Refereed paper

Impact of the implementation of electronic guidelines for cardiovascular prevention in primary care: study protocol

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ABSTRACT

Background The electronic medical records software of the Catalan Institute of Health has recently incorporated an electronic version of clinical practice guidelines (e-CPGs). This study aims to assess the impact of the implementation of e-CPGs on the diagnosis, treatment, control and management of hypercholesterolaemia, diabetes mellitus type 2 and hypertension.

Methods Eligible study participants are those aged 35–74 years assigned to family practitioners (FPs) of the Catalan Institute of Health. Routinely collected data from electronic primary care registries covering 80% of the Catalan population will be analysed using two approaches: (1) a cross-sectional study to describe the characteristics of the sample before e-CPG implementation; (2) a controlled before-and-after study with 1-year follow-up to ascertain the effect of e-CPG implementation. Patients of FPs who regularly use the e-CPGs will constitute the intervention group; the control group will comprise patients assigned to FPs not regularly using the e-CPG. The outcomes are: (1) suspected and confirmed diagnoses, (2) control of clinical variables, (3) requests for tests and (4) proportions of patients with adequate drug prescriptions.

Results This protocol should represent a reproducible process to assess the impact of the implementation of e-CPGs. We anticipate reporting results in late 2013.

Conclusion This project will assess the effectiveness of e-CPGs to improve clinical decisions and healthcare procedures in the three disorders analysed. The results will shed light on the use of evidence-based medicine to improve clinical practice of FPs.

Keywords: electronic health records, physicians, practice guidelines as topic, primary care, primary health care

Introduction

Evidence-based medicine was presented as a new paradigm in the teaching and practice of medicine that stresses the examination of evidence from clinical research and discourages clinical decision-making based on intuition, unsystematic clinical experience and pathophysiologic rationale.[1] The development and implementation of evidence-based clinical practice guidelines (CPGs), one of the most promising and effective tools for improving the quality of care, was clearly linked to this movement.[2,3] The main objectives of CPGs are to standardise procedures, reduce unjustified variations in clinical practice and change physician behaviour to promote the use of interventions supported by the best evidence available.[3–7]

Several strategies have been described for the dissemination and implementation of CPGs once they have been developed.[4] The rapid expansion of computer usage in health care in recent years has allowed the development of computer-based CPGs.[8–13] For instance, the region of Catalonia (Spain) has a computerised primary care system and the use of information technology in routine practice is set to increase. Indeed, the electronic medical record software has recently incorporated the electronic version of CPGs (e-CPGs) for the most common chronic disorders in the population (hypercholesterolaemia, diabetes mellitus type 2 and hypertension).[14–16] This electronic version includes the three key points that Grimshaw *et al*[4] defined for successful CPG dissemination and implementation procedures: easy access to the e-CPG, the use of reminders to guide the actions of healthcare professionals and finally, useful feedback to inform healthcare professionals about the appropriateness of their actions.

The main characteristic of the e-CPG system implemented by the Catalan Institute of Health is that it is linked to the electronic medical record system. This innovation allows the generation of individualised recommendations for the diagnosis, treatment, control and management of disorders considering patient characteristics. The e-CPG also includes information on drug safety (e.g. interactions, secondary effects) and can be updated whenever new drugs or diagnostic tests appear.

In addition, independently of e-CPG use, the contract for family practitioners (FPs) has been financially incentivised based on the degree of control for these chronic disorders.[17] All FPs are able to activate the software from a badge incorporated in the main page of the electronic medical record system.

