

RESEARCH ARTICLE

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# The effectiveness of computerized clinical guidelines in the process of care: a systematic review

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## Abstract

**Background:** Clinical practice guidelines have been developed aiming to improve the quality of care. The implementation of the computerized clinical guidelines (CCG) has been supported by the development of computerized clinical decision support systems.

This systematic review assesses the impact of CCG on the process of care compared with non-computerized clinical guidelines.

**Methods:** Specific features of CCG were studied through an extensive search of scientific literature, querying electronic databases: Pubmed/Medline, Embase and Cochrane Controlled Trials Register. A multivariable logistic regression was carried out to evaluate the association of CCG's features with positive effect on the process of care.

**Results:** Forty-five articles were selected. The logistic model showed that Automatic provision of recommendation in electronic version as part of clinician workflow (Odds Ratio [OR]= 17.5; 95% confidence interval [CI]: 1.6-193.7) and Publication Year (OR = 6.7; 95%CI: 1.3-34.3) were statistically significant predictors.

**Conclusions:** From the research that has been carried out, we can conclude that after implementation of CCG significant improvements in process of care are shown. Our findings also suggest clinicians, managers and other health care decision makers which features of CCG might improve the structure of computerized system.

## Background

Clinical practice guidelines have been developed to improve the quality of care, patient access, treatment outcomes, appropriateness of care and achieve cost containment by improving the cost benefit ratio [1-4].

At the same time many healthcare organizations have widely promoted the development of computerized clinical decision support systems (CDSS) with the aim of improving practitioners' performance [5-7].

According to the indications of regulatory systems, professional bodies and consumer organizations, CDSS can also support the implementation of the computerized clinical guidelines (CCG) [8].

An effective model of CCG consists of computer accessibility, patient-specific reminders in the clinician's

workflow and its integration with medical records, as demonstrated by Wang et al. [9].

Even though different studies in literature are focused on demonstrating that CDSS can have an impact on physicians' behaviour regarding to patients' care [6,10-12], there are very little evidence about the effectiveness of electronic guidelines [13-15] and impact of computerized support on implementing of clinical recommendations. In a qualitative systematic review, Shiffman et al. [13] highlighted higher effect of CCG versus non-electronic systems. Due to the lack of studies containing quantitative evaluation, research was focused on a systematic review of available literature about the impact of CCG upon the process of care compared with non-computerized clinical guidelines (NCCG) (such as paper guidelines, peer-to-peer consultation and previous experience.). Moreover, were analysed specific features

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of the computerized guidelines which are potentially linked with the improvement of the process of care.

## Methods

### Search strategy

An extensive search of scientific literature was carried out querying electronic databases to identify relevant studies: Pubmed/Medline, Embase and Cochrane Controlled Trials Register. The search covered the period from January 1992 to March 2006. The search of articles were carried out using the following key words, related to:

1. Exposure variables: computerized clinical guidelines, computer-based guidelines, computerized clinical recommendations, computer decision support aids, software guidelines, computerized clinical pathways, computerized critical pathways, computer-based pathway\*, electronic care map, electronic care pathways, electronic clinical pathways, electronic critical pathways, integrated care pathway, electronic clinical reminder, electronic clinical reminders, electronic reminder AND practice guidelines AND electronic medical record, computerized reminders AND guidelines;
2. Effect variables: medical outcomes, organisation's outcomes, patients' outcomes; process of care
3. Population variables: medical doctors, health personnel.

The search in grey literature was carried out using general purpose search engines (GOOGLE, VIVISIMO) in order to identify missing articles. Rest of the articles were identified through the analysis of bibliographic citations.

### Inclusion and exclusion criteria

Considering study's design, only experimental or analytical studies were included while descriptive studies were excluded. The main exposure variable in our research was the comparison between CCG and NCCG (such as paper guidelines, peer-to-peer consultation and previous experience). Papers which did not contain comparison between CCG and NCCG were excluded from analysis. So, only the papers in which the guidelines were coming from a scientific society recommendations or approved by a National body, a scientific society, union or corporation of physicians or universities were included in this study. Articles not matching these criteria were excluded. Also, only articles focusing on adult patients (age  $\geq 18$  years) were taken into consideration. Studies involving children and adolescents (age  $< 18$  years) were excluded due to the fact that there are specific factors linked with the paediatricians adherence to guidelines in this specific age group [16-18].

