Effect of an educational intervention in primary care physicians on the compliance of indicators of good clinical practice in the treatment of type 2 diabetes mellitus [OBTEDIGA project]

J. I. Vidal-Pardo, T. R. Pérez-Castro, X. L. López-Álvarez, M. I. Santiago-Pérez, F. J. García-Soidán and J. Muñiz

Summary

Aim. To evaluate the effect of an educational intervention among primary care physicians on several indicators of good clinical practice in diabetes care.

Methods. Two groups of physicians were randomly assigned to the intervention or control group (IG and CG). Every physician randomly selected two samples of patients from all type 2 diabetic patients aged 40 years and above and diagnosed more than a year ago. Baseline and final information were collected cross-sectionally 12 months apart, in two independent samples of 30 patients per physician. The educational intervention comprised: distribution of educational materials and physicians' specific bench-marking information, an on-line course and three on-site educational workshops on diabetes. External observers collected information directly from the physicians and from the medical records of the patients on personal and family history of disease and on the evolution and treatment of their disease. Baseline information was collected retrospectively in the control group.

Results. Intervention group comprised 53 physicians who included a total of 3018 patients in the baseline and final evaluations. CG comprised 50 physicians who included 2868 patients in the same evaluations. Measurement of micro-albuminuria in the last 12 months (OR = 1.6, 95% CI: 1.1-2.4) and foot examination in the last year (OR = 2.0, 95% CI: 1.1-3.6) were the indicators for which greater improvement was found in the IG. No other indicator considered showed statistically significant improvement between groups.

Conclusions. The identification of indicators with very low level of compliance and the implementation of a simple intervention in physicians to correct them is effective in improving the quality of care of diabetic patients.

Introduction

Diabetes is a common disease, with an estimated prevalence in Spain of 13.8% of the population aged 18 years or more, showing higher percentages in the age groups above 60 years [1]. In Europe, prevalence ranges between 10% and 20%, with higher prevalences among the older age groups (60–79 years old) [2-4].

Diabetes is a chronic disease associated with the development of macro- and microvascular complications. The incidence of these complications increases with the duration of the disease. Up to 20% of the population with diabetes will have a cardiovascular event 10 years after diagnosis [5], and more than 25% of this population will have some degree of retinopathy [6]. Worldwide as well as in Spain, with small local variations, diabetes is the first cause of terminal renal disease, as measured by the number of those admitted for dialysis programmes [7]. Health costs of diabetes are very high and directly related to the time since diagnosis and to the presence of complications and hospital admissions [8, 9].

The Statement of Saint Vincent [10] defined aims for the fight against diabetes complications to be used by governments and other organisations. Following these principles, different groups designed specific indicators to evaluate the process and the results of treatment of diabetic patients, the usefulness of which was proven by an improvement in quality [11-13].

Adequate metabolic control, as well as control of other cardiovascular risk factors, is essential to prevent complications of diabetes [5, 14-16]. Early detection and control of these complications also improves the medium- and long-term prognosis [17, 18]. That is why different societies and organisations have designed guidelines for the diagnosis and treatment of diabetic patients [19-22]. Nevertheless, there is a gap between the guidelines and their application in the clinical setting among type 2 diabetic patients [23-26]. This study evaluates an intervention among primary care physicians aimed at reducing the gap between guideline recommendations and clinical practice regarding diabetic patients.

Methods

Study design

The study was conducted in Galicia (north-west Spain) and consisted of two independent cross-sectional evaluations performed 1 year apart (2008 and 2009). Between the evaluations, an intervention was implemented among the physicians of the intervention group (IG). In the control group (CG), baseline data collection was done retrospectively, coinciding with the final evaluation (Figure 1).



Figure 1. Participation and study design flow-chart

Participants

Participating physicians were selected by stratified random sampling (by primary care area) from the list of physicians with a stable job, without any intention to change place of work in the immediate future and with an assigned population of at least 500 people aged 40 or over. The control group was recruited immediately before the second cut to avoid modifications in behaviour between the evaluations owing to participation in the study.

