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Patient-reported outcome for 17,648 patients in 5 different Swedish orthopaedic quality registers before and 1 year after surgery: an observational study

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Background and purpose — The EQ-5D is a patient-reported outcome measure (PROM). To make priorities and allocate resources between patients and surgical procedures it is necessary to evaluate outcome differences, which is why comparing PROMs between registers is important. We compared EQ-5D data and the follow-up rate for selected diagnoses reported to Swedish orthopedic registers before and 1 year after surgery.

Patients and methods — Patients from 5 orthopedic registers (Swespine, Swedish Hip Arthroplasty Register, Swedish Knee Arthroplasty Register, Swedankle, and Swe-foot) who, in 2014–2018, underwent surgery in southern Sweden were included in the study. Data on the EQ-5D index, individual questions, and the EQ-VAS at baseline and at the 1-year follow-up was compared.

Results — 17,648 patients had completed the EQ-5D pre- and 1-year postoperatively. The follow-up rate ranged from 32% to 88%. All registers showed a statistical and clinically relevant improvement in the EQ-5D index (mean improvement 0.29–0.39), where patients who underwent hip arthroplasties experienced the largest improvement. The EQ-5D index improvements in patients with foot and ankle surgeries were larger than for patients with knee arthroplasties and spinal surgeries. The dimensions “self-care” and “usual activities” had the largest change in patients reporting “some problems.”

Conclusion — All 5 registers showed a clinically relevant improvement 1 year postoperatively regarding the EQ-5D index, supporting continuous resource allocation to these groups of patients and surgical procedures. However, using PROM data to present register differences was challenged by the high number of non-responders.

In Sweden, there are 13 national orthopedic surgery registries (www.ortopediregister.se). Patients' own assessments of their health status have played an increasingly important role when evaluating medical treatments, explaining why patient-reported outcome measurements (PROMs) are included in most orthopedic registries (1,2). Generic PROMs that are designed to measure the patient's overall health status can be used to compare one patient population with another, regardless of disability, thereby possibly providing information to support health policy decisions (3,4). Most orthopedic registers in Sweden use the EQ-5D, which provides opportunities to compare patient-reported health status before and after a variety of surgical procedures (5-7). Studies comparing different types of orthopedic disorders in different parts of the body are sparse (8-10). When the healthcare resources are limited, it is also important to be able to define patients with severe disabilities who can be improved by a surgical procedure and allocate resources based on their needs and expected improvements, in turn based on patient-reported data before and after surgery. The follow-up rate is important. The International Society of Arthroplasty Register PROMs working group (ISAR) recommends a threshold of 60% for an acceptable follow-up rate (11,12). The aim of our study was to compare EQ-5D data reported in conjunction with surgical procedures for selected orthopedic diagnosis reported to quality registers pre- and 1-year postoperatively. We also wanted to study whether the registers reach the recommended follow-up rate of 60%.

Patients and methods

We requested collected pre- and 1-year postoperative data from 5 orthopedic registers: Swespine (Swedish Spinal Register: www.swespine.se), SHR [Swedish Hip Arthroplasty Register: shpr.registrecentrum.se], SKAR [Swedish Knee

Arthroplasty Register: www.myknee.se], Swedankle [Swedish Ankle Register: www.swedankle.se] and Swefoot [Swedish National Register for Foot and Ankle Surgery: www.riksfot.se]. We limited the request to registered patients in southern Sweden (the counties of Skåne and Halland) who, in 2014–2018, underwent surgery for degenerative orthopedic diagnoses in the lower extremities and the lower spine. The included diagnoses were lumbar spinal stenosis, primary hip and knee osteoarthritis, ankle osteoarthritis, and hindfoot disorders (osteoarthritis, flatfoot, and cavovarus deformities).