Despite the considerable amount of money spent on e-CPG development and implementation, relatively little attention has been paid to ensuring adherence to e-CPG recommendations and success in reaching the established primary care treatment goals. So far, no single strategy effectively ensures that e-CPGs are put into practice.[2,17–23] Moreover, most of the studies conducted to ascertain the effectiveness of implementation procedures and adherence to clinical guidelines

have been conducted using a single disorder and selected FP samples.[8–12]

We propose a study to ascertain the effect on FP habits of implementing the e-CPGs in a population-based sample of records obtained from routinely collected general practice data. This population-based approach will allow us to include not only individuals with a wide range of severity of hypercholesterolaemia, diabetes mellitus type 2 and hypertension, but also those who do not meet all criteria for diagnosis but are at high risk of developing a disorder (suspected diagnosis). Finally, the sample size of the study will provide sufficient statistical power to estimate the effect of CPG implementation.

We hypothesise that a complex e-CPG integrated at several appropriate points in an electronic medical record (e.g. reminders and feedback) could increase FPs' access to e-CPG recommendations and achieve better results because complex assessments can be performed quickly. At the same time, point-of-care implementation will achieve consistent exposure to e-CPG recommendations and the evidence behind it, which should reduce variability in clinical practice regarding the control of clinical variables, and the diagnosis, treatment and management of hyper-cholesterolaemia, diabetes mellitus type 2 and hypertension.

Objectives

The main goal of this study is to assess the impact of the implementation of an e-CPG software for the control of clinical variables, and the diagnosis, treatment and management of hypercholesterolaemia, diabetes mellitus type 2 and hypertension.

Methods

Electronic clinical practice guidelines

The combination of a successful and flexible electronic medical record and rigorous, evidence-based e-CPGs may be ideal for introducing evidence-based practice into a wide variety of environments. The clinical guidelines for the prevention of hypercholesterolaemia,[14] diabetes mellitus type 2[15] and hypertension[16] to be used in the present study were developed between 2007 and 2011. To encourage the use of the newly available resources, official supporting materials were disseminated in routine seminars held in all primary care centres of the Catalan Institute of Health.[24]

The incorporation of the e-CPG software throughout the medical record includes a screen that integrates the clinical information of patients with all preventive activities described in the CPG.[14–16] The e-CPG is a two-level interactive software that guides the FPs' actions through pop-up windows with reminders. FPs are free to choose the level of interaction they want to work with. In the first level, the alert system recommends changes towards the diagnosis, treatment, control and management of each disorder (i.e. hypercholesterolaemia, diabetes mellitus type 2 and hypertension). In the second level, the FPs have access to the algorithms included in e-CPGs that point to the best evidence-based activities regarding diagnosis, treatment and follow-up in each particular case (Figure 1).

Additionally, the software assesses the FP's actions concerning: (1) the accuracy of diagnosis and pharmacological treatment; (2) the control of clinical variables; and (3) the appropriateness of follow-up undertaken, including tests performed. Each of the three items is colour-coded. The classification colours are white (patient values are correctly controlled), yellow (alerting FP to suspected diagnoses, such as a patient with systolic blood pressure $\geq$ 140 mmHg in a single measurement and without diagnosis of hypertension) and red (poorly controlled values, such as a diagnosis of diabetes mellitus type 2 and glycated haemoglobin > 7%). Two specific items referring to diagnosis and follow-up could also appear in red: (1) a missing primary or secondary prevention diagnosis for a patient whose values fulfil all the CPG criteria (e.g. a record with two total cholesterol determinations > 250 mg/dl and no diagnosis of hypercholesterolemia, or no secondary prevention diagnosis in the medical record of an individual with history of cardiovascular disease); (2) missing follow-up such as relevant tests for a particular diagnosis (e.g. microalbuminuria test) not performed within the last year in a patient with diabetes mellitus) (Figure 1).

Tables 1 and 2 include the diagnoses recognised and treatments recommended by e-CPGs, respectively.

Study setting and selection of participants

The timeline of this project follows the e-CPG implementation process, which started in March 2010 with the hypercholesterolaemia guideline and finished in September 2011 with hypertension and diabetes guidelines.

