59 (100.0)	0 (0.0)	54 (93.1)	4 (6.9)	6 (10.2)	36 (61.0)	8 (13.6)	9 (15.3)	9 (15.25)	12 (20.34)
Germany	103	30 (29.1)	73 (70.9)	3 (2.9)	99 (97.1)	84 (81.6)	19 (18.5)	61 (59.2)	42 (40.8)	26 (25.2)	74 (71.8)	3 (2.9)	0 (0.0)	101 (98.06)	4 (3.88)
Greece	68 (21.4)	34 (50.0)	34 (50.0)	0 (0.0)	68 (100)	67 (98.5)	1 (1.5)	20 (29.4)	48 (706)	24 (36.4)	22 (33.3)	7 (10.6)	13 (19.7)	11 (16.18)	9 (13.24)
Israel	75 (22.1)	38 (50.7)	37 (49.3)	17 (23.0)	57 (77.0)	71 (97.3)	2 (2.7)	66 (88.0)	9 (12.0)	7 (9.3)	43 (57.3)	18 (24.0)	7 (9.3)	6 (8.0)	9 (12.0)
Italy	63 (31.5)	20 (33.3)	40 (66.7)	4 (6.5)	58 (93.5)	36 (83.7)	7 (16.3)	31 (49.2)	32 (50.8)	22 (34.9)	22 (34.9)	10 (15.8)	9 (14.3)	12 (19.05)	8 (12.7)
Netherlands	113	51 (46.4)	59 (53.6)	17 (15.3)	94 (84.7)	32 (91.4)	3 (8.6)	55 (49.1)	57 (50.9)	5 (4.5)	76 (67.9)	29 (25.9)	2 (1.8)	13 (11.5)	10 (8.85)
Norway	90	40 (44.4)	50 (55.6)	20 (22.2)	70 (77.8)	73 (100.0)	0 (0.0)	50 (55.6)	40 (44.4)	3 (3.3)	58 (64.4)	26 (28.9)	3 (3.3)	12 (13.33)	11 (12.22)
Poland	(18.0) 152	110 (73.3)	40 (26.7)	52 (34.4)	99 (65.6)	145 (96.0)	6 (4.0)	108 (71.1)	44 (29.0)	9 (5.9)	84 (55.3)	41 (27.0)	18 (11.8)	50 (32.89)	27 (17.76)
Portugal	(36.0)	48	17	39	26	65	0	44	21	2	14	36	13 (20.0)	(32.89)	2 (3.08)
Romania	(28.6) 177	(73.9) 154	(26.2)	(60)	(40) 167	(100.0)	(0.0)	108	(32.3)	(3.1)	70	(55.4)	22	56	38
Scotland	(-)	(88.0)	(12.0)	(4.6)	(95.4)	(98.9)	(1.1)	(61.7)	(38.3)	(37.7)	(41.2)	(8.2)	(12.9)	(31.64)	10
Slovenia	(18.6) 104	(47.7) 78	(52.3)	(7.8)	(92.2) 87	(98.4)	(1.6)	(32.3)	(67.7)	(0.0)	(27.7)	(27.7)	(44.6)	(15.38)	(15.38)
Spain	(29.5) 446	(75.7) 312	131	(16.4)	(83.7) 417	(99.0) 438	(1.0)	(42.3) 302	(57.7) 143	(6.7)	(32.7)	(26.0) 69	(34.6) 312	(41.35) 133	(29.81)
Swadon	(-) 79	(70.4)	(29.6)	(6.5)	(93.5)	(98.9)	(1.1)	(67.9) 29	(32.1)	(1.1)	(13.3)	(55.5)	(70.1) 9	(29.82)	(18.16)
Sweden	(19.8)	(46.8)	(53.2)	(25.3)	59 (74.7)	66 (95.7)	(4.4)	(36.7)	(63.3)	(0.0)	(43.6)	(44.9)	(11.5)	3 (3.8)	(6.33)
Switzerland	64 (64.0)	11 (17.2)	53 (82.8)	1 (1.6)	63 (98.4)	61 (95.3)	3 (4.7)	18 (28.6)	45 (71.4)	21 (33.3)	38 (60.3)	2 (3.2)	2 (3.2)	26 (40.63)	7 (10.94)
Totals *	2086	1274	790	331	1737	1841	58	1238	836	286	806	431	542	521	291
Median percentages [IQR]**		56.0 [46.7- 73.5]	44.0 [26.5- 53.3]	15.9 [6.4- 23.6]	84.2 [76.4- 93.7]	98.2 [95.9- 99.3]	1.8 [0.8- 4.1]	57.4 [42.9- 68.7]	42.6 [31.3- 57.1]	8.0 [3.2- 33.7]	38.0 [29.3- 60.4]	25.0 [12.9- 30.0]	12.5 [3.3- 19.8]	15.3 [7.0- 32.0]	12.1 [3.8- 17.9]