EQ-5D

The EQ-5D consists of a descriptive profile, a single index, and a self-reported visual analog scale (VAS) for the patient's self-estimated health status (3,5). The descriptive profile includes 5 dimensions: (i) mobility, (ii) self-care, (iii) usual activities, (iv) pain/discomfort, and (v) anxiety/depression. In the EQ-5D-3L version, each dimension has 3 identical response options: no problem, some problems, and severe problems/unable to (13). The newer EQ-5D-5L version has 5 response options instead of 3, with the aim of improving the measurement properties of the PROM (14-16). The highest EQ-5D index, 1, represents full health and the lowest EQ-5D index, 0, represents dead. The index may result in negative values where the lowest value in the UK tariff is -0.594 , which represents a state that is as bad as being dead. The EQ-VAS measures the patient's self-rated health, with best imaginable health (100 points) and worst imaginable health (0 points) as the 2 endpoints of the scale. The EQ-5D has been thoroughly validated, with confirmed good measurement properties (5). The MIC (minimal important change) is of value in defining thresholds when a treatment should be regarded as clinically relevant, i.e., reflects the smallest change in a score that patients perceive as important (17-21).

In 2016, the SHR changed from the EQ-5D-3L version to the 5L version (16). The consequence of this change was that a single patient could respond to different versions pre- and postoperatively. However, the 5L version has been transformed to the 3L version. The other registers in our study all used the EQ-5D-3L during the entire period. The County of Halland does not register PROMs in the SKAR register, which explains why, in the SKAR, only data from Skåne are included in the data set.

Statistics

Data is reported as numbers and proportions (%), means with standard deviations (SD), 95% confidence intervals (CI), and ranges where appropriate. Outcome measurements are EQ-5D index (UK tariff), EQ-VAS, and the summary score for each question in the EQ-5D preoperatively and 1 year postoperatively. The Δ score is the postoperative value minus the preoperative value. A MIC of 0.06 in the EQ-5D index and an improvement of 11 points on the EQ-VAS are regarded as clinically relevant (19).

Recommended by the Euroqol group, EQ-5D can be described as number and percentage of patients reporting “no problem,” “some problems,” and “severe problems/unable to” on each EQ-5D question. The combination of “some problems” and “severe problems/unable to” can be collapsed into “some problems” when reporting proportions in each dimension and in change over time. Percentage of change can thereafter be ranked (euroqol.org).

We used IBM SPSS Statistics version 26 (IBM Corp, Armonk, NY, USA) to perform the statistical analyses.

Ethics, registration, funding, and disclosures

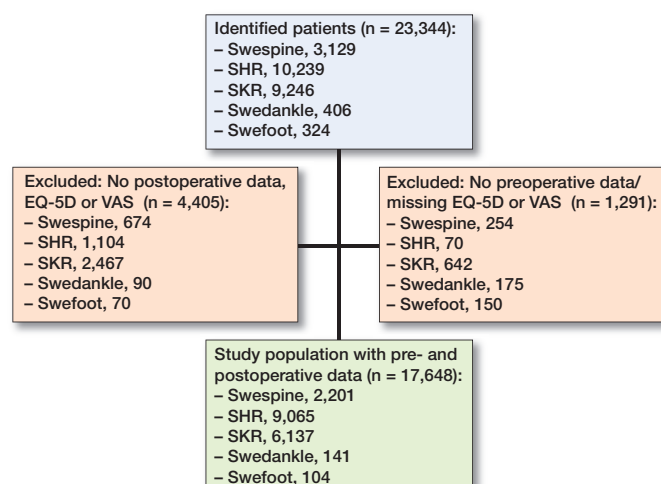
The study protocol was approved by the Ethical Review Board (Etikprövningsmyndigheten) in Sweden (reference number 2019-04208). The study was conducted in accordance with the Helsinki Protocol and according to Swedish and EU data protection rules. The study involves data in pseudoanonymized structured format preventing patient identification. Data has been requested and approved from the Registry Center Southeast (Swespine), Centre of Registers Västra Götaland (SHR, Swefoot), and Registry Center South (SKAR and Swedankle). The study population was treated according to clinical practice at the time of surgery. Informed consent was not requested from individual study participants in this registry-based study, but they can at any time opt out of being recorded in the registries and demand that existing data be removed. Data may be accessible upon application to the registries.

