

Clinical governance and internal medicine: a marriage of convenience?

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ABSTRACT

Amplification in health expectations, increase in new technologies, decrease in economic resources and the breakdown of traditional control systems have led to the development of clinical governance (CG). The aim of the present pilot study was to investigate the application of CG tools in significant sample of Italian internal medicine wards (IMW). A 37-item questionnaire was developed and administered to 39 physicians, within 33 IMWs throughout Italy. Thanks to the data analysis, the perceived usefulness, the utilization rate of CG tools, the correlations between CG use, wards characteristics, and/or localization were studied. We identified at what organizational level the CG tools were applied and used. fifty-two percent of the studied tools were being used in the investigated hospitals. The average utility and utilization rate was different depending on the region of provenance. This research showed that CG is a methodology often used by Italian hospitals physicians, especially for inpatient care. The encouraging results of this pilot study could suggest opportunities to extend the survey at national level, to generalize the results.

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Introduction

An increase in health expectations, advances in innovations and technologies used, a decrease in economic resources, and the breakdown of traditional controlling systems have led to the development of clinical governance (CG), a multi-dimensional tool which aims to improve appropriateness, promote excellence and control systems in health care.¹ In 1997, the UK Department of Health published the White Paper titled *The New NHS: modern, dependable*, which introduced the concept of CG as an accounting method for clinical quality in health care.² In 1998, Scally and Donaldson, set out the vision of CG: *a framework through which organizations are accountable for continually improving the quality of their services and safeguarding high standard of care by creating an environment in which excellence in clinical care will flourish*.³ Four components of quality revealed to be really interesting: the technical quality of the professional performance; the efficiency of the resource used; the risk of injury or illness associated with the service provided and the patients satisfaction. These four issues constitute the four pillars of the CG.⁴

Over the past decade, CG has been promoted as a systematic, integrated approach assuring safe, good quality health care. Despite this consideration, CG is already assimilated to an umbrella term,^{5,6} under which administrative activities and clinical elements work together, providing a framework in order to create a com-

plete accountability.⁷ Even if terms and way of application are not so homogeneous, a significant number of Regional and National healthcare systems formally embraced the structures and ideas of CG.⁸⁻¹³ The intention has been to move beyond the organizational magic bullet of single strategies (*e.g.*, professional education, audit, risk management) to a systematic, multi-faceted approach aimed at quality improvement using a range of locally implemented strategies.¹¹

Despite this good purpose, the government concerns related to the problem of top down performance measurements, especially considering the measure of outcomes, and the provision of related services, have undermined the potential of CG development, reducing it very much.¹⁴

To be totally effective, CG needs to be applied at all organizational levels in a hospital or in a healthcare organization, also requiring functional and process integration,^{3,10} engaging medical staff¹⁵ and solving internal problems between managers and frontline staff.¹⁶

However, we believe there is still a need, today, to clarify models of CG and, in particular, of its application in order to improve the quality of health care.¹¹

Although 59.2% of the literature citations related to clinical governance, refers to a time horizon that goes from 1998 to 2003,¹⁷ several surveys have recently been conducted on the topic of the clinical governance tools practical application.

This knowledge area is very captivating and a lot of investigation could be already developed in particular to analyse the specific internal medicine field.

Three main topics are still to evaluate in the literature landscape: i) if are existing, in practice, different application levels of CG tools; ii) if there are similarities, considering perceived usefulness and utilization rate of the clinical governance instruments; iii) if some organizational characteristics of the hospitals where CG tools will be applied could have an impact on the practices, outcomes or results.

We would like to investigate these three key points, thanks to a pilot analysis, for the first time, developed in the internal medicine wards (IMWs). The results of this pilot project may lead to suggest a development of a national (country-based) study.

Materials and Methods

The primary objective of the present pilot evaluation, was to develop the current use of CG, in a significant sample of IMWs of Italian hospitals. In particular, the investigation of the perceived usefulness and utilization rate of CG tools, and correlations between CG use, wards characteristics, current use level, and/or geographical location.