We will analyse routinely collected data from electronic primary care registries corresponding to 279 primary care practices of the Catalan Institute of Health in Catalonia, with a total population of more than 2,800,000 patients aged 35–74 years (80% of the
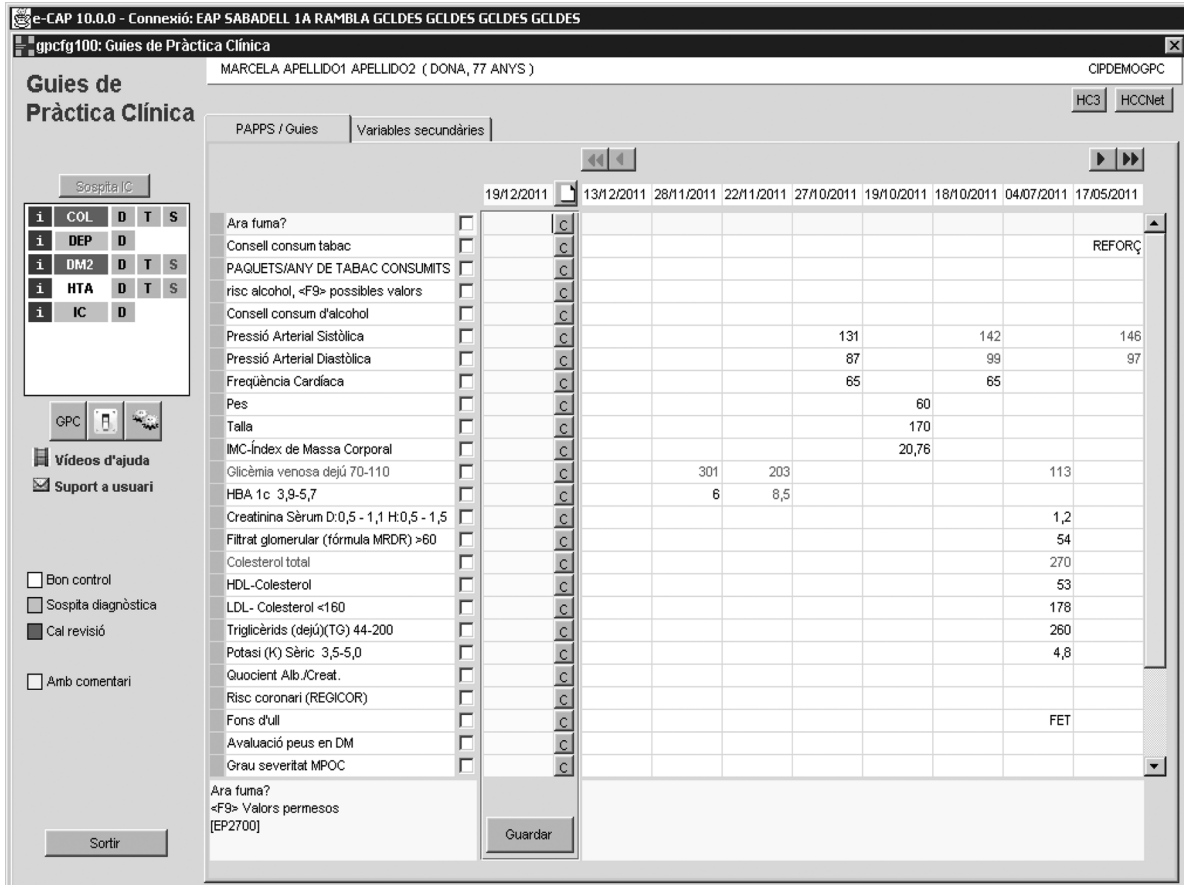
Figure 1 Electronic clinical practice guidelines software interface for the control of clinical variables, diagnosis, treatment and management of hypercholesterolaemia, diabetes mellitus type 2 and hypertension. COL, hypercholesterolemia; DM-RISC, diabetes mellitus type 2; HTA, hypertension; D, diagnosis; T, treatment; S, standards for follow-up