### Study selection

Titles and abstracts of the selected studies were reviewed independently by two authors (C.S.C and A.R.) and were rated as "potentially relevant" or "not relevant" using search strategies based on study design, subjects and type of intervention. If one of the reviewers considered a reference potentially relevant, full-text articles were retrieved and examined independently, using the full set of inclusion and exclusion criteria to select the final number of studies for research. Disagreements between reviewers were resolved by discussion or by third author (G.D.).

### Data extraction

Two reviewers (C.S.C. and A.R.) assessed whether the use of computerized guidelines was going to improve the process of care and evaluated the positive or negative impact of computerized guidelines on the process of care.

Afterwards, the outcomes were distributed in two groups: favouring CCG and favouring NCCG based on evaluation of results of inference analysis. Then, the effect of computerized guidelines was defined as positive when reported improvement was more than 50% of the outcomes. Effect was defined as negative when the improvement was equal or less than 50% of the outcomes. Positive or negative effects of computerized guidelines were confirmed according to the authors' judgment in the conclusions' section of each single paper. Finally, were analysed the variables potentially linked to positive effect on the process of care. Some variables were not included in the analysis because it was not possible to obtain them from most studies (patients' age, health care givers' age, health care providers' degree, duration of observation). The analysed system's features were identified referring to Kawamoto [12] or they were extracted by the authors from the studies. So, 21 features related to the following categories were analysed:

- General system features;
- Clinician-system interaction features;
- Communication content features;
- Auxiliary features;
- Guidelines features.

The description of each feature is reported in Table 1.

### Quality assessment

The methodology of each study was assessed independently by two authors (C.S. and A.R.) according to a score assessing five potential sources of study bias [10,19-21]. Disagreements were solved by consulting the third author (G.D.) or according to a consensus. The studies were evaluated using following system:

**Table 1 Description of 21 CCG's features in five categories and proportion# of study containing each feature**

CATEGORY	FEATURE	EXPLANATION	PROPORTION
General system features	Presence of networks *	User has access to recommendation in computer terminals, available at several workstations in the hospital.	0.20
	Type of suggestion *	Recommendation is provided in different ways including reminders of overdue health care tasks, alerts of critical values, prompts for various active care issues.	0.78
	Conflict of interest *	Software designer or producer is involved in the design of study.	0.38
	Degree of automation *	User automatically receives prompts (complete automation) instead of active initiation of the system by user (incomplete automation).	0.80
Clinician-system interaction feature	Automatic provision of recommendation in paper version as part of clinician workflow **	Recommendations printed on paper forms and attached to patient charts by clinical support staff, so that clinicians do not need to look for the computer advice.	0.29
	Automatic provision of recommendation in electronic version as part of clinician workflow **	Electronic recommendations linked to patient charts display automatically to clinicians when a clinician accesses the database.	0.82
	Data updating via network *	Data of patient are updated via network link to servers storing information about all contacts of patient with the hospital.	0.33
	Request documentation of the reason for not following recommendation **	The user is asked to justify the decision of disagreement with a reason such as "the patient refused" or "I disagree with the recommendation".	0.56
	Provision of recommendation at time and location of decision making **	Recommendations provided as chart reminders during an encounter, rather than as monthly reports listing all the patients in need of services.	0.13
	Recommendation executed by noting agreement **	Computerised system provides recommendations in response to an order and the user simply clicks "OK" to order the recommended tests.	0.11
Communication content features	Provision of a recommendation, not just an assessment **	Systems show better actions to perform, rather than simply providing a diagnosis.	0.11
	Promotion of action rather than inaction **	Systems recommend an alternative view, rather than simply recommending the order to be cancelled.	0.11
	Justification of recommendation via provision of reasoning **	Recommendation for a check justified by noting date of last exam and recommended frequency of testing.	0.18
Auxiliary features	Local user involvement in development process **	Recommendation design finalised after testing preliminary versions of software (beta version) with representatives from targeted user group.	0.09
	Provision of recommendations to patients as well as providers **	As well as providing chart reminders for clinicians, system generates postcards that are sent to patients to inform them of existing recommendation.	0.18
	Recommendation accompanied by periodic performance feedback **	Users are sent e-mails periodically that summarise users compliance with recommendations.	0.02
	Recommendation accompanied by conventional education **	Implementation of a recommendation is accompanied by a presentation or an appropriate explanation for following such suggestion.	0.27
	User training *	A training period is provided for users to experience the basic features of the software.	0.22
Guidelines features	Type of guideline*	Recommendations are focused on preventive or treatment issues or both options.	0.31 0.62 0.07
	Type of condition*	Recommendations are oriented towards acute or chronic patients or both options.	0.16 0.60 0.24
	Type of intervention*	Recommendations suggest to administrate tests or/and drugs to patients or to perform other type of intervention on them or both options.	0.53 0.16 0.31