CG tools are represented by instruments that ensure the pursuit of high quality in health care (*i.e.*, guidelines,

clinical pathways and procedures, risk mapping, incident reporting systems, quality standards, *etc.*).^{10,11}

The secondary objective of the study was the analysis of the characteristics of the wards, related to the managerial profile, investigating the presence of correlations between them, and their productivity, practices, or results.

In order to achieve these objectives, we developed a 37-item questionnaire with closed-ended questions; a qualitative instrument that would allow us to better understand the application of CG tools in IMWs of Italian hospitals.

The questionnaire consisted of 37 items, divided into 11 analysis forms (Table 1): evidence based medicine; performance evaluation; continuing medical education, professional training and accreditation; information/data management; clinical and critical pathways; patient based-risk adjustment; health technology assessment; clinical audit and indicators; clinical risk management; patient involvement; and quality. Each of the items refers to essential structural and functional tools of CG.

In March 2012, we administered the questionnaire to 39 physicians from 33 IMWs throughout Italy, clinicians who voluntarily joined the pilot study, and participants to the Second Level Master Course in Clinical Governance for Internal Medicine. We then analyzed the answers to the questions, thus allowing us to measure the perceived usefulness (graded from 0: not at all useful to 4: very useful) and the utilization rate of any GC tool (never, at least once a day, at least once a week, at least once a month, at least once a year) and the correlations between CG use and ward characteristics or location.

In addition, we also investigated the current use level (organization, department, or ward) at which CG was applied in each hospital and, furthermore, some managerial aspects related to the wards' characteristics.

Results

In order to validate the questionnaire, we considered all those items in the questionnaire with appropriate size and variables to be reliable, using the coefficient of reliability expressed by Chronbach's alpha test. The internal consistency, measured by Chronbach's α test, showed good results for the entirety of the areas investigated (all 37 items >0.9 and significant).

The 33 IMWs geographical distribution showed a greater involvement of central and northern areas of Italy, equal to the 55% of the pilot analysis sample. In particular 7 from north, 11 from central Italy, and 15 from south Italy and islands (45% of the whole sample). This apparently uneven distribution is a truthful and accurate representation of the areas belonging to

the Master Course participants, and therefore can be considered as a realistic picture of the situation, and not as a bias of selection for the analysis sample.

The dimensions of the hospitals involved in the pilot analysis were investigated, including in the questionnaire administered, an introductory section useful to understand the number of inpatients and outpatients, the total length of stay, the occupancy rate and the average diagnosis-related group (DRG) weight.

The wards involved in the pilot analysis cared, in 2011, a total amount of 44,700 inpatients and 197,000 outpatients. In the same year, the mean length of stay was equal to 8.83 days; mean occupancy rate 94.6, and mean DRG weight 1.2.

The mean age of the medical staff involved in the survey was 43±6.21 years. On average, 51.91% of the examined tools were being used in the investigated hospitals (with a range of utilization from 8% to 89%).

Clinical guidelines were followed in order to identify which CG tools were the most used and which tools were perceived to be the most useful. The average utility and utilization rates were different, depending on the region of provenance (significant Pearson correlation equal to 95% and 99%, respectively), considering all the responders region of origin. However, taking into account some aggregation of regions, comparing three macro-areas, the north, the central Italy, the south and Islands (in particular 7 regions from the north of Italy, 11 in central Italy, and 15 from south and islands), using a T test, there were found not significantly differences ($P>0.05$) related to these geographical areas of provenance.

In the regression analysis, the utilization rate appeared to be related to the age of medical staff ($r=-0.44$, $P=0.013$): the younger the physicians are, the more frequently CG tools are used (Figure 1).

Two other significant correlations between the IMWs size and the number of admission were identified; the number of health services provided by the hospital increases, the utilization CG rate increases (significant Pearson correlation =99%) and if the hospital is larger in size, the number of CG tools proposed and used in the different organizational levels is greater (significant Pearson correlation =95%).

The mean age distribution (related to the age of interviewed physicians) of an IMW's medical staff, the number of hospitalizations, the region of provenance, and the number of beds are, however, all variables and they accounted for only 54% of the variability of utilization rate (Tables 2-4; Figures 1-3).