Selection of diabetic patients

Each participating physician provided information from 30 diabetic patients, randomly selected from the total list of diabetic patients aged 40 years and above and with more than 1 year of diagnosis of type 2 diabetes. There were two independent sampling processes. Women with gestational diabetes were excluded from the study.

Sampling considerations

Sample size was calculated to detect an absolute difference of 5% between the two groups at the end of the intervention in accomplishment of the indicators analysed, assuming a proportion of 50% in the control group and with errors $\alpha = 0.05$ and $\beta = 0.2$ (power = 0.8)

Data collection

Participating physicians answered a questionnaire with demographic characteristics and data from their workplace, whereas information on the patients was obtained from the patient medical records by a team of independent trained nurses. This included: social and demographic data, family and personal history of disease, characteristics of the patient's diabetes, anthropometry and analytical data. Body mass index (BMI) was computed (weight/height²) and classified as normal (18.5 \leq BMI < 25), overweight (25 \leq BMI < 30) and obesity (BMI \geq 30). The criterion of Adult Treatment Panel- III (ATP-III) was used for central obesity (waist circumference \geq 102 centimetres in men and \geq 88 centimetres in women). Indicators used to assess quality of care, derived from the 'Health Plan' of Galicia [27], were previously defined in detail [26].

Educational intervention

Baseline results [26] were used to identify needs and define the intervention to be implemented in the IG. It comprised the following activities through 6 months:

Bench-marking (audit and feedback)

Overall results were presented to the participating physicians in a group session. Every physician received the data from his/her own practice, which allowed him/her to compare every indicator with peers.

Teaching activities

(i) Delivery of printed material on DM-2: a Clinical Guide and materials to facilitate (developing automatisms) the management of the diabetic patient. (ii) A comprehensive on-line course that included reading and reference materials, learning tasks (problem-solving based on clinical scenarios) and other teaching resources (forum, tutorial and case-resolution). The course also included a final test to evaluate the students. Those who completed the course were given 12.5 h in CME credits. The on-line platform that remained open 1 month permitted adapting the completion of the course to the personal time availability of every participating physician thus facilitating completion of the course. (iii) Face-to-face training workshops on management of type 2 diabetes: in 1 day, there were three consecutive workshops of 90 min each on the following topics: (i) diagnosis, management and control objectives in DM-2; (ii) therapeutic update in type 2 diabetes; (iii) how to explore the diabetic foot. CME credits were given to the participating physicians in the workshops.

Statistical analysis

Mean and standard deviation (SD) or proportion were used to describe the characteristics of physicians and patients. In every evaluation (baseline and final), IG and CG were compared by means of Student *t*-test, Mann–Whitney *U*-test or Chi-squared (adjusted by the cluster effect of the physician).

Proportion (and 95% confidence interval) of compliance of every quality indicator was estimated in every group (IG and CG) and the hypothesis of equality pre- and post-intervention was tested by means of corrected Chi-square.

In the final evaluation, a logistic regression model was developed to compare the fulfilment of criteria between the intervention and control groups. The dependent variable in each model was the corresponding indicator (1 = compliant, 0 = non-compliant) and the independent variable was the group (intervention-control); other variables included in the model for adjustment were characteristics of the patient and the proportion of compliance of each physician at baseline. Finally, the physician was considered as a clustering variable to adjust the variance. The adjustment variable was defined as follows: (i) the percentages of compliance of each doctor in the baseline were calculated, (ii) each patient's final cross-section was given the basal rate for their physician. CG was the reference group for calculating the adjusted OR: therefore, an OR > 1 indicated that belonging to the IG improved the performance of the indicator, and an OR < 1 indicated that it worsened the performance. Adjusted OR and 95% confidence intervals are presented.

