

Does Clinical Governance influence the quality of medical records?

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Abstract

Background. Clinical Governance (CG) is a validated framework for continuous quality improvement in health care settings. Quality medical records may reflect the quality of care delivered and are a viable tool to implement CG skills.

Aim. Aim of this study is to investigate the correlation between the level of implementation of CG dimensions and the quality of medical records.

Material and methods. A cross-sectional study was carried out in an Italian Teaching Hospital. CG implementation levels were quantified through a systematic methodology (OPTIGOV®). The overall quality of medical records was measured through a revised version of a National-validated scale. A multiple linear regression model was used to test the likely influence of all the variables constituting the OPTIGOV evaluation on the quality of medical records. 47 hospital wards and 1458 medical records were assessed.

Results. A significant and positive association between the quality of medical records and the accountability score ($\beta = 0.15$; $p < 0.01$) and the clinical audit score ($\beta = 0.11$; $p = 0.02$), was found. Conversely, the risk management score shown a negative and significant correlation ($\beta = -0.17$; $p < 0.01$). This study confirms that CG plays a central role in driving quality improvement and advocates a systematic implementation of such an approach within healthcare organizations.

Key words

- Clinical Governance
- quality assessment
- medical records
- OPTIGOV®

BACKGROUND

In the last decades, health systems have started to cope with the growth of demand and the reduction of financial resources, so that new tools have been developed to seek the value in healthcare based on the best available research evidence on efficiency, cost-effectiveness and appropriateness [1]. Clinical Governance (CG) is a validated framework for continuous quality improvement and accountability in health care settings, through which efficient and effective services and strategies can be appointed and disseminated by health professionals and policy makers [2]. CG provides a framework for bringing together managerial, organizational, and clinical approaches into a single coherent program which encourages everyone in the organization to be a part of and work to improve quality and safety of patient care [3, 4]. The identification of governance standards is structured through different components which act simultaneously and in a synergic way to ensure high quality and appropriate care, especially in health organizations which are becoming technologically advanced as well as progressively expensive.

Medical records are part of these components, facilitating the provision of safe, high quality care and support quality improvement, audit and research. In this regard, medical records may reflect the quality of care delivered and are a viable tool to implement CG skills, offering a way to collect and report issues about effective care through health metrics [5-7]; this is useful for the development of a patient-centered awareness to drive quality improvement. The rapid development of health technologies was also reflected into the evolution of records, causing the rise of a number of quality problems, which could be related in a more global vision to the governance structure of the organization. Nevertheless, despite the growing interest in CG issues, there is little evidence on the interaction between quality of health records and specific CG dimensions [8].

"OPTIGOV" (Optimizing Health Care Governance) is a systematic methodology developed in 2006 by the Department of Public Health of the Catholic University of the Sacred Heart in order to assess CG implementation globally and in its dimensions within health-

care organizations [9]. It has the potential to produce a realistic representation of the organization status, to pinpoint both criticism and transferable best practices. The application of this methodology in several hospitals has demonstrated its ability to represent the attitude towards appropriateness and quality implementation both at Board and Units level [10].

The aim of this study was to investigate the correlation between the level of implementation of CG dimensions and the quality of medical records and the extent to which it could promote quality assessment/improvement in the context of a large Teaching Hospital.

METHODS

A cross-sectional study was conducted between July and December 2012 in an Italian Teaching Hospital with the aim to simultaneously represent CG implementation levels, as measured through OPTIGOV®, and the overall quality of medical records, as measured through a revised version of a National-validated scale.

OPTIGOV®

The OPTIGOV® methodology is aimed at assessing the CG implementation level within a health care organization by assigning an overall CG score and partial scores referred to the single CG areas (min = 0 – max = 100). OPTIGOV® constitutive elements, characteristics and steps have been previously described in detail [9].

A joint project team from the Department of Public Health and the Hospital Top Management, consisting of 4 public health experts and 2 health economists, assessed the CG implementation at the Unit level (47 clinical wards) in each of the 10 Departments of the Teaching Hospital.

The CG areas analyzed were represented by: Evidence Based Medicine (EBM), Accountability, Clinical Audit, Performance Evaluation, Risk Management, Patient Involvement. These areas were assessed through hospital audits, supported by an assessment tool: the OPTIGOV® Scorecard.

The EBM area was assessed as the practice of medicine based on the integration of the physician's clinical experience with the best scientific proof available applied to each patient's unique features and values.

The Accountability area was tested as the availability within the organization of univocal systems of identification of those responsible for the clinical procedures (doctors, nurses and other health professionals).