N (%) = number of participants in each county (response rate), n = absolute value in each variable, PCP = primary care physician, GP= general practitioner, AbdUS = abdominal ultrasonography, PelUS= pelvic ultrasonography *Absolute numbers given in each variable (n) do not add up to the total number of participants in each country (N) due to missing values.

^{**} IQR = interquartile range

Table 2 Associations between in-house access to ultrasonography and characteristics of Primary Care Physicians and clinics.

	AbdUS n (%)	OR (95% CI)*	P value**	PelUS n (%)	OR (95% CI)*	P value**
Characteristics of the PCP						
Male	233 (29.5)	1.1 (1.0-1.3)	0.101	116 (14.7)	1.0 (0.9-1.2)	0.888
Female	285 (22.4)	-	-	175 (13.7)	-	-
< 10 years of experience	65 (19.6)	1.0 (0.8-1.2)	0.944	46 (13.9)	1.0 (0.8-1.2)	0.798
≥ 10 years of experience	453 (26.1)	-	-	244 (14.1)	-	-
General practitioner	468 (25.4)	0.9 (0.5-1.5)	0.657	271 (14.7)	1.4 (0.8-2.4)	0.304
Not general practitioner	53 (21.6)	-	-	20 (8.2)	-	-
Characteristics of the clinic						
Urban location	350 (28.3)	0.7 (0.4-1.2)	0.247	195 (15.8)	0.5 (0.2-0.9)	0.028
Not urban location	170 (20.3)	-	-	96 (11.5)	-	-
Large practice	212 (39.1)	2.5 (1.2-4.9)	0.008	144 (26.6)	1.9 (1.3-2.7)	<0.001
Medium practice	78 (18.1)	1.1 (0.5-2.5)	0.765	57 (13.2)	0.8 (0.4-1.3)	0.324
Small practice	182 (22.6)	0.6 (0.3-1.2)	0.130	78 (9.7)	0.6 (0.4-0.9)	0.011
Solo practice	47 (16.4)	_	-	12 (4.2)	-	-
In-house colleague qualified in medical a speciality which traditionally uses ultrasonography***	90 (36.1)	2.1 (1.1-3.8)	0.016	99 (29.7)	3.0 (1.8-5.1)	<0.001

AbdUS = Access to in-house abdominal ultrasonography, PelUS = Access to in-house pelvic ultrasonography. PCP= primary care physician