Ethical issues

The study was approved by the Ethical and Clinical Research Committee of Galicia. All patients received information about the study and signed an informed consent form. Information from diabetic patients was collected anonymously and the individual evaluations of physicians were treated as confidential.

Results

Five of the 58 physicians of the IG did not complete the study for important reasons (death, illness and three changes of workplace), giving a completion rate of 91%. Data for the remaining 53 physicians who completed the study are presented in Figure 1.

Regarding participation in the different components of the intervention: (i) Every physician (100%) in the IG received the feedback information in electronic support and the written materials in his workplace. (ii) 71% attended the presentation of baseline results and bench-marking. (iii) 82% followed the on-line course and 85% participated in the formative workshops on diabetes. Overall, 76% of the physicians participated in at least two of the three components of the intervention (42% participated in all three). There are no differences between the two groups in the characteristics of the physicians and their clinical practices (Table 1).

Table 1. Characteristics of primary care physicians. Comparison of the groups

	Intervention $(n = 53)$		Control $(n = 50)$		
	n	Value	n	Value	p-value
Gender (men)	53	52.8	50	46.0	0.488
Age in years (mean) (SD)	52	50.6 (4.1)	37	49.0 (3.5)	0.057
Professional activity in years (median) (IR)	48	25.5 (7.5)	37	22.0 (7)	0.346
MIR training*	51	17.7	39	23.1	0.523
Type of centre (urban)	52	51.9	40	35.0	0.162
Integrated practice	28	96.4	17	94.1	0.715
Nursing consultation	52	94.2	43	93.0	0.810
MIR training performed in their health centre	53	37.7	41	26.8	0.265
Tutor of FCM residents	52	13.5	40	17.5	0.593
Diabetological education**	52	94.2	41	87.8	0.273
Education done by physician and nurse	49	69.4	36	75.0	0.844

Results in percentages (unless otherwise stated). IR, interquartile range. *MIR training: professionals who were trained in family and community medicine (FCM) for at least 3 years after graduating in Medicine. †Type of centre where they work (urban or rural). ‡Integrated practice: Full time family physicians. \$Nursing consultation: Nurse who has her own and independent consultation from the physician. ¶Tutor of FCM residents: the participating physician is tutor of FCM physicians in training. **Diabetological education: Diabetic patients are educated in diabetes.

Table 2 compares the groups of patients. Differences between the intervention and control groups are slight and not statistically significant, except for some variables at baseline such as family history of ischaemic heart disease, personal history of prior coronary revascularisation, presence of neuropathy and insulin use. Some differences in the variables favour one group and others the other one.