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Results

Patients

We retrieved data on 23,344 identified patients who had answered a PROM at least once, from all 5 registers. Of these, 17,648 (76%) had complete data on the EQ-5D index and the EQ-VAS pre- and 1-year postoperatively (study population). The excluded patients had either missing preoperative or postoperative data (Figure). The study population had a mean age ranging from 63 to 69 years. A larger proportion of women were included, except in the registers related to foot and ankle surgery. The patients' mean BMI indicated overweight or obesity (≥ 25) (Table 1). The largest number of patients were registered in the SHR and the smallest number in the Swefoot register (Table 1). Swespine, SHR, and SKAR had a follow-up rate of at least 60%, as requested



STROBE flowchart. SHR = Swedish Hip Arthroplasty Register; SKR = Swedish Knee Arthroplasty Register

by the IASR, while neither Swedankle nor Swefoot reached the requested level (Table 1).

Dropout analysis

The largest proportion of dropouts at 1 year was found in the Swefoot register (68%) and the fewest in the SHR (12%), i.e., the follow-up rate differed widely between the registers. The dropout analysis showed that the patients with missing data at follow-up were slightly younger than the study population (mean age 68 [SD 10] vs. 69 [SD 10], $p < 0.001$). The BMI, EQ-5D index, and EQ-VAS were similar in both groups; however, the differences were statistically significant (mean BMI 28.0 [SD 4.4] vs. 27.8 [SD 4.3]; EQ-5D index 0.40 [SD 0.32] vs. 0.43 [SD 0.30]; EQ-VAS 58 [SD 26] vs. 61 [SD 24], $p < 0.001$, in dropouts vs. study population). Concerning sex, there was no difference between the 2 groups.

Change in EQ5D data

In the study population ($n = 17,648$), the preoperative EQ-5D index ranged from mean 0.34 (CI 0.32–0.35) in Swespine to

mean 0.49 (CI 0.49–0.50) in SKAR, indicating severe problems for all patients who underwent surgery for the selected diagnosis. At follow-up, the EQ-5D index showed a clinically relevant and statistically important increase in all registers, with mean EQ-5D ranging from 0.64 (CI 0.63–0.65) in Swespine to 0.80 (CI 0.80–0.80) in SHR. The largest improvement was seen in the SHR. The 2 foot- and ankle-related registries showed a larger improvement than the Swespine and SKAR (Table 2). The proportion of patients who reported a clinically relevant change ($> \text{MIC}$) was in Swespine 70%, SHR 87%, SKAR 75%, Swedankle 72%, and Swefoot 70%.

The largest EQ-VAS improvement was found in Swespine, while the smallest improvement was found in SKAR (Table 3). The mean changes were larger than MIC in all the registers except in SKAR.

EQ5D described by item level

Preoperatively, 98–100% of the patients rated pain/discomfort at level 2–3 (“some problems”) in comparison with 50–81% of the patients 1-year postoperatively. We found that a large proportion of the patients improved at least 1 level in EQ-5D, resulting in a lower proportion of patients reporting “some problems” at follow-up in all EQ-5D dimensions, in all 5 registers (Table 4). Referring to the rank of dimensions in terms of percentage changes, the dimensions “self-care” or “usual activities” most often had the highest or 2nd highest rank, while change in “pain/discomfort” was ranked lower (Table 5).

Discussion

In the present study we compared EQ-5D data preoperatively and 1-year postoperatively, as an outcome of surgery for selected diagnosis in 5 Swedish orthopedic quality registers. All registers showed a clinically relevant improvement regarding EQ-5D index, and a lower proportion of patients reported “some problems” postoperatively on all dimensions in all 5 registers. Concerning EQ-VAS, SKAR was the only

Table 1. Preoperative data for all patients included in 5 national orthopedic registries with data from southern Sweden during 2014–2018 and for the study population ^a. Age and BMI are presented as mean (SD) and [range]. Sex is presented as the proportion (%) of females

Register	All				Study population ^a			
	n	Female sex %	Age mean (SD) [range]	BMI mean (SD) [range]	n (%)	Female sex %	Age mean (SD) [range]	BMI mean (SD) [range]
Swespine	3,129	54	65 (14) [18–93]	28 (4.2) [15–49]	2,201 (70)	53	66 (13) [18–93]	28 (4.2) [15–49]
SHR ^b	10,239	56	69 (10) [20–95]	27 (4.3) [16–56]	9,065 (88)	56	69 (10) [20–95]	27 (4.3) [16–56]
SKAR ^c	9,246	57	69 (9) [33–94]	29 (4.4) [17–63]	6,137 (67)	57	69 (9) [35–94]	29 (4.3) [17–63]
Swedankle	406	47	63 (13) [15–85]	28 (4.6) [17–43]	141 (35)	51	64 (12) [27–83]	28 (5.2) [17–41]
Swefoot	324	43	63 (12) [26–85]	29 (4.7) [17–43]	104 (32)	48	64 (12) [27–82]	29 (5.2) [17–41]
Total	23,344	56	68 (10) [15–95]	28 (4.4) [14–62]	17,648 (76)	56	69 (10) [18–95]	28 (4.3) [14–62]

^a Patients with complete EQ-5D and EQ-5D VAS data pre- and 12 months postoperatively.