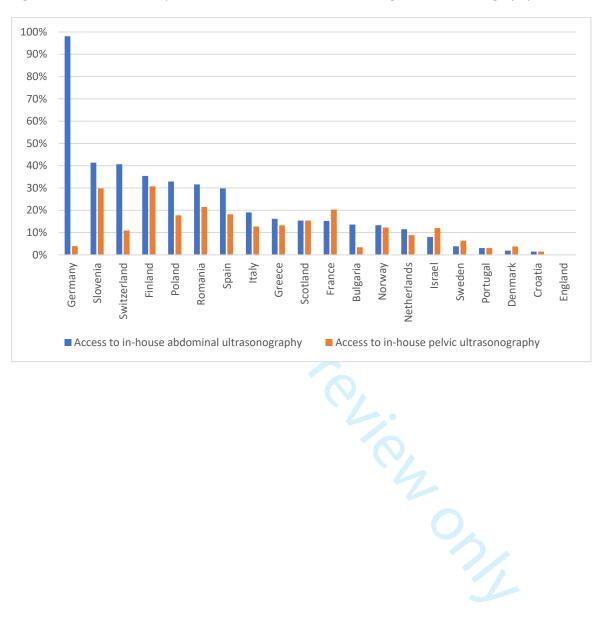
- n (%) = Absolute number and percentage of dependent variable for each independent variable.
- * Odds ratios with 95% confidence interval calculated using a mixed effects logistic regression model including fixed effects for all variables and random effects variables interacting with country.
- ** P values for adjusted odds ratio
- *** An in-house colleague who had specialized in internal medicine (for AbdUS) or gynaecology or obstetrics (for PelUS) was considered to have qualified in a medical speciality that traditionally uses ultrasonography.

Figure 1.

[Attached in a separate file]

Figure legend: Between-country differences in access to in-house diagnostic ultrasonography

Figure 1. Between-country differences in access to in-house diagnostic ultrasonography



Supplementary file 1. Predefined protocol for Örenäs ultrasound study

Primary Care Physicians' access to Ultrasound Examinations across Europe

Version 14.0

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1 Background and Rationale

Ultrasound (US) imaging is increasingly used by clinicians to facilitate diagnosis and guide processes. [Morris 2015] Traditionally US required large expensive devices and was performed by highly trained specialists to provide a full anatomical description of an organ or pathological findings, but as the development in technology has made US devices smaller, cheaper, and better, the use of US has become intergraded in most medical areas as point-of-care ultrasound (POC-US)[Moore, Dietrich]

POC-US is a focused US scan for a predefined condition and it is performed by healthcare professionals trained to use POC-US to answer simple clinical question, typically with yesno answers e.g., "is there a gallbladder stone?" Thus POC-US is an extension of the physical examination of the patient, where positive and negative findings are evaluated in context with the patient's signs and symptoms and the result is noted in the patient's record similar to how we record auscultation findings when using the stethoscope. [Moore] POC-US is typically performed "bed-side" by the clinician, in patients, who would otherwise be referred to the specialist for a more comprehensive examination and POC-US only replaces the specialist US if the clinical question has been adequately answered [Dietrich]

Potentially there are great advantages of using POC-US: It may improve success in US guided procedures e.g. vascular access [Brandt], it may lead to more correct diagnoses

[Laursen], and supplement or replace more advanced imaging [Colli]. It may also facilitate screening e.g. of abdominal aorta aneurism[Blois] in high risk patients. In a small Canadian study [Siu] 78% of PCPs had previous experience with US. While none of these PCPs were using US in their offices, 78% felt sure that US would change their clinical decisions and 72% that US would improve patient care.

However, an increased use of US imaging may lead to overdiagnosing [Shabanzadeh], spurious findings or diagnosing of clinically unimportant conditions [Zülke].

US is a user-dependent examination that requires appropriate training and quality assurance [Moore, Morris]. Misinterpretations may lead to flawed diagnoses that could raise an unnecessary concern in patients; and even worse, it could delay proper treatment if a serious condition is overlooked and the scanning health care professional and patient feel confident that everything is fine [Wittenberg].

A recent systematic review [Andersen] showed that there are only few studies describing the use of US in primary care. There are no randomized trials and most of the studies are only descriptive reports with only a few scanning Primary Care Physicians (PCP)s. The review showed that POC-US was mainly used for abdominal and pelvic examinations.

Since there is no sufficient registration of POC-US in general practice [Wittenberg] we do not know how disseminated ultrasound is among PCPs. Three studies explored this: A French study [Maurin] with military general practitioners showed that 20% used US regularly. Another study [Heidemann] showed that 70 % of PCPs in Germany had access to an US device. Finally a questionnaire send to experts in ultrasound, in 12 European countries, showed a variation in the estimated proportion of users of ultrasound in general practice from less than 1% to 67 % [Mengel-Jørgensen]. We do not know what determines this variation.