From a ward management point of view, other significant correlations were found, and in particular: between the IMW's size and the number of admissions, and the services offered to the patients; if the number of health services provided by the hospital increases, the number of health services related to the IMWs increases (significant Pearson correlation =99%).

Discussion

Health systems and governments worldwide are engaged in developing new processes aimed at ensuring and improving the quality of health care. However, there is often a gap between the rhetoric of policy and the reality of organizational practice. In Italy, for example, professionals work alone towards the improvement of the healthcare quality¹⁴ as there is no clarity concerning the national strategy that aims to be outlined with respect to this topic.

Hospitals, not only in Italy but also in other countries, as with most of their public administrations, con-

Table 1. Areas of the pilot survey, clinical governance tools.

Evidence-based medicine	Which tools are used in the process of taking decision Guidelines/on line desk research
Performance evaluation	Final/economical/process/results
ECM, professional training and accreditation	Staff meetings, clinical pathways, outward procedures
Information/data management	ICT applied to Lab analyses, Radiology, tablets, etc.
CCP	Clinical and critical pathways
Patient based - risk adjustment	Predictive analyses, clinical prognostic scores
HTA	Mini HTA, observational studies, technology evaluating units
Clinical audit and indicators	Clinical audits
Clinical risk management	Incident reporting/FMEA-FMECA/root cause analysis
Patient involvement	Customer satisfaction questionnaires
Quality	Quality procedures, QCV

ECM, continuing medical education; ICT, information and communication technology; HTA, health technology assessment; FMEA, failure mode and effect analysis; FMECA, failure mode, effects, and criticality analysis; QCV, quality, convenience, value.

tinue to operate with contradiction between the need for change and organizational inertia. In addition to this, there is contradiction between the rate of institutional change and a low rate of real change; this is often conducted under conditions of financial crisis, decline in performance, and growth expectations.¹⁸

The encouraging results of this pilot analysis demonstrate the interest and the potential to develop the same subject of research, but within a broader context, focusing on a significant national reality.

Our specifically developed 37-item questionnaire allowed us to make inter-organizational comparisons in order to evaluate the use of CG tools and to give a realistic representation of the organizational status. CG is directed towards the integration of all activities impacting on patients into a single strategy, with different key research and development components, including: education; continuous training and professional development; evidence based practice; clinical audits; clinical practice variability reduction; clinical leadership; team working and partnership promotion; performance measurement and appraisal; clinical risk management; patients and health care professionals involvement.^{16,17}

In the context of CG, guidelines are one of the main supports of the quality of care, together with the information provided on institutional websites. The adoption of guidelines and their translation into clinical

or critical pathways correlates with both organizational and locally available resources.^{19,20} The implementation of CG will, however, require a re-definition of duties and accountability as a prerequisite in order to develop and achieve an overall improvement in clinical care through a culture of assessment and monitoring of quality.²¹

The study also highlighted the contextual conditions (*i.e.*, cultural, institutional, and organizational skills) for the introduction of CG.

A hospital department is the natural place of application and implementation of CG tools. Indeed, according to the interpretation of CG, the department is the synthesis between professional practice and resources management in the development of CG policy. Consequently, the department has the role of guarantor for correct use of methods and tools of CG; developing a medical practice oriented to evidence-based medicine, clinical audit, risk management, communication, guidelines, and accreditation.²²

The data suggested that the most important mechanisms to drive CG are those that recognize professional leadership and that are perceived as being locally relevant, thus allowing one to reflect on own professional practice. In particular, there is strong evidence to suggest improvements that are driven by health professionals at the practice level, with support from regional networks. Such activity at regional and service levels, however, would need support through structural

Table 2. Ward and physicians characteristics.