	Baseline			Final			
	Intervention $(n = 1501)$	Control (<i>n</i> = 1437)	p- value	Intervention $(n = 1517)$	Control $(n = 1431)$	p- value	
Gender			0.804			0.676	
Men	52.1	52.7		52.4	51.6		
Age			0.100			0.268	
< 60	20.1	17.5		19.1	18.1		
60–69	27.9	26.0		28.7	26.2		
≥ 70	52.0	56.6	0.550	52.3	55.7	0.222	
Employment status	21.2	20.1	0.550	21.0	19.4	0.225	
Palu work	21.5	20.1		21.9	10.4		
Retired	73.1	4.2		5.5 72.8	אינ ד דר		
HBP (ves)	71.1	73.6	0.307	76.3	75.2	0.627	
Diet	89.6	87.1	0.578	87.4	84.5	0.627	
Pharmacological treatment	93.1	90.8	0.212	90.8	94.1	0.099	
Hypercolesterolaemia (ves)	53.4	58.7	0.265	57.8	59.8	0.606	
Diet	90.3	85.5	0.318	85.2	82.2	0.671	
Pharmacological treatment	83.9	85.3	0.665	82.3	86.3	0.225	
Smoking habit			0.113			0.642	
Smoker	9.1	11.7		9.8	11.1		
Ex-smoker	16.8	18.2		18.2	17.5		
Never smoked	74.0	70.1		72.0	71.4		
Personal history							
Relatives with sudden death or	11.9	19.4	0.005	17.3	193	0 460	
IHD	11.9	17.4	0.005	17.5	17.5	0.400	
Myocardial infarction	5.3	6.0	0.454	6.4	5.7	0.415	
Angina pectoris	4.8	5.2	0.689	6.7	5.5	0.335	
Prior revascularization	3.7	11.8	0.000	12.5	13.4	0.836	
Heart failure	7.3		0.792	7.0		0.851	
Stroke	6.5	/.1	0.599	7.3	7.5	0.892	
(PAD)	5.2	4.9	0.790	5.9	5.6	0.835	
Years since diagnosis of	8.7 (6.8)	8.9 (5.8)	0.072	9.1 (6.7)	9.0 (6.0)	0.754	
diabetes, mean (SD)	× /				· · ·		
Complications of diabetes	0.2	0.1	0.077	10.2	0.0	0.040	
Nonhronothy	9.3	9.1	0.877	10.2	9.8	0.842	
Neuropathy	4.9	3.5	0.080	3.0	0.0	0.218	
Control of glycaemia	4.1	2.0	0.029	2.4	30.7	0.236	
Diabetes dietetic (ves)	90.6	857	0.187	86.6	82.6	0.050	
Quantitative	3.6	2.1	0.107	3.1	3.0	0.470	
Qualitative	78.0	95.4		92.5	94.1		
Both	18.4	2.5		4.4	3.0		
Calories, mean (SD)	1551.7 (176.1)	1523.6 (239.9)	0.547	1539.9 (224.4)	1509.7 (196.8)	0.776	
Oral antidiabetic drugs	76.5	73.1	0.894	81.3	77.3	0.108	
Insulin	19.9	12.1	0.000	16.7	14.4	0.195	
BMI			0.729			0.581	
Non-obese	38.5	36.8		39.6	37.6		
Overweight	9.0	9.2		9.2	10.2		
Obesity	52.5	54.0		51.2	52.2		
Central obesity (ATP-III)							
Men	55.7	56.8	0.929	61.8	59.3	0.764	
Women	87.8	96.2	0.235	87.1	95.1	0.171	
BP > 130/80 mmHg	19.0	19.7	0.769	18.3	16.8	0.557	
ECG (last 2 years)		(2.2	0.126		50.2	0.206	
INOFMAI Bathological	00.4	02.2		04.4	58.5 41.7		
i amoiogicai	55.0	57.0		57.0	+1./		

Table 2. Characteristics of patients included. Comparison between intervention and control groups at baseline and final exam

Results in percentages (unless otherwise stated). HBP, high blood pressure (if mean arterial pressure is above 130/80); IHD, ischaemic heart disease; BMI, body mass index; ATP-III, Central obesity according to the 'Adult Treatment Panell III'; BP, blood pressure; ECG, electrocardiogram.

The degree of accomplishment of the indicators in each group before and after the intervention and the comparison of the two groups in the final exam are presented in Table 3. All indicators related to the measurement of risk factors (blood pressure, LDL-cholesterol) have a compliance rate of more than 75% in both groups and at baseline and final exam. The IG had statistically significant improvement in both the micro-albuminuria and foot examination indicators.

Table 3. Quality of care. Absolute degree of compliance of indicators in both groups before and after educational intervention and comparison between both groups at the final cross-section