In this study we intend to explore the variation in the proportions of in-house ultrasound availability in general practice across 20 European countries as well as the associations between in-house ultrasound availability and PCP and clinic characteristics.

2 Research objectives

We aim to:

- Describe the difference in the proportion of in-house abdominal and pelvic ultrasound in primary care across 20 European countries.
- Describe how access to in-house abdominal and pelvic ultrasound in primary care is associated with PCP characteristics. (gender, speciality, experience as a PCP)
- Describe how access to in-house abdominal and pelvic ultrasound in primary care is associated with characteristics of PCP clinics. (number of PCPs, location)

3 Design

Cross-sectional survey

4 Study Setting

The study uses data from the Örenäs-EGPRN survey, which was conducted in 2016 among PCPs in 20 European countries (Belgium, Bulgaria, Croatia, Denmark, England, France, Germany, Greece, Israel, Italy, Netherlands, Norway, Poland, Portugal, Romania, Scotland, Slovenia, Spain, Sweden, and Switzerland). The survey set out to explore factors that may affect a PCPs' decisions to refer patients for further investigation.

In this survey, the PCPs were asked whether they had abdominal diagnostic ultrasound and (b) pelvic diagnostic ultrasound available to them (i) in their own practices, (ii) at their request outside their practices, or (iii) not directly available to them or only available via a specialist.

Developing the Örenäs survey:

The Örenäs survey was developed by the Örenäs Research Group, which is a pan-European group of primary care researchers (Appendix A). This group was formed in 2013 to study potential factors influencing national variations in the early diagnosis of cancer in primary care.

At a research symposium, the Örenäs-EGPRN group identified a large variety of non-clinical factors that are likely to have a significant impact on referral decisions (Harris et al. 2015). These include levels of gatekeeping responsibility, funding systems, access to special investigations, fear of litigation, and relationships with specialist colleagues. The Örenäs survey was conducted to investigate how these system factors influence the thinking of individual PCPs when faced with patients who may have cancer, and how that compares across European countries with varying cancer survival rates.

A preliminary questionnaire containing five clinical vignettes (adapted from ICBP vignettes), and the 45 identified decision-making factors, was piloted by the Örenäs-EGPRN investigators in January 2015 to check validity. One of the vignettes and six of the factors were found to be unhelpful and were removed.

A questionnaire with only the remaining 39 decision-making statements was circulated to all Örenäs Research Group members in July 2015 to identify the statements on which there was little or no difference in responses between countries. These 19 statements have been removed from the final questionnaire, leaving 20 statements.

The final questionnaire then contained demographic questions, four patient cases with a question asking for the PCP's most likely immediate investigation/referral action and a list of 20 system factors that may have affected the PCP's referral decision in these cases, requesting an answer on a 5-point Likert scale ranging from 'Strongly agree' to 'Strongly disagree' for each.

The questionnaire was then forwards- and backwards-translated by two separate researchers in each participating country (Appendix 2). The validation and cultural adaption was lead by Michael Harris in collaboration with the national researchers.

Participants

Local PCPs including doctors and general practitioners, who have had specialist training, work in the community and can be accessed directly by patients without referral.

6 Recruitment

This was a convenience sample. Each national researcher was asked to recruit at least 50 local PCPs. The national researcher will be asked to declare how they recruited participants.

7 Data

We will extract the following data from the Örenäs survey.

Access to abdominal and pelvic ultrasound

Will be explored through part of question 6 in the Örenäs survey.

Access in your own practice: Abdominal diagnostic ultrasound (Yes/No), Pelvic diagnostic ultrasound (Yes/No)

No access in your own clinic (including Direct access outside your practice and Indirect access through a specialist): Abdominal diagnostic ultrasound (Yes/No), Pelvic diagnostic ultrasound (Yes/No)

Country of origin

From the online server "SurveyMonkey" we are able to extract data on the country of origin for each questionnaire (Belgium, Bulgaria, Croatia, Denmark, England, France, Germany, Greece, Israel, Italy, Netherlands, Norway, Poland, Portugal, Romania, Scotland, Slovenia, Spain, Sweden, and Switzerland).

