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Adaptive capacity of the Adjusted Clinical Groups Case-Mix System to the cost of primary healthcare in Catalonia (Spain): a observational study

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ABSTRACT

Objectives: To describe the adaptive capacity of the Adjusted Clinical Groups (ACG) system to the cost of care in primary healthcare centres in Catalonia (Spain).

Design: Retrospective study (multicentres) conducted using computerised medical records.

Setting: 13 primary care teams in 2008 were included.

Participants: All patients registered in the study centres who required care between 1 January and 31 December 2008 were finally studied. Patients not registered in the study centres during the study period were excluded.

Outcome measures: Demographic (age and sex), dependent (cost of care) and case-mix variables were studied. The cost model for each patient was established by differentiating the fixed and variable costs. To evaluate the adaptive capacity of the ACG system, Pearson's coefficient of variation and the percentage of outliers were calculated. To evaluate the explanatory power of the ACG system, the authors used the coefficient of determination (R^2).

Results: The number of patients studied was 227 235 (frequency: 5.9 visits per person per year), with a mean of 4.5 (3.2) episodes and 8.1 (8.2) visits per patient per year. The mean total cost was €654.2. The explanatory power of the ACG system was 36.9% for costs (56.5% without outliers). 10 ACG categories accounted for 60.1% of all cases and 19 for 80.9%. 5 categories represented 71% of poor performance (N=78 887, 34.7%), particularly category 0300-Acute Minor, Age 6+ (N=26 909, 11.8%), which had a coefficient of variation =139% and 6.6% of outliers.

Conclusions: The ACG system is an appropriate manner of classifying patients in routine clinical practice in primary healthcare centres in Catalonia, although improvements to the adaptive capacity through disaggregation of some categories according to age groups and, especially, the number of acute episodes in paediatric patients would be necessary to reduce intra-group variation.

ARTICLE SUMMARY

Article focus

- In health management, separating financing, purchasing and the provision of services requires more precise instruments and measurement of healthcare activity.
- The ACG Case-Mix System is a system of risk adjustment that classifies persons according to the diseases they present over a given period.

Key messages

- The ACG system is an appropriate manner of classifying patients in routine clinical practice in primary healthcare centres in Catalonia.
- Although improvements to the adaptive capacity through disaggregation of some categories according to age groups and, especially, the number of acute episodes in paediatric patients would be necessary to reduce intra-group variation.

Strengths and limitations of this study

- The greatest limitations of the study are related to the quality of the records and information systems.
- Without standardisation of methodologies in terms of patient characteristics and the number and measurement of variables, the results and their generalisability should be interpreted with caution.

INTRODUCTION

In health management, separating financing, purchasing and the provision of services requires more precise instruments and measurement of healthcare activity.[1 2] Various countries are developing methods of per capita funding as a mechanism for allocating healthcare resources in a given region.[3] The Adjusted Clinical Groups (ACG) Case-Mix System is a system of risk adjustment that classifies persons according to the diseases they present over a given

period. The main objective is to measure the degree of disease in patient populations according to different levels of morbidity.[4 5]

Classification systems for ambulatory patients, especially primary healthcare (PHC) patients, have not been widely used even in the USA, where they mainly originated. In addition, there is some uncertainty about the adaptive capacity of these instruments in health fields other than that for which they were designed. These classification systems relate the burden of disease, consumption of resources and the real costs of care.[6–11] Therefore, studies aimed at improving knowledge of the relationships between these factors can provide valuable evidence.

In general, ACG are accepted as useful in our setting and their use is increasing in various areas. However, some ACG categories seem to have excess variability and therefore we decided to study the performance of each ACG category in PHC centres in Catalonia.[6 12 13]

The aim of this study was to identify the retrospective adaptive capacity and poorly performing categories of the ACG system according to the cost of care in various PHC centres in Catalonia (Spain) in daily clinical practice.

METHODS

Design and study population

We conducted a retrospective, multicentre study based on computerised medical records of PHC patients. All records were dissociated to ensure the confidentiality of the data. The study population consisted of all patients (N=310 235) assigned to 13 PHC centres in Catalonia belonging to four service providers. The patient population was predominantly urban, lower-middle class, with industrial occupations. All centres included provide universal free-at-the-point-of care healthcare with private provision of services in concert with the Catalan Health Service. All patients registered in the study centres who required care between 1 January and 31 December 2008 were finally studied. Patients not registered in the study centres during the study period were excluded.