Table 1 Diagnoses recognised by electronic clinical practice guidelines

	International Disease Classification 10
Cardiovascular risk factors	
Hypertension	I10, I15
Diabetes mellitus type 2	E11
Hypercholesterolaemia	E78
Cardiovascular diseases	
Myocardial infarction	I20, I21, I22, I23, I25
Stroke	I60, I61, I62, I63, I64
Intermittent claudication	I73.8, I73.9

Catalan population). The volume of data guarantees population representativeness.[25] Eligible study participants are those aged 35–74 years at baseline, assigned to FPs working 36 hours or more per week. Those individuals who have changed their FP assignment during the study period will be excluded. The protocol

Table 2 Treatments recommended by electronic clinical practice guidelines

Hypercholesterolemia	ATC Codes	Diabetes mellitus type 2	ATC Codes	Hypertension	ATC Codes
Atorvastatin	C10AA05	Exenatide	A10BX04	Losartan	C09CA01
Lovastatin	C10AA02	Liraglutide	A10BX07	Valsartan	C09CA03
Pravastatin	C10AA03	Metformin	A10BA02	Amplodipine	C08CA01
Simvastatin	C10AA01	Repaglinide	A10BX02	Nifedipine	C08CA05
Gemfibrozil	C10AB04	Acarbose	A10BF01	Diltiazem	C08DB01
Colestyramin	C10AC01	Miglitol	A10BF02	Verapamil	C08DA01
		Saxagliptin	A10BH03	Atenolol	C07AB03
		Sitagliptin	A10BH01	Bisoprolol	C07AB07
		Vildagliptin	A10BH02	Metoprolol	C07AB02
		Glibenclamide	A10BB01	Chlorthalidone	C03BA04
		Glicazide	A10BB09	Hydroclorthiazide	C03AA03
		Glimepiride	A10BB12	Indapamide	C03BA11
		Gliquidone	A10BB08	Captopril	C09AA01
		Pioglitazone	A10BG03	Enalapril	C09AA02
				Lisinopril	C09AA03
				Peridopril	C09AA04
				Ramipril	C09AA05
				Trandolapril	C09AA10

of the present study was approved by the Institut d'Investigació en Atenció Primària Jordi Gol Clinical Research Ethics Committee (authorisation number P09/28). All the registries analysed are codified and the investigators have no access to individual identifiers for FPs or their patients.

The study includes two differentiated designs:

- A cross-sectional study to describe the characteristics of the population-based sample before the e-CPGs implementation (January 2006 to December 2009).
- A controlled before-and-after study with 1-year follow-up to ascertain the effect of e-CPGs implementation.[26] The patients will be divided into intervention and control groups according to the assigned FP and the number of times each FP accesses the e-CPGs, considered as a proxy of the use of these resources. Data will be collected in both groups contemporaneously, using similar methods before and after the intervention; therefore, all individuals are expected to experience similar secular trends or sudden changes. We will divide the sample in quartiles of FPs according to the number

of patients whose record adheres to the e-CPGs. The intervention group will include the individuals assigned to FPs who use the e-CPGs system regularly (exposed, fourth quartile); the control group will include those assigned to FPs who do not use the CPGs regularly (non-exposed, first to third quartiles).

In June 2011, we analysed CPG adherence for hypercholesterolaemia at 1 year.

The CPG adherence analysis for diabetes and hypertension at 1 year and for hypercholesterolaemia at 2 years was performed in June 2012.

Outcome measures

Information about the benefits of this implementation strategy will be described regarding patients and FPs. First, outcomes will be expressed as: (1) control of clinical variables (e.g. cholesterol, glycated haemoglobin, blood pressure); (2) suspected and/or confirmed diagnoses; (3) proportions of patients with appropriate drug prescriptions; and (4) requests for tests (Tables 3–5).