The PCPs' characteristics

Will be measured through questions 1-3 in the Örenäs survey:

Years since graduation as a doctor: <=20 years, >20 years

Gender: female, male

Speciality: general practitioner, another speciality

The characteristics of the PCPs' clinics

Will be measured through questions 4-5 in the Örenäs survey:

Location: Urban, not urban (incl. rural, island, mixed)

Number of PCPs in the clinic: 1, 2-5 (including 2, 3, 4-5), 6-9 (including 6-7, 8-9), 10 or more.

Outcome measures:

We will describe the difference between European PCPs access to abdominal and pelvic ultrasound in their own clinics in relative frequencies. For each country we will describe the proportion of PCPs, who have direct access in their own clinic and those who do not have direct access in their own clinic (including those who have direct access through referral and those who have access through a specialist).

	Proportion in each country
Abdominal US	
Access in your own practice	
No access in your own practice	
Pelvis US	
Access in your own practice	
No access in your own practice	

In order to describe, how access to abdominal and pelvic ultrasound is associated with PCPs, we will compare relative frequencies of the PCPs characteristics (experience as a medical doctor, gender, and speciality) with access to ultrasound.

			Access to pelvic ultrasound in your own practice	
	Yes	No	Yes	No
Gender				
Male				
Female				
Experience as a PCP				
< 20 years	6			
> 20 years				
Specialty				
GP				
Not GP		12		

In order to describe, how access to abdominal and pelvic ultrasound is associated to the PCPs clinics, we will compare relative frequencies of the characteristics of the PCP clinics with access to ultrasound.

	Access to abdon in your own pra	ninal ultrasound ctice	Access to pelvic ultrasound in your own practice		
	Yes	No	Yes	No	
Type of Practice					
Urban					
Not urban					

Number of PCP in the clinic		
1		
2-5		
6-9		
10 or more		

8 Data management

All data has been collected in the online server "SurveyMonkey" by the Örenäs research group. Information relating to individual PCPs are anonymised. The data can only be accessed by Michael Harris. Appendix 3 lists the data management plan for the Örenäs study.

Data extraction for this study will follow the approval of the study protocol.

The data extraction will be safely stored at a secure server at CAM-AAU Aalborg University, Fyrkildevej 7 1.sal lejl. 3, 9220 Aalborg Øst, Denmark. Only Martin Bach Jensen and Camilla Aakjær Andersen will have access to the data. Data management agreements have been made between the Research Unit for General Practice in Aalborg and Aalborg University. Data will be saved for five years.

9 Statistical analysis

All categorical variables will be collected on nominal scale and the results will be reported as relative frequencies expressed in proportions with 95 % confidence intervals.

We will use odds ratios to measure associations.

10 Ethical considerations

Consent by the participating PCDs was implied by agreeing to take part in the survey.

Ethical approval for the study has been given by the University of Bath Research Ethics Approval Committee for Health (approval date: 24th November 2014; REACH reference number: EP 14/15 66; UK National Health Service ethical approval is not required).

Approval by the he Danish Data Protection Agency or Ethical approval is not needed. The Danish Committee of Multipractice Studies in General Practice has approved the Örenäs study on July 26th 2016 (MPU 21-2016)

11 Funding

The study on the GPs access to ultrasound examinations has received no external funding.

12 Dissemination policy

The results of this study will be submitted for publication in an international peer reviewed journal. The knowledge of this study will also be disseminated through conferences and research networks.

13 Protocol amendment

After receiving the data on the included variables in September 2017, we decided to include colleagues qualified in different specialties (ear, nose & throat, internal/general medicine, obstetrics/gynaecology, oncology, orthopaedics, paediatrics or other) as a variable describing the clinic characteristics. We received data on this variable in October 2017. We aimed to assess the proportion of PCPs with colleagues in their clinic who were qualified in a speciality in which ultrasonography is traditionally used. We estimated this as the *Proportion of PCPs having specialist in internal medicine* in their clinic and the *Proportion of PCPs with an obstetrician/gynaecologist colleague in their own clinic.* Finally, we included free-text comments with *Sonographer/radiologist colleague in the clinic*, elaborated under the reply "other". Free text comments were translated using Google Translate.