The Clinical Audit area was estimated as the organizational level and the quality of organized and structured peer reviews, aimed at systematically examining one's own activity and results by comparing these with explicit standards, with the purpose of improving healthcare quality and outcomes.

The Performance Evaluation area was assessed by evaluating the ability of the healthcare organization and units to systematically monitor the results of clinical practice in terms of efficacy, suitability, efficiency, quality and time.

The techniques and methods to manage risk, the existence of insurance coverage, the identification of risks, the procedures to prevent risks and medical errors have been evaluated in the "Risk Management" area.

Finally, for the "Patient Involvement" area the structured and systematic methods of discussion and dialogue with the patient/citizen about clinical decisions taken in healthcare wards were assessed.

A CG global score and 6 partial scores referred to the above mentioned CG areas were obtained by applying the OPTIGOV® Scorecard [9, 11].

At the end of the OPTIGOV® evaluation a feedback to the Heads of the Departments and of the Units was given through specific written reports. Moreover several meetings with health professionals were organized to display and discuss the overall results.

Quality evaluation of medical records

The evaluation of the quality of medical records, including sampling and retrospective assessment, have been carried out by Healthcare Management Physicians with the support of two medical residents in Hygiene and Preventive Medicine and one trained professional nurse.

The sample size has been calculated according to the criteria provided by the law in force for the institutional (external) hospital evaluation [12]. The sample was selected using a random sampling strategy and was representative of 3% of the total amount of inpatient hospitalizations of the previous year in order to ensure an equitable distribution of the sample among the hospital units. Furthermore, within each unit, the sample strategy reflected also the length of the hospital stays (0-1 day, > 2-3 days, > 3 days).

The quality assessment was performed using a 48-item evaluation grid deduced from the Lombardy Region manual of the medical record, divided into 4 domains: patient medical history and physical examination; medical notes (including daily clinical progress notes and discharge summary); nursing notes (including drug therapy chart and pain chart); informed consent. The 48 questionnaire items were expressed in the form of dichotomous questions (yes/no) and were published elsewhere [13]. A guide of the analysis with the criteria of assessment was built in order to support the teams and standardize the analysis.

For each clinical record analyzed it was given a score of acceptability defined as the ratio between the number of affirmative responses to each of the criteria evaluated and the total of evaluable criteria.

Statistical analysis

The results obtained were aggregated by the evaluation teams for each ward and medical department. Descriptive analyses of the outcome variables (Quality of Medical Record and OPTIGOV®) were carried out and shown in Table 1 and Table 2. A multiple linear regression model was used to test the likely influence of all the variables constituting the OPTIGOV evaluation on the quality of medical records. In our model, beta coefficients represented unstandardized regression coefficients, indicating the increase in the overall quality of the medical record for an increase of one unit in each CG dimension. Covariates with $p > 0.05$ were removed by backward selection. A p -value less than 0.05 was considered statistically significant. Statistical analysis was performed by using STATA 14 software.

Table 1

Clinical Governance (CG) global and partial scores from the assessment of medical records

	Mean	SD	Min	Max	95% CI
Overall Clinical Governance	48.8	14.2	28.00	85.6	43.6 - 51.8
EBM	49.0	13.2	15.5	85.7	44.6 - 52.2
Accountability	59.0	19.4	28.6	100.0	53.0 - 63.9
Clinical audit	36.5	29.4	3.8	97.8	26.0 - 42.4
Performance evaluation	60.0	18.7	18.8	100.0	53.5 - 63.9
Risk management	26.5	26.1	00.0	100.0	18.1 - 32.7
Patient involvement	62.0	14.6	29.4	94.1	57.1 - 65.5

SD: standard deviation; CI: confidence interval.

Table 2

Results of the quality assessment

	Mean	SD	Min	Max	95% CI
Number of medical record per unit	29	20	8	124	-
Overall quality	62.7%	8.8%	30.6%	79.2%	60.1% - 65.3%
Patient medical history and physical examination	67.3%	19.1%	19.5%	98.7%	61.7% - 72.9%
Medical notes	63.2%	13.2%	12.5%	89.5%	59.3% - 67.0%
Nursing notes	45.0%	20.1%	8.3%	73.4%	39.0% - 50.9%
Informed consent	76.1%	11.1%	33.1%	100%	72.8% - 79.3%

SD: standard deviation; CI: confidence interval.