Data retrieval and processing

Dependent variables were defined as the mean number of episodes and the direct costs of PHC. The independent variables analysed were age, sex, care provider and clinical service (family medicine (age ≥15 years) and paediatrics (age 0–14 years)). An episode or reason for consultation was considered as a care process equivalent to a diagnosis. The health problems diagnosed were coded using the International Classification for Primary Care (ICPC-2).[14] A conversion (mapping) from ICPC-2 codes to ICD-9-CM was made by a working group (one documentalist, two clinicians and two technical consultants). Relationships between the ICPC-2 and ICD-9-CM were divided into three groups: (1) no relationship (ICPC-2 code with no equivalent in ICD-9-CM), (2) one-way relationship (one ICPC-2 code with a single equivalent in ICD-9-CM, the optimal situation) and (3) multiple relationships (one ICPC-2 code with several possible equivalents in ICD-9-CM).

The following measures were used to calculate overall morbidity: (1) the Charlson comorbidity index[15] as an approximation of severity and (2) the individual case-mix index obtained using the ACG. The operating algorithm of the ACG Grouper V.8.2 (http://www.acg.jhsph.edu)[16] consists of a series of consecutive steps that result in 106 ACG, which are mutually exclusive groups for each patient treated.

To construct an ACG, the age, sex and the reasons for consultation or diagnosis according to ICD-9-CM are required. The first stage groups the diagnoses of the ICD-9-CM in 32 Ambulatory Diagnostic Groups (ADG) (a patient may have one or more ADG), the second step groups the ADG into 12 Collapsed Ambulatory Diagnostic Groups, the third step transforms these into 25 Major Ambulatory Categories and finally these are transformed into an ACG category. At the end of the process, each patient is assigned to a single group with similar resource consumption. The application provides resource utilisation bands (RUB), with each patient being grouped into one of the five mutually exclusive categories according to their morbidity (1: healthy users, 2: low morbidity, 3: moderate morbidity, 4: high morbidity and 5: very high morbidity).[4 5]

To measure the performance or adaptive capacity of each ACG category (intra-group variability of the total cost of care), we used: (1) the Pearson's coefficient of variation (CV), in which a coefficient >100% was considered poor performance and (2) the percentage of outliers obtained through data refining of variables. The cut-off point (T) for outliers was established using the formula: $T = Q_3 + 1.5\ (Q_3 - Q_1)$, where Q_3 and Q_1 are the third and first quartile of the distribution, respectively.

Use of resources and cost model

The design of the system of costs took into account the information requirements and degree of development of available information systems. The unit of care product used as the basis for the final calculation was the cost per patient treated during the study period. For each patient, we differentiated fixed costs and variable costs. The main fixed costs were staff (salaries and wages), purchases (drugs, medical supplies, etc), outsourced services (building repair and maintenance, professional services, etc) and a set of costs relating to structural services and centre management according to the General Accounting Plan for Health Care Centers. Fixed costs were allocated per visit (mean/unit: fixed costs/total number of visits). Variable costs per patient were calculated according to diagnostic petitions (laboratory, radiology, diagnostic or therapeutic, referrals to specialists and drug prescriptions). The tariffs used to calculate costs came from analytical cost-accounting studies (see table 1). Finally, the cost per patient was

Table 1 Mean unit costs in 2008

Health resources	Unit cost (€)
Health visit	23.62
Laboratory tests	22.70
Conventional radiology	18.84
Diagnostic tests/therapy	37.85
Referral to reference specialist	106.29
Drug prescriptions	RRPvat

Analytical accounting conducted for this study.
RRPvat, recommended retail price including Value Added Tax.

calculated as: Cp = (mean cost per visit × number of visits (fixed costs)) + (variable costs).

Data confidentiality

According to Spanish law, being a retrospective design and because it is not investigated the effectiveness of any medicine, the study does not need specific approval from an institutional review board or the patient's consent but instead required the dissociation of the data. The confidentiality of records according to the Organic Law on Data Protection (15/1999, 13 December) was respected by dissociating the data.

Data quality and statistical analysis

In a preliminary analysis, we carefully reviewed the medical records to observe their frequency and distribution and to search for possible errors in recording or coding. We performed a descriptive univariate analysis including mean values, SD, proportions and percentiles. The normal distribution of variables was confirmed using the Kolmogorov–Smirnov test. In the bivariate analysis, we used the χ^2 test, the Student t test, ANOVA, Pearson's linear correlation and the Mann–Whitney–Wilcoxon non-parametric test. To evaluate the explanatory power of the ACG system, we used the coefficient of determination (R^2) obtained from the ratio intra-group variability/total variability (ANOVA). The analysis was made using the SPSS for Windows V.18 statistical package. Statistical significance was established as $p<0.05$.