	Intervention group			Control group			Final evalua (adjusted	Final evaluation (adjusted)	
	Baseline % (95% CI)	Final % (95% CI)	p- value	Baseline % (95% CI)	Final % (95% CI)	p- value	OR % (95% CI)	p- value	
Glycated haemoglobin measurement*	54.3 (49.1– 59.5)	57.4 (52.8– 62.0)	0.319	50.3 (44.2– 56.4)	54.2 (49.0– 59.4)	0.156	1.1 (0.8–1.4)	0.584	
BP measurement	85.9 (82.7– 89)	87.7 (84.6– 90.7)	0.355	83.4 (79.0– 87.9)	83.5 (79.1– 87.9)	0.961	1.2 (0.9–1.8)	0.234	
If mean average BP is above 130/80, is there a specific monitoring and/or treatment plan?*	35.7 (27.1– 44.3)	28.8 (20.6– 37.0)	0.240	31.1 (20.0– 42.3)	25.8 (16.2– 35.2)	0.026	1.0 (0.5–1.8)	0.911	
LDL measurement	78.6 (74.8– 82.5)	80.2 (77.1– 83.3)	0.488	77.1 (72.4– 81.8)	76.2 (72.4– 79.9)	0.703	1.2 (0.9–1.6)	0.117	
If total cholesterol is > 200 mg/dl or LDL > 100 mg/dl, did this cause diagnosis and/or treatment to change?*	27.3 (19.6– 35)	20.7 (13.9– 27.5)	0.191	26.1 (16.2– 36.1)	21.212.5– 29.9)	0.070	0.9 (0.5–1.8)	0.844	
Recommendation of physical exercise	63.8 (54.5– 73)	77.0 (69.8– 84.2)	0.036	74.9 (66.3– 83.6)	75.4 (66.7– 84.1)	0.860	1.4 (0.7–2.6)	0.373	
Eye examination	35.4 (29– 41.7)	36.5 (30.1– 43.0)	0.720	25.1 (19.9– 30.4)	27.6 (23.0- 32.2)	0.150	1.2 (0.9–1.6)	0.343	
Micro-albuminuria measurement	43.2 (34.9– 51.4)	50.6 (44.2– 57.1)	0.067	31.7 (25.0– 38.4)	33.6 (26.6– 40.6)	0.428	1.6 (1.1–2.4)	0.009	
Micro-albuminuria measurement, < 75 years old without nephropathy	44.4 (36.2– 52.7)	52.7 (46.1– 59.2)	0.043	32.2 (25.6– 38.8)	34.1 (27.1– 41.0)	0.481	1.8 (1.2–2.6)	0.002	
Foot examination, measuring at least peripheral pulses	19.5 (12.9– 26)	30.1 (21.3– 38.9)	0.015	9.8 (4.6– 15.0)	14.0 (7.9– 20.2)	0.011	2.0 (1.1–3.6)	0.023	

*Last 6 months; †Last 12 months; ‡Last 24 months; \$The variance of the ORs was adjusted in every model by the cluster effect of several patients being treated by the same physician. The logistic regression model for every indicator also included as covariate the baseline situation for that particular indicator (see 'Methods'). LDL, low-density lipoprotein.

Figure 2 shows an example of two indicators with different responses to the intervention. For the foot examination during the last year, there was improvement in the IG (from 19.5% to 30.1%) compared with the CG (from 9.8% to 14%) (p = 0.023). Measuring the glycated haemoglobin in the past 6 months improved similarly in both groups (p = 0.584).



Figure 2. Foot examination and glycosylated haemoglobin measurement. Compliance and difference between intervention and control groups./LEGEND: The p-value shows the signification of the OR. The OR compares the compliance of the corresponding indicator in the IG vs. the CG in the final evaluation, adjusting for baseline situation

Discussion

This study shows that an intervention such as the one performed here, including an audit with personalised feedback and teaching activities (face-to-face and on-line), can achieve improvements of modest magnitude in selected quality of care indicators among diabetic patients, especially those who are far from optimal compliance at baseline.

This finding largely corresponds with that presented in other studies [24, 28, 29], especially those where multifactorial interventions have been performed. In our case, the designed intervention aimed at primary care physicians in the public health system was based on the results of a baseline study [26] to be viable in our health system and repeatable in the future.

Within a multifactorial intervention such as the one performed here (the type recognised as the most useful) [28-34], it is very difficult to assess the effectiveness of each of the procedures, but it would be of great help to be able to focus efforts on these activities. In our project, special relevance was given to the audit and feedback, as well as the activities of interactive format (face-to-face workshops, on-line courses). These, generally, have proved to be more useful than didactic materials [23, 28, 30, 31, 35-38]. This is particularly true when high participation is achieved, as in this case.