Appendix A. List of Örenäs-EGPRN investigators

These investigators were jointly responsible for the study design:

Davorina Petek, University of Ljubljana, Slovenia

Hans Thulesius, Lund University, Sweden

Magdalena Esteva, Gerencia Atenció Primaria Mallorca, Spain

Marija Petek Ster, University of Ljubljana, Slovenia

Mercè Marzo-Castillejo, IDIAP Jordi Gol, Institut Català de la Salut, Spain

Peter Frey, Berner Institut für Hausarztmedizin, Switzerland

Svjetlana Gašparović-Babić, Teaching Institute of Public Health of Primorsko-Goranska, Croatia

Michael Harris, University of Bath, England (Principal Investigator)

Appendix B. Protocol for translation and back-translation of questionnaire

Adapted from Prof Gergana Foreva's original protocol.

- 1) One "forward" translation (preferably by a bilingual native speaker).
- 2) One blind "backward" translation (i.e. by someone who was not involved in the forward translation stage; if possible a bilingual native English speaker).
- 3) Review of back translations by Örenäs-EGPRN group and adjustment as necessary (to check linguistic equivalence).
- 4) Test corrected version on small sample of (preferably monolingual) local GPs to evaluate the instructions, response format and the items of the instrument for clarity, and to check cultural equivalence; each participant is asked to rate the instructions and items as "clear" or "unclear"; if rated as "unclear", asked to provide suggestions as to how to rewrite the statements to make the language clearer.
- 5) Further improvement of questionnaire as needed, after discussion between local lead and Örenäs-EGPRN group.

Appendix C. Data Management Plan

What data will be collected or created?

Each Örenäs national lead that agrees to take part in the project will aim to recruit at least 50 primary care doctors to complete an on-line survey.

How will the data be collected or created?

The survey and responses will be on a single on-line questionnaire platform.

What documentation and metadata will accompany the data?

Dates of completion and IP address will be captured by the on-line survey platform.

Respondents will be asked for demographic data.

Data will be downloaded in Excel format.

How will any ethical issues be managed?

Respondents will be sent a Participant Information Sheet (PIS) along with their invitation to complete the survey.

Consent will be implicit by agreeing to take the survey.

The PIS and survey will be in participants' own languages. The survey will be validated by back-translation.

No information that may result in participant identification will be requested.

Data will be stored on password-protected systems.

How will copyright and Intellectual Property Rights (IPR) issues be managed?

The University of Bath will own the copyright and IPR of any data that is collected or created, along with the licence(s) for its use and reuse.

How will the data be stored and backed up during the research?

Data will be stored by the on-line questionnaire platform and on a password-protected computer.

There will be automated hourly backup to a remote hard disk.

How will access and security be managed?

Access will be controlled by the Principal Investigator. Any dissemination to collaborators will be by password-controlled file transfer.

Which data are of long-term value and should be retained, shared, and/or preserved?

Data will be retained for at least three years so that they can be accessed for use for scientific papers and preparation for new studies.

What is the long-term preservation plan for the dataset?

Data will be held on password-protected personal computer and hard-disk backup.

There are no significant time or equipment costs.

How will the data be shared?

Data will be shared with co-investigators. Data requests will be handled directly.

Are any restrictions on data sharing required?

Any personally identifiable information will be withheld.

Who will be responsible for data management?

Dr Michael Harris, Principal Investigator.

What resources will be required to deliver the plan?

No additional specialist expertise is needed.

Data analysis software may be needed but is expected to be covered by existing institutional provision.