\*\* Feature referring to Kawamoto

\* Feature selected by authors

# Calculated on the total of 45 studies

- allocation to study groups (random, 2; quasi-random, 1; selected concurrent controls, 0);
- data analysis and presentation of results (appropriate statistical analysis and clear presentation of results, 2; inappropriate statistical analysis or unclear presentation of results, 1; inappropriate statistical analysis and unclear presentation of results, 0);
- presence of baseline differences between the groups that were potentially linked to study outcomes (no baseline differences present or appropriate statistical adjustments made for differences, 2; baseline differences present and no statistical adjustments made, 1; baseline characteristics not reported, 0);
- objectivity of the outcome (objective outcomes or subjective outcomes with blinded assessment, 2; subjective outcomes with no blinding but clearly defined assessment criteria, 1; subjective outcomes with no blinding and poorly defined, 0);
- completeness of follow-up for the appropriate unit of analysis (> 90%, 2; from 80% to 90%, 1; < 80% or not described, 0).

The cut-off value for including an article in our paper was 5/10.

The quality assessment of each study is reported in Table 2.

### Statistical Analysis

Each study, comparing the impact of CCG versus NCCG, was considered as a unit of analysis.

We estimated, within 95% confidence interval:

- **Positive Effect Prevalence**, calculated as the proportion of studies showing a positive effect of CCG on the total of selected studies.
- **Negative Effect Prevalence**, calculated as the proportion of studies not showing any or negative effect of CCG on the total of selected studies.

Chi-square test was performed in order to identify whether the differences between the proportions of the studies' positive and negative effects were statistically significant. The significance level was set at 5% ( $\alpha = 0.05$ ).

The effect of each specific feature on the process of care was also analysed in a backward logistic regression analysis which was carried out to evaluate the association of features with the positive effect of CCG, adjusting for the following variables:

- publication year, using 1999 (after publication of Shifman's article) as a cut-off year (1994-1999; 2000-2006);
- design of the study: observational and experimental studies;
- quality of the study, using 7 as cut-off score (5-7; 8-10)

Hosmer-Lemeshow test was applied to evaluate the goodness of fit of model. All analyses were carried out using SPSS package, version 13.0.

### Results

A total number of 2,996 articles out of 3,502 was excluded because of the title and the content of abstract. Then, 191 out of 506 studies met the inclusion criteria. Forty-five articles were included in the final selection [14,15,22-64]. (Figure 1). Some of the articles included in Garg's and Kawamoto reviews [6,12] were excluded by our selection [see Additional file 1]. The characteristics of selected studies are shown in Table 3.

*Automatic provision of recommendation in electronic version as part of clinician workflow* (proportion = 0.82) and *Degree of automation* (proportion = 0.80) were the most frequent features used in the CCG software described in the selected articles. On the contrary, the least frequent features were *Recommendation executed by noting agreement*, *Provision of a recommendation not just an assessment*, *Promotion of action rather than inaction* (proportion = 0.11) as shown in Table 1.