Table 3 Outcomes measured for hypercholesterolaemia according to CPG recommendations

Conditions	Goal (% of patients)
Suspected/confirmed diagnoses	Changes in FP attitude after CPG recommendation on hypercholesterolaemia diagnosis Changes in FP attitude after CPG alert on hypercholesterolaemia diagnosis Patients with suspected hypercholesterolemia diagnosis confirmed by FPs after CPG alert Registry of secondary prevention diagnosis in the electronic medical record of individuals with CVD history
Control of clinical variables	LDL cholesterol < 130 mg/dl in individuals on lipid-lowering treatment and with no CVD history LDL cholesterol < 100 mg/dl in individuals with CVD history or diabetes mellitus type 2 and proteinuria
Requests for tests	Estimation of coronary risk in men aged 35–74 and women aged 45–74, with total cholesterol > 200 mg/dl (5.2 mmol/l) and with no CVD history Estimation of coronary risk in individuals diagnosed with hypercholesterolaemia in the follow-up LDL cholesterol determination in the last year in individuals with and without CVD history
Drug prescription adequacy	Justified indication of pharmacologic treatment for hypercholesterolemia in individuals with no CVD history and coronary risk > 10% Adequacy of lipid-lowering drug selection in individuals with no CVD history Changes in FP attitude after CPG recommendation on hypercholesterolaemia treatment Changes in FP attitude after CPG alert on hypercholesterolaemia treatment

CPG, clinical practice guideline; CVD, cardiovascular disease; LDL, low-density lipoprotein.

All clinical variables will be measured following standard methodology by healthcare professionals (nurses and FPs) of the Catalan Institute of Health. Blood pressure is measured with a periodically calibrated sphygmomanometer with a cuff adapted to upper arm perimeter (young, adult, obese). Measurements are performed after a 5-minute rest with individuals seated. Two measurements were taken and the lower value was recorded in the electronic medical record. Blood is withdrawn after at least 8 hours fasting, with less than 60 seconds' duration. Lipid profile, glycaemia and glycated haemoglobin are determined following standard procedures at laboratories accredited by the Catalan Institute of Health with external quality control.

For pharmacological indicators, patients are considered as previously untreated for the disorder diagnosed if they have no medication prescriptions recorded in the 3 months prior to the beginning of the study.

Process-of-care variables are also considered study outcomes; all are aimed at assessing FP behaviour changes for the 12 months following the implementation, and at 24 months for the hypercholesterolaemia

guidelines. The indicators of e-CPG usage are described in Table 6.

Statistical analysis

Age-standardised prevalence will be determined for each goal described in Tables 2–4. Individuals will be categorised in 5-year age groups and a rough percentage or means calculated. This will be standardised by the direct method, with reference to the European population, for the purpose of the cross-sectional analysis.[27] These figures will be accompanied by the 95% confidence interval and stratified by sex.

To analyse the data of the controlled before-and-after design, categorical variables will be described as percentages; continuous variables with normal distribution will be described as mean and standard deviation. Variables in which normal distribution cannot be assumed will be described as median and interquartile range. Student's *t*-test for independent samples, Mann–Whitney *U*-test and chi-square tests will be used as

Table 4 Outcomes measured for diabetes mellitus type 2 according to CPG recommendations