As regards the materials used, we believe that some such as the 'leaflet' pocket or desk material may, by virtue of their ease of access and readability, be useful for the development of automatisms in clinical practice.

It has been reported that concentrating on just a few specific issues with a low degree of compliance improves the outcome [23, 33, 36, 39]. Our intervention was not directed specifically at these issues, but the analysis at baseline allowed us to identify key points where the situation was worse and consider them in designing the intervention. This may partly explain the improvement in some indicators. For example, there was a workshop specifically dedicated to the examination of the foot, and in another, in which the follow-up plan was reviewed, we discussed the indicators with lowest compliance. In addition, benchmarking and corresponding feedback allow every physician to make the necessary improvements.

Special consideration needs to be given to the examination of the eye, in which, despite low baseline compliance, no significant improvement was observed. A possible explanation may be that this exploration in Spain is predominantly performed by an ophthalmologist, to whom the patient has to be

referred. This process may complicate and slow down the accomplishment of this indicator, particularly considering the usual long delay between the time of the referral and the appointment with the ophthalmologist. This is one of those barriers attributable to the system, which in many cases are more difficult to address [25] and may explain part of the gap between knowledge and usual clinical practice [40], which cannot be modified by the intervention performed.

One possible limitation is the 'Hawthorne' effect, i.e. improvement attributable to being observed. Although the health administration did not take part and all information was treated anonymously, the IG, but not the CG, was aware of being evaluated. Our interpretation is that knowing that one is being evaluated can be considered part of the intervention, something to be considered in future improvement programmes.

Another potential limitation is the possibility of 'contamination' of the CG by the IG, as both worked in the same healthcare system. Although this cannot be entirely ruled out, we tried to limit the damage by the late inclusion of the CG in the study and the retrospective collection of basal data in this group.

The low participation rate of physicians (32 and 33% in both IG and CG) may limit the generalisability of the results. Although it is difficult to verify, in favour of the study, we do know that the participating physicians do not differ in basic characteristics from the population from which they derive [26], suggesting non-selective participation.

It should also be mentioned that the intervention, although multifactorial, is only aimed at the physician. Although it is known that effectiveness improves when all team members are involved and there is an opportunity to make structural changes [28, 41-44], this was considered unfeasible in our case.

One of the strengths and a singularity of our study is the analysis by participating physicians. The fact that the information was collected by independent teams reduced the possibility of bias as well as the workload of the participating physicians, facilitating their participation.

There is still room for improvement in type 2 diabetes care, particularly in some of these indicators. It is necessary to continue efforts to identify effective interventions that could improve them further, such as those that treat the entire organisational system and target all the team members capable of modifying complex problems.

The main conclusion of this study is that the identification of variables with very poor compliance and the implementation of a simple intervention among physicians aimed to correct them are effective in the improvement of the quality of care of diabetic patients.

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Author contributions

Vidal Pardo, JI: as the lead investigator contributed to the study concept and participated in study design, fund-raising, recruitment of participants, administration of the intervention, writing of the manuscript and critical revision of the article. Pérez Castro, TR: contributed to recruitment of participants, fieldwork coordination in monitoring of patients, writing of the manuscript and critical revision of the article. López Álvarez, XL: A contributed to recruitment of participants, administration of the intervention, writing of the manuscript and critical revision of the intervention of the article. García Soidán, FJ: contributed to recruitment of participants, administration of the intervention and critical revision of the article. Santiago Pérez, MI: contributed to statistical data analysis and critical revision of the article. Muñiz García, J: contributed to the study concept, and participated in its design, fund-raising, recruitment of participants, administration of the manuscript and critical revision of the article. All the authors have read and given their approval to the final manuscript.