Proportions of studies with Positive and Negative Effect of CCG versus NCCG are shown in Figure 2. In the selected 45 articles the positive effect proportion of CCG was 0.64 ( $p = 0.053$ ) [see Additional file 2].

The multivariable analysis highlighted two variables as statistically significant predictors of CCG positive impact on the process of care: *Automatic provision of recommendation in electronic version as part of clinician workflow* (Odds Ratio [OR]= 17.5; 95% confidence interval [CI]: 1.6-193.7) and *Publication Year* (OR = 6.7; 95%CI: 1.3-34.3). Besides, the feature *Justification of recommendation via provision of reasoning* (OR = 14.8; 95%CI: 0.9-224.2) resulted marginally significant in logistic analysis.

The goodness of fit of the logistic model was confirmed in the Hosmer-Lemeshow test ( $p = 0.905$ ).

### Discussion

Previous researches [6,10,11] reviewed controlled clinical trials classified within different categories (e.g. drug dose determination, diagnosis, prevention) in order to assess the effects of CDSS on physician's performance and patient's outcomes. Enhancements on clinical performance were reported after the use of these tools. Furthermore, role of specific features of CDSS affecting clinical practice were identified by Kawamoto et al [12].

Our study instead focused on the effectiveness of CCG (a group of CDSS strictly related to the medical decision making). The functionality and the effectiveness of CCG until 1998 had been studied by Shiffman et al. [13]. They reviewed the literature showing that CCG delivered positive effect, but no quantitative and synthetic

**Table 2 Study design and quality assessment of selected articles**

Authors	Year of publication	Rivista	Study Design	Quality assessment					Total
				Method of allocation to study group	Data analysis and results	Presence of baseline differences between groups potentially linked to study outcome	Type of outcome measure	Completeness of follow-up	
Burack	1997	Medical Care	Experimental	2	2	2	2	2	10
Burack	1994	Medical Care	Experimental	2	2	2	2	2	10
Butzlaff	2003	Family Practice	Experimental	2	1	2	0	2	7
Cannon	2000	JAMIA	Experimental	2	2	2	1	2	9
Carton	2002	Clinical Radiology	Observational (time series)	0	1	0	2	2	5
Dayton	2000	Medical Decision Making	Experimental	2	1	0	0	2	5
Demakis	2000	JAMA	Experimental	2	2	2	2	2	10
Derose	2005	American Journal Manag Care	Experimental	2	1	0	2	2	7
Dexter	2001	New England Journal of Medicine	Experimental	2	2	2	2	2	10
Durieux	2000	JAMA	Observational (time series)	0	1	1	2	2	6
Feldman	2005	Health Services Research	Experimental	1	1	2	1	2	7
Feldstein	2006	Journal American Geriatric Soc	Experimental	2	1	2	2	2	9
Filippi	2003	Diabetes Care	Experimental	2	1	0	2	2	7
Fitzamaurice	2000	Arch Intern Med	Experimental	2	1	2	1	2	8
Frank	2004	Australia	Experimental	1	1	2	2	2	8
Hetlevik	1999	Scand J Health Care	Experimental	2	1	2	2	1	8
Hetlevik	2000	Int J Technol Assess Health Care	Experimental	2	1	2	2	0	7
Jousimaa	2002	Int J Technol Assess Health Care	Experimental	2	1	2	2	1	8
Kitahata	2003	Clinical Infectious Disease	Observational (before and after)	0	1	2	2	2	7
Kucher	2005	The New England Journal of medicine	Experimental	2	1	0	2	2	7
Lafata	2002	JGIM	Experimental	2	2	2	2	2	10
Lobach	1997	Am J Med	Experimental	2	0	2	2	2	8
Raebel	2005	Arch Intern Med	Experimental	2	1	2	2	2	9
McCowan	2001	Medical Informatics	Experimental	2	2	2	1	0	7