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Supplementary file 2. Ethical and other approvals obtained in each Örenäs Research Group participating jurisdiction

	Date of Ethics Approval	Approvals obtained	Reference
Bulgaria	29 October 2015	Medical University Plovdiv Ethical Commission	P-7820
Croatia	16 December 2016	Nastavni Zovod Za Javno Zdravstvo	08-820-61/31-15
Denmark	7 May 2016	Danish Data Protection Agency; according to Danish law and the Central Denmark Region Committees on Health Research Ethics, approval by the National Committee on Health Research Ethics was not required as no biomedical intervention was performed.	2009-41-3471
Finland	16 November 2016	Academic Ethics Committee of the Tampere Region	16 November 2016
France	N/A	In France, research ethics approval was not required as no biomedical intervention was performed.	
Germany	15 January 2016	Ethik-Kommission Universität Duisberg-Essen	16-6747-B0
Greece	N/A	In Greece, research ethics approval was not required as no biomedical intervention was performed.	
Israel	N/A	In Israel, research ethics approval was not required as no biomedical intervention was performed.	
Italy	N/A	In Italy the approval of the ethical committee is not required when a study is neither an interventional nor an observational study on pharmacological treatment.	Decreto Legislativo n. 211 (24 giugno 2003)<2001/20/EC
Netherlands	27 June 2016	medisch- ethischetoetsingscommissie (METC) azM/UM Maastricht UMC+	METC 16-4-113
Norway	N/A	In Norway, research ethics approval was not required as no biomedical intervention was performed.	
Poland	28 January 2016	Komisja Bioetyczena Uniwersytetu Medycznego w Bialymstoku	R_I_022/10/2016

	•	-
N/A	In Portugal, research ethics approval was not required as no biomedical intervention was performed.	
N/A	In Romania, research ethics approval was not required as no biomedical intervention was performed.	
8 December 2014	Komisija Republike Slovenije Medicinsko Etiko	KME 113/08/14
25 October 2015	Comissio d'Investigacio Govern de les Illes Balears	Palma 27oct15
23 Decmber 2015	Informe del Comite Etic d'Investigacio Clinica	P15/159
N/A	In Sweden, research ethics approval was not required as no biomedical intervention was performed. It does not fall under the law of research on human subjects to ask professionals about their work and how they perceive it.	
N/A	Swiss law on human research (Humanforschungsgesetz, HFG) does not require that an ethics committee approve collection and analysis of non-medical and anonymous data.	
24 November 2014	Research Ethics Approval Committee for Health, University of Bath	EP 14/15 66
	N/A 8 December 2014 25 October 2015 23 Decmber 2015 N/A N/A	was not required as no biomedical intervention was performed. N/A In Romania, research ethics approval was not required as no biomedical intervention was performed. Romania, research ethics approval was not required as no biomedical intervention was performed. Komisija Republike Slovenije Medicinsko Etiko Comissio d'Investigacio Govern de les Illes Balears Informe del Comite Etic d'Investigacio Clinica N/A In Sweden, research ethics approval was not required as no biomedical intervention was performed. It does not fall under the law of research on human subjects to ask professionals about their work and how they perceive it. N/A Swiss law on human research (Humanforschungsgesetz, HFG) does not require that an ethics committee approve collection and analysis of non-medical and anonymous data. Research Ethics Approval Committee

40		BMJ Open BMJ Open	
	ST	ROBE 2007 (v4) Statement—Checklist of items that should be included in reports of <i>cross-</i>	
Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1 and 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction		20	
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported 90	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods		bload	
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5 and 6
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	5 and 6
measurement		comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	7
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results		op y Gi	

		BMJ Open pen-20	Page 4
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examine (a) confirmed eligible, included in the study, completing follow-up, and analysed	7 and Table 1
		(b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	N/A N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 and Table 1
Outcome data	15*	(b) Indicate number of participants with missing data for each variable of interest Report numbers of outcome events or summary measures	7 and Table 1 8 and Table 1
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision teg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8 and Table 2
		(b) Report category boundaries when continuous variables were categorized	N/A
Other analyses	17	(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time eriod Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A N/A
Discussion		http	
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9 and 10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9 and 10
Other information		Apri	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in controls in case-control studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine prg/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.stobe-statement.org.