Variables	Mean	Median	Standard deviation	Minimum	Maximum
Age of respondent physicians	43.03	43.00	6.21	33.00	55.00
Number of beds of local hospital	381	270	311	35	1450
Total admissions, 2011	1720	1650	918	235	4800
Number of beds in the wards	36.42	30	20.81	8	96
Number of medical staff in ward	10	9	5	4	26
Number of nursing staff in ward	21	19	11	10	52
Number of supporting staff in ward	7	6	6	0	24
Number of surgeries	5.29	5	3.37	0	13
Number of services provided	4405	3257	4480	0	17250
Average length of stay, 2011	8.76	8.00	2.96	4.30	17.20
Average DRG weight, 2011	1.24	1.20	0.22	0.95	1.70
Bed occupation rate, 2011	95.45%	90.00%	14.22%	80.00%	144.00%
Number of complaints, 2011	6.42	1.00	19.61	0.00	100.00
Number of sentinel events, 2011	0.64	0	0.99	0	4
Age of ward physicians	48.41	48.00	4.85	38.00	58.00
Number of physicians	8	7	6	2	26
Number of specialists in equivalent disciplines	6	5	5	0	22

DRG, diagnosis-related group.

changes initiated at national level; this should include the funding of time for clinical governance, supported by information systems which provide ready access for practitioners to their own clinical data.¹¹

The pilot analysis conducted, allowed us to make *intra* and *inter* organizational comparisons by showing differences in the level of adoption and spreading of CG tools. The data demonstrated the presence of different CG tools in the regions involved and, also, an uneven distribution across the three macro-areas (north, central, south and islands); two findings related to the lack of clarity in the phase of strategic planning both at national and regional level.

Starting from these considerations, we suggest that CG tools, in order to be effective, should not be used sporadically or confined exclusively to the (good) will of the professionals, but be integrated into all processes of corporate governance: structural-organizational, financial, and professional.^{6,19}

The management of healthcare organizations, according to the clinical governance objectives and tools, will require a cultural change among both professionals and administrators, with resulting advantages for the citizens/users in terms of quality of care received (*i.e.*, more appropriateness, effectiveness, safety, *etc.*). A higher percentage of CG tools application was found where the medical staff age was lower. This was an important finding. The younger generation does not appear to have limitations or cultural resistance to innovation and continuous quality improvement and, therefore, has more contact and impact with the model of CG.²⁰

The data also showed that the implementation and use of the CG tools was proportional to the size and

number of health services provided by an IMW, the number of hospitalizations, and the size of the hospital. These characteristics allow one to reach, through the involvement of several organizational units, the critical mass of activity that justifies the adoption of complex CG tools and of effective and cost-effective economic and organizational management tools (*e.g.*, clinical risk management, clinical audit, clinical guidelines, integrated reporting).²¹

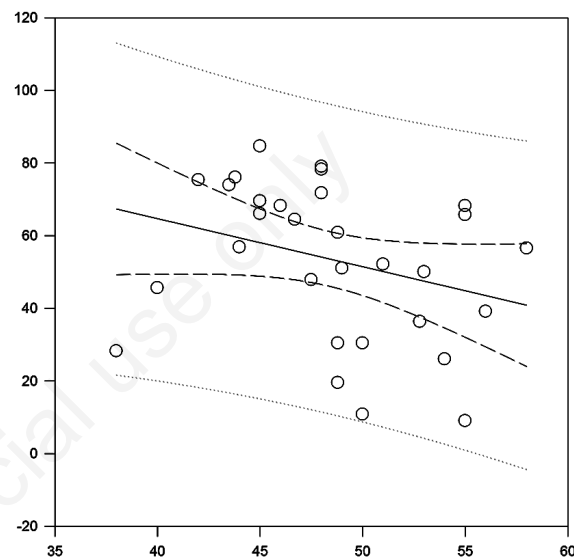


Figure 1. Linear regression: % clinical governance tools' use (dependent variable) vs physicians' age (independent variable); P=0.013, r=-0.44.

Table 3. Ward and physicians characteristics.