Conditions	Goal (% of patients)
Suspected/confirmed diagnoses	Changes in FP attitude after CPG recommendation on diabetes mellitus type 2 diagnosis Changes in FP attitude after CPG alert on diabetes mellitus type 2 diagnosis Patients with suspected diabetes mellitus type 2 diagnosis confirmed by FPs after CPG alert
Control of clinical variables	Glycated haemoglobin < 7% in individuals diagnosed with diabetes mellitus type 2 LDL cholesterol < 130 mg/dl in individuals diagnosed with diabetes mellitus type 2 and with no CVD history LDL cholesterol < 100 mg/dl in individuals diagnosed with diabetes mellitus type 2 with CVD history or proteinuria
Requests for tests	Glycated haemoglobin determination in the last year in individuals diagnosed with diabetes mellitus type 2 Electrocardiogram obtained in the last year in individuals diagnosed with diabetes mellitus type 2 Inner eye test performed in the last year in individuals diagnosed with diabetes mellitus type 2 Albumin-to-creatinin ratio or microalbuminuria test performed in the last year in individuals diagnosed with diabetes mellitus type 2
Drug prescription adequacy	Justified indication of pharmacologic treatment for diabetes mellitus type 2 in individuals diagnosed with this disorder in the follow-up Adequacy of hypoglycaemic drug selection Changes in FP attitude after CPG recommendation on diabetes mellitus type 2 treatment Changes in FP attitude after CPG alert on diabetes mellitus type 2 treatment

CPG, clinical practice guideline; CVD, cardiovascular disease; LDL, low-density lipoprotein.

appropriate to compare the clinical variables in the exposed and non-exposed groups. Between-groups analysis will be performed concerning the goals proposed in the follow-up: (1) suspected and confirmed diagnoses; (2) control of clinical variables; (3) requests for tests and (4) drug prescriptions adequacy; logistic regression models adjusted for potential confounders (i.e. variables significantly different between exposed and non-exposed groups in the bivariate analysis) will be used throughout.

Discussion

This study will evaluate the implementation of three e-CPGs that started in 2010 and concluded in 2011. Population-based samples obtained from routinely collected general practice data will be used for this purpose. Indeed, notable information on quality of care that can be used for health service planning can be obtained from these data, with large potential use for research provided that three conditions are met. First, quality standards should be achieved; second, the databases should meet the information governance and research ethics guidelines; and finally, the data management system should ensure the traceability of data.[28,29]

Evaluation of e-CPGs implementation

In recent years, many evidence-based CPGs have been developed for several disorders.[30] In 2001 the European Union funded the Appraisal of Guidelines Research & Evaluation (AGREE) Collaboration, which created the AGREE Instrument to provide a framework for assessing the quality of CPGs.[31] Despite these major investments by governments and scientific societies to create and evaluate evidence-based CPGs, the effect of CPG implementation on healthcare

Table 5 Outcomes measured for hypertension according to CPG recommendations

Conditions	Goal (% of patients)
Suspected/confirmed diagnoses	Changes in FP attitude after CPG recommendation on hypertension diagnosis
	Changes in FP attitude after CPG alert on hypertension diagnosis
	Patients with suspected hypertension diagnosis confirmed by FPs after CPG alert
	Registry of hypertension severity in the electronic medical record of individuals diagnosed with hypertension in the follow-up
Control of clinical variables	Systolic blood pressure < 140 mmHg in individuals diagnosed with hypertension
	Diastolic blood pressure < 90 mmHg in individuals diagnosed with hypertension
Requests for tests	Blood pressure determination in the last six months in individuals diagnosed with hypertension
	Albumin-to-creatinin ratio or microalbuminuria test performed in the last year in individuals diagnosed with hypertension
	Electrocardiogram obtained in the last two years in individuals diagnosed with hypertension
Drug prescription adequacy	Justified indication of pharmacologic treatment for hypertension in individuals diagnosed with this disorder in the follow-up
	Adequacy of antihypertensive drug selection
	Changes in FP attitude after CPG recommendation on hypertension treatment
	Changes in FP attitude after CPG alert on hypertension treatment

CPG, clinical practice guideline.

quality has been sparsely evaluated in population-based samples.[9,32–37] The use of routinely collected data increases the sample representativeness and therefore the external validity of the study and provides an accurate description of such effect on FP attitudes.[28,29,38]