^b Swedish Hip Arthroplasty Register.

^c Swedish Knee Arthroplasty Register.

Table 2. The EQ-5D index before surgery is presented for all patients, the patients without postoperative data, and before (preoperatively) and 1 year after surgery (postoperatively) with the change from before to 1 year after surgery (Δ) in the study population ^a. The data is presented as mean (CI)

Register	All n = 23,344 Preoperative	No post-operative data ^b n = 4,405 Preoperative	Study population ^a n = 17,648		
			Preoperative	Postoperative	Δ
Swespine	0.33 (0.31–0.33)	0.27 (0.24–0.29)	0.34 (0.32–0.35)	0.64 (0.63–0.65)	0.30 (0.29–0.32)
SHR ^c	0.40 (0.40–0.41)	0.33 (0.32–0.35)	0.41 (0.40–0.42)	0.80 (0.80–0.80)	0.39 (0.38–0.40)
SKAR ^d	0.48 (0.47–0.49)	0.45 (0.43–0.46)	0.49 (0.49–0.50)	0.78 (0.78–0.79)	0.29 (0.28–0.30)
Swedankle	0.35 (0.30–0.39)	0.34 (0.26–0.41)	0.36 (0.31–0.41)	0.68 (0.64–0.73)	0.32 (0.27–0.38)
Swefoot	0.34 (0.29–0.39)	0.33 (0.24–0.41)	0.35 (0.29–0.42)	0.68 (0.61–0.73)	0.33 (0.26–0.40)

^a Patients with complete EQ-5D index pre- and 12 months postoperatively.
^b Patients with complete EQ-5D index preoperatively.
^c Swedish Hip Arthroplasty Register. The 5L version data from SHR is transformed to 3L version by the register.
^d Swedish Knee Arthroplasty Register.

Table 3. EQ-5D VAS before surgery is presented for all patients, the patients without postoperative data, and before (preoperatively) and 1 year after surgery (postoperatively) with the change from before to 1 year after surgery (Δ) in the study population ^a. The data is presented as mean (CI)

Register	All n = 23,344 Preoperative	No post-operative data ^b n = 4,361 Preoperative	Study population ^a n = 17,648		
			Preoperative	Postoperative	Δ
Swespine	43 (42–43)	39 (37–41)	44 (43–45)	66 (65–67)	22 (21–23)
SHR ^c	60 (59–60)	55 (54–57)	60 (60–61)	79 (79–80)	19 (18–19)
SKAR ^d	67 (66–67)	64 (63–65)	68 (67–68)	77 (77–78)	9 (9–10)
Swedankle	54 (51–57)	50 (45–55)	56 (52–59)	70 (67–73)	14 (10–18)
Swefoot	53 (50–56)	50 (45–56)	54 (50–58)	70 (66–73)	16 (11–21)

^{a–d} See Table 2

Table 4. Reported levels within EQ-5D dimensions pre- and postoperatively presented as percentages (%) for Swespine, SHR, SKAR, Swedankle, and Swefoot in the study population ^a. Values are percentages

Register	Level ^b	Mobility		Self-care		Usual activities		Pain/discomfort		Anxiety/depression	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Swespine (n = 2,307)	1	12	47	82	91	28	64	1	20	41	61
	2	87	52	17	8	55	30	149	64	52	34
	3	1	1	1	1	17	6	50	16	7	5
SHR b (n = 3,680)	1	9	67	83	95	44	83	1	50	60	81
	2	91	33	16	5	48	16	56	46	37	18
	3	0	0	1	0	8	1	43	4	3	1
SKAR c (n = 6,247)	1	13	65	94	96	56	80	2	37	66	79
	2	87	35	5	4	39	19	63	58	31	19
	3	0	0	1	0	5	1	35	5	3	2
Swedankle (n = 148)	1	3	36	85	96	35	64	0	21	49	63
	2	95	64	14	4	52	33	50	68	45	32
	3	2	0	1	0	13	3	50	11	6	5
Swefoot (n = 104)	1	4	34	84	94	36	64	0	19	48	64
	2	93	66	14	6	49	34	52	71	48	33
	3	3	0	2	0	15	2	48	10	4	3

^a Patients with complete EQ-5D VAS data pre- and 12 months postoperatively.