RESULTS

A total of 227 235 patients were registered in the study centres in 2008 (86.5% in family medicine and 13.5% in paediatrics). Table 2 details the general characteristics of the patient population, the comorbidity and the total costs. Patients had a mean of 4.5 (3.2) episodes and 8.1 (8.2) visits per year. The percentage of men (51.1% vs 43.3%, p<0.001) and visits (9.7 vs 7.8, p<0.001) were higher in paediatric patients. The mean age of women was higher than that of men, 39.2 vs 37.8 (p<0.001). The total cost was €148.7 million (93.3% for family medicine). Drugs were prescribed to 80.1% of patients. Fixed costs accounted for 29.1% of total costs and variable costs for 70.9% (including 47.5% on drug prescriptions). Therefore, the mean total cost per patient/year

Table 2 General characteristics of study: comorbidity and cost model

Characteristics Patients	Total N=227 235	
General		
Number of physicians	224	
Number of episodes	1 020 606	
Number of visits	1 834 326	
Mean age, years	44.1 (23.7)	
25 percentile	27.0	
50 percentile	43.0	
75 percentile	67.0	
Sex (female)	55.6%	
General comorbidity		
Mean ADG	3.7 (2.2)	
25 percentile	2.0	
50 percentile	3.0	
75 percentile	5.0	
Mean episodes	4.5 (3.2)	
Mean Charlson index	0.2 (0.6)	
RUB	2.4 (0.8)	
1	16.9%	
2	31.0%	
3	47.9%	
4	3.8	
5	0.5	
Outliers (N=14 066)	6.2%	
	Mean/unit	**%**
Cost model (in euros)/year		
Fixed costs	190.7 (193.3)	29.1
Laboratory	51.9 (73.8)	7.9
Conventional radiology	21.4 (34.1)	3.3
Complementary tests	6.2 (19.6)	1.0
Referrals to specialists	73.1 (117.3)	11.2
Drug prescriptions	310.8 (681.2)	47.5
Total cost of PHC	654.2 (851.7)	100.0
Cost of family medicine	92.9%	
Cost of paediatric medicine (0–14 years)	7.1%	

Values expressed as mean (SD) or percentage.
RUB, resource utilisation bands; ADG, Ambulatory Diagnostic Groups; PHC, primary healthcare.

was €654.2 (851.7), €702.5 in family medicine and €344.6 in paediatric (p<0.001). A total of 6.2% of patients were considered outliers, and after data refining, the mean unitary cost per year was €556.7. The association between the mean/unit cost according to age is shown in figure 1.

The performance (patient distribution) and adaptive capacity (intra-group variation in categories) of the ACG classification are shown in table 3. All patients were grouped in a category. However, no patients were grouped in 37 of the 106 categories, meaning that all patients were grouped in the remaining 69 categories. Furthermore, 61% of all patients were grouped in 10 categories and 80.9% in 19 (N=183 721, table 3). This distribution showed no significant differences according to the service provider. In 10 ACG categories, a poor

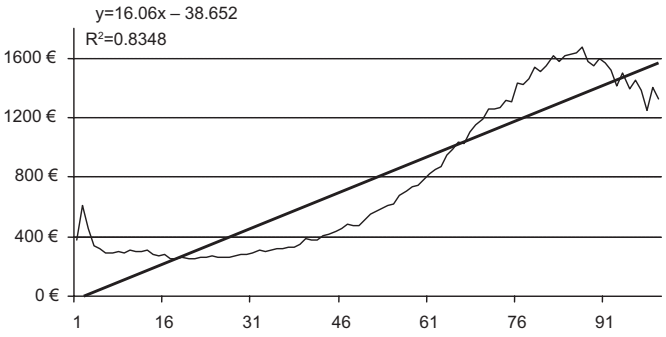

Figure 1 Correlation of the cost of care according to age. R^2: coefficient of determination.

performance (poor adaptive capacity) was observed (CV >100%, N=110 917, 48.8% of patients, table 3 and figure 2). The two categories with the highest CV were 1600-Preventive/Administrative (N=8527, 3.8%, outliers: 12.5%) and 1300-Psychosocial, w/o Psychosocial Unstable (N=3653, 1.6%, outliers: 10.7%).