Characteristics and limitations of the study

Several limitations are inherent to outcomes research in the evaluation of CPG adherence. First, the observational nature of the study makes the choice of the study population and of the compared groups susceptible to selection bias.[39] However, the representativeness of our sample is guaranteed because it includes a broad sample of individuals aged 35–74 years from Catalonia (80% of the population). To avoid temporal trend bias we have chosen a controlled before-and-after design. All individuals are expected to experience similar secular trends or sudden changes because both groups are contemporaneous and the methods used before and after the intervention are similar.[26] In this

study we will also evaluate the behaviour of FPs towards three common disorders in the population (hypercholesterolemia, diabetes and hypertension). All three disorders meet the four conditions that make them amenable to outcomes research: they have a precise diagnostic definition and a diagnostic test with high sensitivity and specificity, are reproducible among different individuals and locations, can be easily coded, and are common in the population.[39] Although e-CPGs may help FPs to improve the quality of health care, those with extensive experience in the field of cardiovascular risk factors will be less likely to rely upon these instruments. Similarly, financial incentives promoted by the Catalan Institute of Health to all FPs for reaching goals for population risk factor control may have an effect on the results. In addition, since we will do a follow-up of one year for adherence to e-CPG indications for diabetes mellitus type 2 and hypertension, some tests may not be completed during this period (e.g. electrocardiograms in individuals diagnosed with hypertension). In these cases a similar a priori effect will be expected in both groups of patients assigned to users and non-users of e-CPGs. Finally, the Hawthorne effect may alter our conclusions because FPs may

Table 6 Indicators of use of electronic clinical practice guidelines

Indicators per family practitioner	Explanation
Patients adhered to CPG	Percentage of patients for whom the family practitioner has accessed CPG
Entries to CPG	Total number of entries to CPG
Entries to different algorithms	Number of individual entries to diagnosis, treatments and monitoring support algorithms
Entries to all algorithms	Total number of entries to all algorithms in the CPG
Entries to recommendations	Total number of recommendations accepted for diagnosis and treatment
Changes after entry to CPG recommendations	Total number of patients for whom the family practitioner has accepted any CPG recommendation
Bad control alerts or lack of monitoring	Number of bad-control alerts registered

CPG, clinical practice guideline.

improve or modify their behaviour simply because they are aware the records are being studied. However, the exhaustive, broad and diverse sample of FPs included in our study (> 3500) will minimise the potential bias and will make our results more relevant and generalisable. Additionally, socio-economic variables of the patient or community are not considered in this study. However, economic differences are minimised because the National Health Service in Spain ensures universal coverage of the population.

The study also has unique strengths in addition to the representativeness of the patient population and the comprehensive access to FP data. All decisions in the implementation of e-CPGs in the Catalan Institute of Health were taken by expert consensus and the methodology used is replicable. Finally, the adherence to e-CPGs may not only reduce clinical practice variability but point-of-care access to the supporting evidence could also be an effective educational intervention for providers and patients.

Summary

This study has been designed to evaluate the implementation of three e-CPGs for the control of clinical variables, diagnosis, treatment and management of three major cardiovascular risk factors: hypercholesterolaemia, diabetes mellitus type 2 and hypertension. Several clinical implications may derive from the potential results. First, a new hypothesis regarding the strategies for implementation of e-CPGs will be generated. In addition, since individual data are available from every FP, we will be able to detect specific problems in CPG implementation. Second, this project will shed light on needs for discussion, education and use of evidence-based medicine to improve clinical practice of FPs. Finally, to know the effect of our actions on patients and on National Health System sustainability, assessment programmes such as the one described in this protocol should be evaluated. If a positive effect is observed from this analysis, such as an increase in the control of hypercholesterolemia, diabetes mellitus type 2 and hypertension, a reduction in non-recommended drugs and an efficient use of complementary tests, this model of e-CPGs could be extended to other regions in Spain or to other countries with electronic medical records systems. The first results of this study should be ready in late 2013.

CONFLICTS OF INTEREST

None.

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