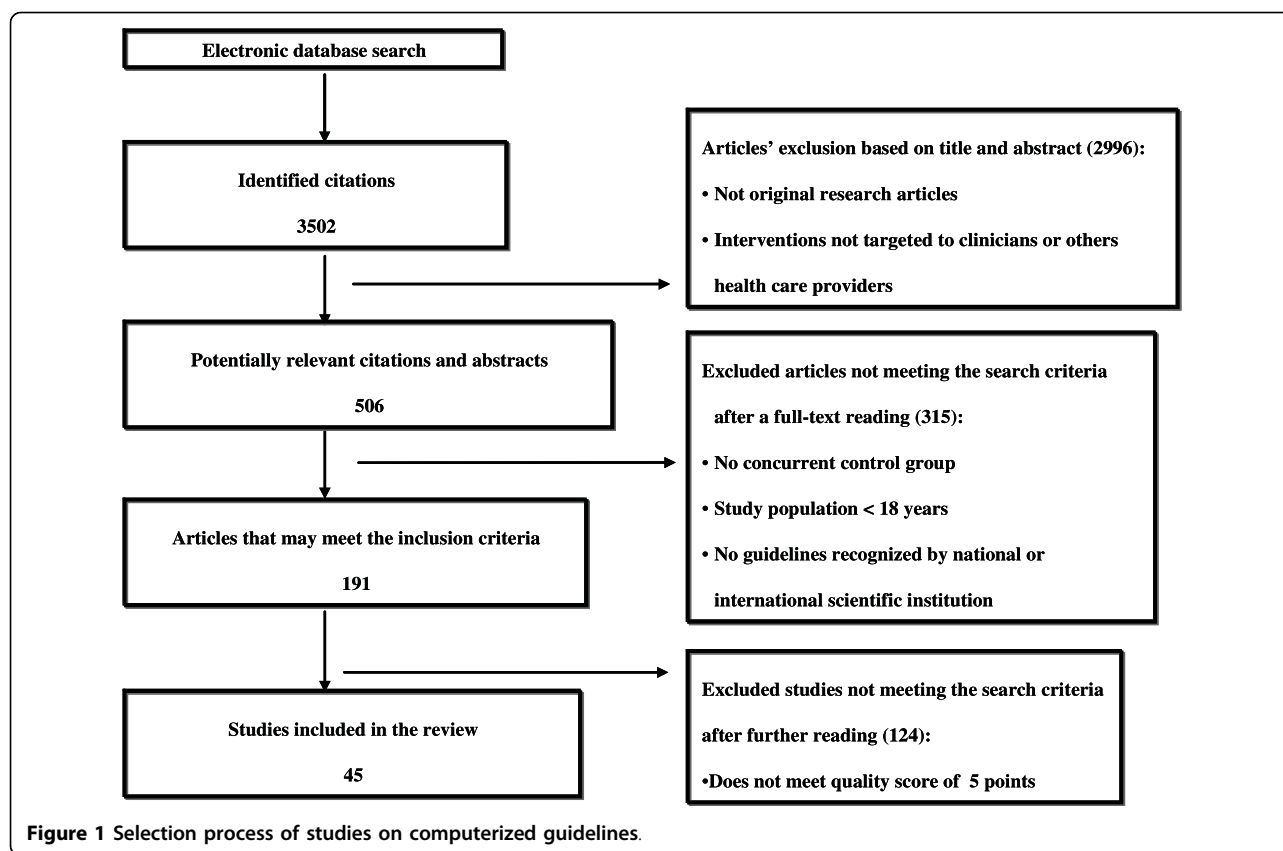
**Table 2: Study design and quality assessment of selected articles (Continued)**