We carried out a more-detailed analysis according to poor performance and the number of patients in each category. Table 4 shows the distribution of five ACG categories (making up 71% of poorly performing categories, N=78 887). Compared with the total of 69 categories (N=227 235), these five categories had a lower explanatory power (coefficient of determination, R^2) in episodes (44.3% vs 77.4%) and total costs (18.8% vs 36.9%), p<0.001. For refined data, the results were 46.4% vs 78.4% for episodes and 36.5% vs 56.5% for total costs, p<0.001. Category 0300-Acute Minor, Age 6+ (N=26 909; 11.8%) had a CV =139% and 6.6% of outliers and showed significant differences before and after data refining. Categories 0400-Acute Major (N=8160) and 1800-Acute Minor/Acute Major (N=9077) performed similarly. Category 4100-2-3 Other ADG Combinations, Age 35+, had the highest number of patients (N=28 864, 12.7%), with a high mean number of episodes (3.9 of total cases compared with 4.5 in outliers, p<0.001), resulting in increased costs in these patients. The R^2 of the five poorly performing categories was 34.7%.

DISCUSSION

This study determined the retrospective adaptive capacity of the ACG classification system according to the cost of PHC in Catalonia (Spain) in daily clinical practice, identifying 10 categories that performed poorly in the Catalan health system. In Catalonia, the use of capitation-based funding is still in its infancy compared with other European healthcare systems. The focus is on incorporating risk adjustment indicators in order to provide unbiased estimates of the expected costs of an individual patient in each health plan.[2–17]

There is abundant published evidence on the use and overall performance of the ACG classification, but evidence on categories that perform poorly is very limited.[4–7 9 12 18–24] It is expected that persons with similar morbidity and demographic characteristics will have a similar use of resources. In this respect, the available empirical evidence shows that it is technically possible to find an adjustment formula to predict at least a portion of the variation in health expenditure per person and also that the highest predictive values are

Table 3 Distribution of ACG categories with the most patients: variability of categories

ACG	ACG description	N	%	Cost*	CV	Outliers†
4100	2-3 Other ADG Combinations, Age 35+	28 864	12.7	776.3	107	6.5
0300	Acute Minor, Age 6+	26 909	11.8	169.6	139	6.6
4910	6-9 Other ADG Combinations, Age 35+, 0-1 Major ADGs	14 876	6.5	1624.4	67	4.5
2100	Acute Minor/Likely to Recur, Age 6+, w/o Allergy	11 867	5.2	304.7	91	5.3
4410	4-5 Other ADG Combinations, Age 45+, no Major ADGs	10 551	4.6	1025.4	74	5.3
4420	4-5 Other ADG Combinations, Age 45+, 1 Major ADGs	10 137	4.5	1336.2	79	4.6
0500	Likely to Recur, w/o Allergies	9872	4.3	187.2	140	6.6
1800	Acute Minor/Acute Major	9077	4.0	353.2	104	5.9
1600	Preventive/Administrative	8527	3.8	229.5	215	12.5
0400	Acute Major	8160	3.6	237.3	160	8.1
0900	Chronic Medical: Stable	6319	2.8	506.7	114	6.2
3900	2-3 Other ADG Combinations, Males Age 18 to 34	5877	2.6	341.7	117	6.0
3200	Acute Minor/Acute Major/Likely to Recur, Age 12+, w/o Allergy	5785	2.5	525.0	89	6.3
2300	Acute Minor/Chronic Medical: Stable	5756	2.5	612.6	95	6.3
3600	Acute Minor/Acute Major/Likely to Recur/Chronic Medical: Stable	5575	2.5	1022.1	72	5.0
4310	4-5 Other ADG Combinations, Age 18 to 44, no Major ADGs	4168	1.8	554.8	86	6.4
4920	6-9 Other ADG Combinations, Age 35+, 2 Major ADGs	4089	1.8	2102.5	67	3.5
2800	Acute Major/Likely to Recur	3659	1.6	351.0	102	6.9
1300	Psychosocial, w/o Psychosocial Unstable	3653	1.6	340.4	175	10.7

Nineteen ACG categories contain 80.9% of patients (N=183 721). No patient was grouped in 37 ACG categories; ACG, Adjusted Clinical Groups (Code)*: Gross cost (mean/unit in euros), CV: Pearson's coefficient of variation† :outliers: percentage of patients, cut-off: $T = Q_3 + 1.5 (Q_3 - Q_1)$, where Q_3 and Q_1 are the third and first quartiles of the distribution, respectively. Total sample: N=227 235, CV =130.0%, outliers: 6.2%.