^b Level 1 is “no problem,” level 2 “some problems,” and level 3 “severe problems/unable to.”

^c Swedish Hip Arthroplasty Register.

^d Swedish Knee Arthroplasty Register.

register that did not show a clinically relevant improvement after 1 year. Notably, missing patient-reported data seems to be a problem for the registers and in the present study only 3 of the 5 registers reached a 60% follow-up rate.

The EQ-5D is the most used generic PROM in national and regional arthroplasty registers and 61% of those, which collect PROMs worldwide, use the EQ-5D. Comparisons between interventions can be useful when making decisions regarding resource allocation and for hospitals and individual surgical units when they must prioritize among different types of surgery (22). One of the goals of orthopedic surgery is to improve health-related quality (HRQoL) of life by reducing pain and improving function (8), which was achieved in our study.

At group level, we found that the EQ-5D index was low (< 0.500) at baseline in all registers, indicating severely affected HRQoL at the time of surgery and worse compared with reports from the UK on people affected by asthma, low back pain, and for a variety of joint disorders and deformities (EQ-5D index ranging from 0.59 to 0.76) (23,24).

We also found that, 1 year after surgery, the patients' HRQoL was in line with population normative data. EQ-5D index data in the Swedish population aged 60–70 years is 0.813–0.836, only slightly higher compared

Table 5. Proportions of patients pre- and postoperatively reporting some problems (levels 2 and 3 within EQ-5D dimensions), percentage change reporting some problems, and rank of dimensions in terms of percentage changes for Swespine, SHR, SKAR, Swedankle, and Swefoot in the study population ^a

Register/Severity level	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
Swespine (n = 2,307)					
Reporting some problems ^b					
pre-/postoperatively (%)	88/53	18/10	72/36	99/80	59/39
Percentage change	-38	-47	-50	-20	-35
Rank ^c	3	2	1	5	4
SHR ^d (n = 3,680)					
Reporting some problems ^b					
pre-/postoperatively (%)	91/33	17/5	56/17	99/50	40/19
Percentage change	-64	-71	-69	-50	-53
Rank ^c	3	1	2	5	4
SKAR ^d (n = 6,247)					
Reporting some problems ^b					
pre-/postoperatively (%)	87/35	4/6	44/20	98/63	34/21
Percentage change	-60	-31	-53	-36	-40
Rank ^c	1	5	2	4	3
Swedankle (n = 148)					
Reporting some problems ^b					
pre-/postoperatively (%)	97/64	15/4	65/36	100/79	51/37
Percentage change	-35	-73	-45	-21	-29
Rank ^c	3	1	2	5	4
Swefoot (n = 104)					
Reporting some problems ^b					
pre-/postoperatively (%)	96/66	16/6	64/36	100/81	52/36
Percentage change	-31	-65	-45	-19	-31
Rank ^c	3	1	2	5	3

^a Patients with complete EQ-5D VAS data pre- and 12 months postoperatively.

^b Some problems = levels 2 + 3.

^c Rank of dimensions in terms of percentage changes.

^d Swedish Hip Arthroplasty Register. ^e Swedish Knee Arthroplasty Register.

with the postoperative levels in the registers (6). Based on this knowledge, we confirm that surgery is an important intervention for patients with degenerative disorders in the spine and lower extremities.

The only previous study we have found that compares EQ-5D in Swedish national registers also showed improvement after surgery (4). Comparisons of EQ-5D among different surgical procedures are scarce but have been made locally (8) and internationally focusing on knee and hip surgery, with improvement in EQ-5D index comparable to our study (25). Improving pain and function is a main goal of orthopedic surgery, supported by reports of high levels of “pain/discomfort” preoperatively in our study. However, the highest-ranking dimensions in terms of percentage improvement were reported in “self-care” or “usual activities,” with a lower ranking for “pain.”