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Appendix

List of participating physicians [OBTEDIGA project]:

Coordinating Group: Vidal Pardo, JI; López Álvarez, XL; García Soidán, FJ; López Vázquez, P; Mato Mato, JA; do Muíño Joga, M; Jorge Méndez, S; López Fernández, MD; Muñiz, J;

Primary Care Medical Group: Gerencia de Atención Primaria (G.A.P.) A Coruña: de Alcalá Torreiro, EM; de Aspe de la Iglesia, EM; Eirís Pérez, R; Esmorís Méndez, M; Garea Cao, B; López Pan; MM; López Toledo, ML; Mesía Alonso, MJ; Pena Babío, MT; Rey López, A; Veras Castro, R; Vigo Arcas, A; Zapata Medín, ML; G.A.P. Ferrol: Alvarez Escudero, A; Cameo Chenlo, MP; Castro Blanco, A; García del Río, ME; Martínez González, A; G.A.P. Lugo: Álvarez Ferreiro, MI; Campo Dieguez, FJ; Castiñeira Pérez, MC; Cobo Domínguez, C; Cobo Rodríguez, B; Fontenla Villamarín, A; Fouz Ulloa, A; García Sierra, A; González-Anleo Rodríguez, MF (†); López Lens, M; López Martín, I; Martínez González, M; Mourín González, MF; Navaza Dafonte, AM; Palmeiro Díaz, M; Parada Mariñas, R; Pensado Barbeira, F; Porto Iglesias, JA; Rodríguez Suárez, F; Santos García, MC; Valledor Puente, JF; Vázquez Gómez, T; Vázquez Seijas, EJ; Vázquez Vázquez, MJ; G.A.P. Pontevedra: Carrera Ligero, JM; Cores Abalo, M; Fuente Martín, LM; Meijide Calvo, LM; Ogando Canabal, AM; Onega Díaz, C; Sánchez Castro, JJ; Segovia Castro, L; Yun Casalilla, MT; G.A.P. Vigo: Dapena Sánchez, R; Eiras Pérez, J; Estévez Antla, J; Fonseca Moretón, T; Izquierdo Fernández, R; Lora Sánchez, A; Martínez Portela, JM; Mena Cao, JI; Nogueiras Santas, C; Oujo Pujales, J; Pache Muíños, C; Ríos Rey, T; Sánchez Ventin, V; Sanisidro Vilaso, FJ; Torre Díez, JL; Ucha Fernández, J; Vázquez Troitiño, F; Vergara Ruiz, M; G.A.P. Ourense: Alberte Castiñeiras, ML; Antolín Novoa; MD; Avila Alonso, AH; Balado Carballido, A;del Alamo Alonso, AJ; Eirís Cambre, MA; Fernández Silva, MJ; Ferreira González, MI; González Afonso, E; González Reza, E; Lamelas García, JA; Madroño Freire, MJ; Merino Beiro, MO; Outeiriño López, ME; Portuburu Izaguirre, MM; Quintela Fernández, A; Rodríguez Domínguez, G; Rodríguez Ferreiros, AM; Rojo Fernández, JC; Salgado Gómez, MC; Salgado Novoa, MM; Valencia Veloso, M; Veiga Vázquez, A; Vilariño Méndez, CR; G.A.P. Santiago: Bugarín González, R; Caneda Villar, MC; Celemín Colomina, I;Cerqueiras Alcalde, MC; Concheiro Coello, G; Estévez Vila, JA; Fernández González, ME; Juiz Crespo, MA; Lorenzo Tomé, JJ; Pazo Paniagua, MC; Rojo Grandío, Y; Seco Otero, M; Vázquez Cacheiro, J; Ventosa Rial, JJ; Verdes Castro, MC.

Nursing group: Rodríguez González, A; Losada Mateo, A; González Castroagudín, S; Prado Nistal, A; Moreira Iglesias, D; Rojo González, S; Alvarez Sequeiro, J; Rodríguez Rey, L.