McMullin	2004	Annals of Family Medicine	Observational (retrospective cohort study)	0	1	0	2	2	5
Medow	2001	Medical Decision Making	Experimental	2	2	0	0	2	6
Meigs	2003	Diabetes Care	Experimental	2	1	2	2	2	9
Montgomery	2000	BMJ	Experimental	2	2	2	1	1	8
Mosen	2004	Chest	Observational (before and after)	0	2	2	2	2	8
Murtaugh	2005	Health Services Research	Experimental	2	1	2	1	2	8
Overhage	1996	Arch Intern Med	Experimental	1	2	2	2	2	9
Overhage	1997	JAMIA	Experimental	2	1	2	2	2	9
Poller	1993	J Clin Pathol	Experimental	2	2	1	2	2	9
Rood	2005	JAMIA	Experimental	2	2	1	2	2	9
Rossi	1997	JGIM	Experimental	2	1	2	2	2	9
Safran	1995	Lancet	Experimental	0	2	2	2	2	8
Schriger	1997	JAMA	Observational (interrupted time series)	1	1	2	2	2	8
Sequist	2005	JAMIA	Experimental	2	1	2	2	2	9
Shojonia	1998	JAMIA	Experimental	2	2	0	2	2	8
Steele	2005	American Journal of Preventive Medicine	Experimental	0	1	0	2	2	5
Thomas	1999	J Med Internet Res	Experimental	2	1	0	1	2	6
Tierney	2003	JGIM	Experimental	2	1	2	2	2	9
Turner	1994	Arch Intern Med	Experimental	2	1	2	2	1	8
Williams	1998	Arch Fam Med	Experimental	2	1	0	2	2	7
Zanetti	2003	Infection control and hospital epidemiology	Experimental	2	2	2	2	2	10

analysis were carried out. Our contribution provides an updated, systematic and quantitative analysis aiming to understand the design factors which are responsible for the success or the failure of computer-based guidelines compared with NCCG.

The resulting evidence showed that the use of CCG seems to have a significant impact on the process of care. In addition to qualitative evidence reported by Shiffman [13], the multivariable analysis highlighted the positive effect of the presence of an operating CCG system, characterized by the automatic provision of recommendation in electronic form as part of clinician

workflow. This system is designed for providing automatic support to clinicians so that they don't need to look for computer advices. The system automatically provides support on clinical or administrative task and recommends execution or avoiding of it during the clinical process, (e.g. automatic recommendation of executing prophylaxis in patients at risk of deep-vein thrombosis [48]), and in decisions, such as the selection from a set of potential alternatives based on predefined criteria (e.g. automatic prompt of further assessment for potential Latent Tuberculosis Infection in patients selected according to specific criteria [38]) [65].



**Table 3 Characteristics of selected studies**

Variables		Countries		
		Europe	USA	Oceania
Study design	Observational	2 (33.3%)	4 (66.7%)	0 (0.0%)
	Experimental	9 (23.1%)	29 (74.3%)	1 (2.6%)
Type of patients	Inpatient	2 (28.6%)	5 (71.4%)	0 (0.0%)
	Outpatient	4 (23.5%)	12 (70.6%)	1 (5.9%)
Guidelines receivers	Physicians	10(28.6%)	24 (68.6%)	1 (2.9%)
	Other care givers	1 (10.0%)	9 (90.0%)	0 (0%)
Population of study	Simulated	1 (25.0%)	3 (75.0%)	0 (0.0%)
	Real	10(24.4%)	30 (73.2%)	1 (3.3%)
Type of centres involved in the study	Non-academic	5 (22.7%)	17 (77.3%)	0 (0.0%)
	Academic	5 (25.0%)	15 (75.0%)	0 (0.0%)
Number of centres involved in the study	Multicentric	7 (36.8%)	11 (57.9%)	1 (5.3%)
	Monocentric	4 (15.4%)	22 (84.6%)	0 (0.0%)
Type of guideline	Preventive	1 (7.1%)	12 (85.7%)	1 (7.1%)
	Treatment	9 (32.1%)	19 (67.9%)	0 (0.0%)
	Both	1 (33.3%)	2 (66.7%)	0 (0.0%)
Type of condition	Acute	2 (28.6%)	5 (71.4)	0 (0.0%)
	Chronic	6 (22.2%)	21 (77.8%)	0 (0.0%)
	Both	3 (27.3%)	7 (63.6%)	1 (9.1%)
Type of intervention	Test or/and drugs	7 (29.2%)	17 (70.8%)	0 (0.0%)
	Other intervention	1 (14.3%)	6 (85.7%)	0 (0.0%)
	Both	3 (21.4%)	10 (71.4)	1 (7.1%)