Nevertheless, the percentage change in reporting “problems” in the EQ-5D items ranged from 19% to 71% in the 5 registers, with the largest proportion in the SHR. However, we used data from before to 1 year after surgery, and we are aware that patients could improve further. Recovery and rehabilitation time differ when comparing surgical procedures such as hip replacements and surgical procedures in the foot and ankle

(26,27). We must also consider that the EQ-5D detects changes better when conditions are more severe due to ceiling effects, which is known from previous systematic reviews (20,28).

We used the MIC values published by Strand et al. (19). MIC values might differ between diagnoses and a slightly higher MIC value of EQ-5D index in patients suffering from low back pain (0.17) has been reported (29). Also, patients treated with hip and knee arthroplasties have higher and different MIC values for the EQ-5D index (0.3 and 0.1 respectively) (30,31). Unfortunately, MIC values are not developed for all types of orthopedic surgical procedures, which means that the thresholds we use for clinical relevance could be too low or high. There is a need to develop MIC values for EQ-5D for different orthopedic procedures to be able to discuss clinical relevance more correctly.

Using PROM data to present national or regional differences in terms of success requires low dropout rates, which is a challenge for most registers (32,33). We used data from 2 different time points and found dropout rates ranging from 12% to 68%, highlighting a severe problem in most registers. However, the requested follow-up rate of 60% or more from the ISAR PROM group seems to be a problem mainly for the smaller and newer registers (2). To obtain a better follow-up rate, a patient-support organization at the surgical units is required. Dedicated and motivated staff,

better feedback to the patients, and digital PROM versions with follow-up reminders may improve response motivation and reduce the dropout rate (1,28,32,34). Additionally, registers with a high dropout rate can learn from registers with a low dropout rate. The low dropout rate in the SHR can be explained by tight follow-up with telephone calls and reminders to those included (2). The added cost needs to be balanced by the importance of a high response rate, and one solution could be to allocate more resources to orthopedic registers with low response rates. The ISAR PROMs working group has evaluated the use of PROMs in their registers and other registers could learn from their recommendations (11,12,33). We searched all the annual reports from the 5 included registers (2018) for the officially presented dropout rate in health status and found none. For this reason, we suggest the more transparent presentation of data to enhance our understanding and interpretation of results. These recommendations should be the target for all registers, but this requires a more equitable distribution of resources to the registers.

Limitations

A major drawback and limitation of this study is the large number of missing PROM data, which naturally affects the

generalizability and interpretation of the results, especially in registers with a smaller number of included subjects. Also, relying on only generic PROMs from registers for comparisons of the effect of surgery will not provide a true picture, which is why adding a disease- or region-specific PROM is of importance as suggested by the ISAR working group (11,12,33,35). To be able to make an even more complete comparison between different surgical procedures and resource allocation a health economic analysis would be desirable.

The strength of the present study is that we present and compare EQ-5D data in different ways, as an index and by reporting findings from the different dimensions, all in line with recommendations from Euler.org and “Methods for Analysing and Reporting EQ-5D Data.” Our data originates from the surgical units in the south of Sweden (Counties of Skåne and Halland), representing 1/6 of the Swedish population, both rural and urban areas, and we believe that this cohort is a good reflection of the Swedish population, i.e., the data is generalizable. If reported by the registers, data from southern Sweden has similar completeness and PROM responsiveness compared with the national mean.

Conclusion

All the 5 studied orthopedic registers showed a clinically relevant improvement in the EQ-5D index and 4 of 5 in the EQ-VAS, supporting continuous resource allocation to these groups of patients and these surgical procedures. However, to be able to make an even more complete comparison it would be desirable to undertake a health economic analysis.

There is a need for innovative solutions to facilitate patient compliance with long-term self-reporting in registers. In addition, the large difference in response rate found in our study indicates that relying on only generic PROMs from registers for comparisons of the effect of surgery will not provide a complete and true picture. There is a need to develop and validate modes of comparison between quality registers.

All authors were equally involved in the study design, interpretation of results (data analysis was performed by a statistician), preparation and revision of the manuscript.

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