Variable	Code	N	%
Type of ward (total)		33	
Type of structure (N=33)			
Public hospital	1	16	48.48
Private hospital	2	0	0.00
Local health authority	3	12	36.36
Teaching hospital	4	3	9.09
Other	5	2	6.06
Geographical area of reference (N=33)			
North	1	7	21.21
Central	2	11	33.33
South (incl. Islands)	3	15	45.45
Specialist training in CG? (N=33)			
No	1	27	81.82
Yes	2	6	18.18
Courses during professional career? (N=33)			
No	1	13	39.39
Yes	2	20	60.61

CG, clinical governance.

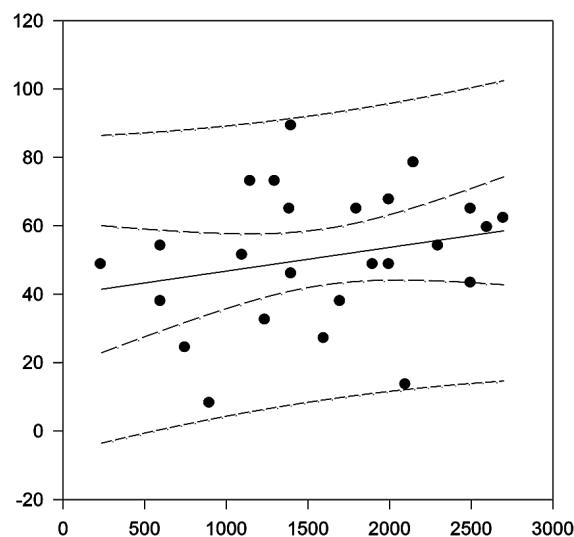


Figure 2. Linear regression: % clinical governance tools' use (dependent variable) vs total admissions 2011 (independent variable); P=0.024, r=0.44.

With regards to any perceived limitations of the present pilot research, one may be that, although we selected the CG items on the basis of the definition of clinical governance and a review of the scientific literature, we are aware that these and the relative questions could be debatable. Another may be that the interviewed physicians were all attendees of the Master in CG in internal medicine, and so they represent a group of professional who already have an interest and/or experience about CG; therefore, there could have been a bias with an interpretation, in a positive sense, of the results when compared with the actual percentage of implementation of tools of CG within internal medicine.

Conclusions

The present pilot survey showed that CG is a tool often used by Italian hospital physicians, especially for

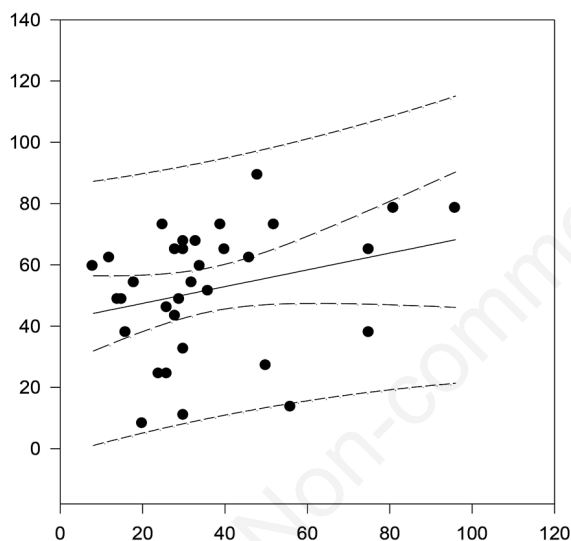


Figure 3. Linear regression: % clinical governance tools' use (dependent variable) vs number of beds of local hospital, 2011 (independent variable); $P=0.001$, $r=0.68$.

inpatient care. The administration of our specifically designed questionnaire was found to be useful in evaluating the use and utilization of CG tools in order to give realistic inter-organizational comparisons.

The encouraging results of this analysis suggest the need to apply the questionnaire to a larger sample of Italian IMW, in order to define a specific country-based picture of the CG instruments use in the current practice.

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Table 4. Clinical governance utility tools.

CG utility tools	Ward	Department	Hospital	Total
Guidelines	28	5	0	33
Research on line	28	2	0	30
Observational study	22	3	0	25
Objectives - activity	10	8	10	28
Objectives - qualitative	7	3	13	23
Objectives - resultative	9	8	6	23

CG, clinical governance.

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