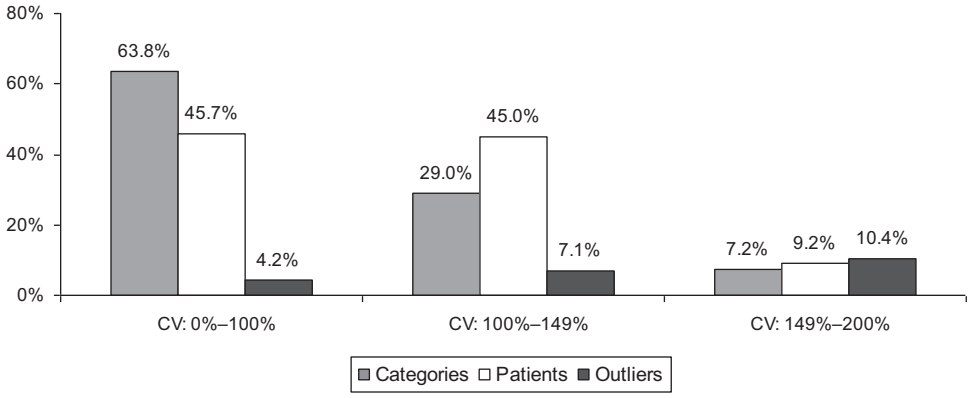

Figure 2 Percentage distribution of coefficients of variation according to the number of categories, patients and outliers. CV: Pearson's coefficient of variation; contrast statistic: χ^2, $p<0.001$ for all categories.

achieved by systems that incorporate diagnostic information.[6 21 25] This has been proven in our study since the number of episodes showed a greater explanatory power with respect to ACG categories than the total costs. Furthermore, data refining may lessen the weight of random factors in predicting expenditure, although it is known that no system of classification of patients into RUB explains all the variation in the use of resources.[6 7 10 26]

In general, the Grouper requires a limited number of variables for each patient: age, sex and diagnosis (not necessarily correlated in time). This simplicity of use is compatible with the needs of PHC, which must work with large daily volumes of information, limited time for each patient, professional cooperation (doctors, nurses, social workers, etc) and repeated visits from the same patient. However, a greater degree of computerisation of PHC and the establishment of mechanisms for consensus between health professionals would be required to increase data quality and the consistency of records, especially in the identification of diagnoses.[11 23]

The general results of the study (demographic variables (age and sex), case mix (morbidity) and resource use levels (RUB)) fall within the parameters expected in PHC in Spain. Furthermore, the distribution of patients within ACG categories is similar to the results obtained in other studies (60% of patients are grouped in 10 ACG categories) and stable over time.[4 6 8 9 12 18–23 25–28]

This may be because the grouping works by binary combinations of ADG, regardless of the number of recurrences and the type of disorder.[4 5] For example, a patient with one or more episodes of upper respiratory

Table 4 Distribution of five poorly performing ACG categories according to age, episodes and cost

ACG categories (coding and description) Variables	Total		No outliers		Outliers	
	N	Mean	N	Mean	N	Mean
4100: 2-3 Other ADG Combinations, Age 35+	28 864		26 992		1872	
Age		60.5 (14.8)		59.7 (14.6)		70.9 (12.8)
Episodes		3.9 (1.3)		3.9 (1.2)		4.5 (1.5)
Total cost		776.3 (828.2)		620.3 (448.7)		3026.1 (1504.4)
0300: Acute Minor, Age 6+	26 909		25 142		1767	
Age		33.1 (16.5)		31.9 (15.4)		50.5 (22.1)
Episodes		1.7 (1.1)		1.7 (0.9)		2.5 (1.4)
Total cost		169.5 (236.5)		125.2 (91.7)		800.0 (554.3)
1800: Acute Minor/Acute Major	9077		8538		539	
Age		32.1 (19.8)		30.8 (18.5)		51.6 (27.1)
Episodes		3.6 (1.5)		3.6 (1.4)		4.8 (2.3)
Total cost		353.2 (366.2)		288.7 (166.5)		1374.2 (843.8)
0400: Acute Major	8160		7503		657	
Age		38.5 (18.2)		36.6 (16.7)		59.9 (20.6)
Episodes		1.6 (0.8)		1.5 (0.7)		2.1 (1.1)
Total cost		237.3 (379.5)		158.3 (108.7)		1139.1 (877.8)
3900: 2-3 Other ADG Combinations, Males Age 18 *to* 34	5877		5523		354	
Age		28.1 (4.5)		28.0 (4.5)		28.7 (4.2)
Episodes		3.3 (1.0)		3.3 (1.1)		3.8 (1.2)
Total cost		341.6 (399.1)		273.7 (154.1)		1401.2 (1040.1)