Author, Year,	Effect		Feature
	Negative	Positive	
Derose, 2005	■		<b>Lack of the feature: Automatic provision of recommendation in electronic version as part of clinician workflow</b>
Meigs, 2003		■	
Butzlaff, 2003	■		
Lafata, 2002		■	
Jousimaa, 2002	■		
Medow, 2001	■		
Fitzmaurice, 2000		■	
Williams, 1998	■		
Feldstein, 2006		■	<b>Presence of the feature: Automatic provision of recommendation in electronic version as part of clinician workflow</b>
Steele, 2005		■	
Sequist, 2005		■	
Rood, 2005		■	
Murtaugh, 2005		■	
Marsha Raebel, 2005		■	
Kucher, 2005		■	
Feldaman, 2005		■	
Mosen, 2004		■	
McMullin, 2004		■	
Frank, 2004	■		
Zanetti, 2003		■	
Tierney, 2003	■		
Kitahata, 2003		■	
Filippi, 2003		■	
Carton, 2002		■	
McCowan, 2001		■	
Dexter, 2001		■	
Montgomery, 2000	■		
Hetlevik, 2000	■		
Durieux, 2000		■	
Demakis, 2000		■	
Dayton, 2000		■	
Cannon, 2000		■	
Thomas, 1999		■	
Hetlevik, 1999	■		
Shoiana, 1998		■	
Schriger, 1997		■	
Rossi, 1997	■		
Overhage, 1997		■	
Lobach, 1997		■	
Burack, 1997	■		
Overhage, 1996	■		
Safran, 1995	■		
Turner, 1994	■		
Burack, 1994		■	
Poller, 1993	■		

**Figure 2** Plot of the effect stratified by "Automatic provision of recommendation in electronic version as part of clinician workflow" feature.



The positive effect might be related to time saving for clinicians, facilitation of the information retrieval and integration among different users.

The evidence of increased probability of positive effect for CCG, showed after 1999, might suggest that the improvement of the process of care may be related to the development of more automated CCG systems [66,67].

The physicians' involvement in decisions regarding clinical recommendations, even though marginally significant in the multivariable analysis, might be a key element for the effective organization of the whole process of care, relating to the improvement of the adherence of physicians to guidelines. This aspect is coherent to the active roles that physicians should play in Clinical Governance context [68,69].

Some limits of our study might be related to the lack of quantitative estimate of specific outcomes linked to clinical conditions. However, the evaluation of synthetic quantitative measures of CCG effect was unfeasible because of the high heterogeneity of analysed guidelines, population and outcomes. However, our work presents the synthetic result on the effectiveness of CCG, providing a quantitative and reproducible evaluation.

## Conclusions

Findings of this paper suggest clinicians, managers and other health care decision makers which features of CCG might improve the structure of an electronic system in health care settings. At the same time, the implementation of CCG may be integrated with more training and investment in user friendly hardware and software. Therefore, specific studies should be carried out to evaluate the cost-effectiveness of implementing CCG systems.

**Additional file 1: Appendix 1.** Articles included in Garg and Kawamoto reviews and excluded in our review.

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**Additional file 2: Appendix 2.** List of outcomes of selected articles.

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## Abbreviations

CCG: computerized clinical guidelines; CDSSs: computerized clinical decision support systems; NCCG: non-computerized clinical guidelines.

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## Authors' contributions

GD, LP and WR contributed to the conception of this paper; GD, LP, RG, LoS designed the study. SCC and RA selected articles that met the inclusion criteria and extracted data. LS, LP conducted the statistical analysis. All authors made substantial contributions to the interpretation of results and have seen and approved the final version.

## Competing interests

The authors declare that they have no competing interests.

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