Contrast statistic: χ^2 test or Mann–Whitney–Wilcoxon test; $p<0.001$ in all cases.
ADG, Ambulatory Diagnostic Groups.

tract infection over time, with or without concomitant pharyngitis, may remain grouped in the same ACG category, resulting in widely differing use of resources and degree of variation in costs. This point has been suggested by some authors as a limitation of the ACG system, although recent years have seen an expansion of categories from 51 to 103 to avoid such problems.[23]

Poor performance or adaptive capacity was observed in 10 ACG categories (N=110 917, 48.8% of patients). The two categories with the highest CV were Preventive/Administrative and Psychosocial, w/o Psychosocial Unstable. These results are difficult to compare for several reasons: (1) these categories include many different circumstances and conditions (administrative processes, preventive actions and health promotion, unstable conditions with an unpredictable risk of recurrence, etc), (2) these conditions tend to be associated with poor-quality medical records (prescriptions not linked to a diagnosis, etc) and (3) the presence of different organisational models between centres (patient circuits, etc) as a result of health policies, causing a high degree of variability that affects the use of resources and their costs.

We found that five categories accounted for 71% of poor performance. In general, acute disease (0300-Acute Minor, Age 6+, 0400-Acute Major and 1800-Acute Minor/Acute Major), representing a large number of paediatric patients, had a poor adaptive capacity. The ACG classification in Catalonia might be improved by expanding some of these categories according to age groups and, especially, by quantifying the number of episodes occurring during the study period. However, in the categories 4100-2-3 Other ADG Combinations, Age 35+ and 3900-2-3 Other ADG Combinations, Males Age 18–34, the performance with respect to classification into RUB could be improved by separating different ranges of episodes or ADG.

Therefore, a possible scenario for the debate on the funding model for PHC teams could be developed using a combination of factors: (1) the weighting of structural costs related to accessibility; (2) the variable costs according to the case mix (ACG) and patient complexity, adapting the classification to the country and (3) quality targets derived from the policy sought by the purchaser and expected by the customer. In this aspect, the adaptive capacity of the ACG system to the Catalan setting could be bettered by improving the definition of some categories. This would facilitate policy making using benchmarking with respect to the complexity (case mix) and efficiency of PHC centres with the population served, enabling capitation payments (risk adjustment).[4 26]

The greatest limitations of the study are related to the quality of the records and information systems. Without standardisation of methodologies in terms of patient characteristics and the number and measurement of variables, the results and their generalisability should be interpreted with caution.[24] In addition, possible differences between health professionals in the selection of diagnoses may contaminate the comparison of costs between groups. However, strength of the study is that the large sample size could minimise these drawbacks. The ACG system was designed to measure the health status and medical resources consumed in a set of patients and, therefore, population-based studies of risk-adjusted capitation payments and the clinical management of PHC centres may be of considerable interest in Catalonia.[23 29]

Conclusions

The ACG system is an appropriate manner of classifying patients in routine clinical practice in PHC centres in Catalonia, although improvements to the adaptive capacity through disaggregation of some categories according to age groups and, especially, the number of acute episodes in paediatric patients would be necessary to reduce intra-group variation.

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Contributors AS-M, SV-V, RN-A, CV-F and AP-T planned the study. AS-M, RN-A and SV-V supervised the campaign registration, data entry and follow-up. AS-M was responsible for the statistical analysis with help from SV-V. AS-M wrote the first draft of the paper and has the primary responsibility for the final content. All authors contributed to and approved the final manuscript. AS-M is the head of the Catalan study.

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Competing interests None.

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

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	X
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	X
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	X
Objectives	3	State specific objectives, including any pre-specified hypotheses	X
Methods			
Study design	4	Present key elements of study design early in the paper	X
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	X
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	X
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	X
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*X*
Bias	9	Describe any efforts to address potential sources of bias	X
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	X
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	X
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	X
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	X

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	X
		(b) Give reasons for non-participation at each stage	X
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	X
		(b) Indicate number of participants with missing data for each variable of interest	X
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	X
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	X
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	X
		(*b*) Report category boundaries when continuous variables were categorized	X
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	X
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	X
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	X
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	X
Generalisability	21	Discuss the generalisability (external validity) of the study results	X
Other information			
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	X

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional 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.org/, 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.strobe-statement.org.