Ethics statement

Approval of the ethics committee was not required for the study because the Italian legislation concerns only clinical research studies and does not provide statements on observational studies on aggregated data collected from administrative databases without the patient's involvement. For the present study anonymous data were extracted from routinely collected administrative databases and there was no need to obtain additional data from individual patients. Indeed, in 2012 the Management of the Teaching Hospital involved in this project decided to launch a quality improvement program. The assessment of quality of medical records was endorsed by the Medical Direction as a part of this improvement program. For the present study, researchers had access only to an anonymous dataset containing aggregated data (Unit level), which ensured patients' privacy. For these reasons, no personal informed consent to the present analysis was requested from study participants.

RESULTS

The implementation of Clinical Governance and the quality of medical records was evaluated in 47 hospital wards (24 surgical and 23 medical wards). A random sample of 1458 medical records was examined.

The results of OPTIGOV® and quality medical records assessment are shown in *Table 1* and *Table 2*.

By applying the multiple regression analysis, a significant and positive association between the quality of medical records and the accountability score ($\beta = 0.15$; $p < 0.01$) and the clinical audit score ($\beta = 0.11$;

$p = 0.02$), was found (*Table 3*). Such association was stronger for accountability, as for a unitary increase of the accountability score, a mean increase of about 0.15 in the overall score of medical records quality resulted, while for a unitary increase of the clinical audit score, the mean increase of medical records quality was about 0.11. Furthermore, the risk management score shown a negative and significant correlation, with a 0.17 decrease in the overall score of medical records quality for each unitary increase in the risk management score.

DISCUSSION

The purpose of our study was related to the analysis of any correlation between the elements of Clinical Governance and the quality of medical records in a healthcare organization. Different models have been described in literature which explore health services and tools and evaluate their impact on healthcare quality, always bearing in mind the evidence based medicine [14]. In this regard, literature has already demonstrated that standardized and validated CG instruments and

Table 3

Specific dimension of Clinical Governance (CG) and overall quality of medical records

R squared = 0.31	β coefficient	95% CI		p
Accountability	0.15	0.02	0.27	0.022
Clinical audit	0.11	0.01	0.20	0.022
Risk management	-0.17	-0.27	-0.07	0.001

evaluation protocols can positively affect healthcare and medical records quality [15].

The results of our study showed that there is, indeed, an association between some aspects of CG evaluation assessed by our tool (OPTIGOV) and the quality of medical records. We found that three of the CG domains analyzed correlated, directly or inversely, with quality records.

Since its definition in literature, CG has been analyzed as an instrument through which health organizations can be made accountable for the services that they provide and influence in a positive manner the improvement in health care values and standards [16]. This involves a “systematic approach to quality assurance and improvement within a health organization”, which is driven by a plurality of dimensions. In this sense, quality reliable records are fundamental to provide clinical information, recording the pathway of the patients and the quality of care and consequently promoting the best practice in an organization [17, 18]. Quality records can represent a direct, measurable tool supporting the validity of dimensions, which can be assessed in a CG methodology within a healthcare setting, and act as an immediate and powerful indicator of the strength of the methodology implemented in the specific context of the organization [19]. The link between the three CG dimensions emerged from this study (accountability, clinical audit and management) and the quality of health records highlights a red thread for all the elements converging in quality development.

The association between accountability and quality of medical records could be explained in terms of the qualitative editing of the latter. Accountability is a key-point for the best practice in a healthcare organization, allowing health professionals to take responsibilities for their activities, guiding the relations with the patients and other members, in order to reduce errors and improve quality [20]. A good process evaluating the assessment of accountability needs valid/valuable data to rely on, which can be the reason we found a statistically relevant correlation – even if weak – between accountability and quality of medical records levels/scores [21]. The presence on records of signatures/stamps or the implementation of the computerized medical record can be considered as benchmark for accounting the clinical practice, indicating that data from records used for healthcare quality measurements in the setting are complete and of good quality [22].

Clinical audit is another CG component which can be correlated to the quality of medical records. The implementation of the best practices in audit requires the availability of good quality and accessible clinical data, and data collection tools are fundamental for the successful development of performance measurement, both in the clinical pathway and for administrative and legal issues [23, 24]. Clinical records are frequently used as a relevant and suitable source of data for audit purposes, and this is even more true when computerized medical record has been effectively implemented [25]. The results of our analysis showed, in fact, that clinical audit is directly associated with the quality of medical records; indeed, a good clinical audit will be related to

good records in terms of accuracy, availability, completeness, relevance, reliability, timeliness and validity [26].

According to the results of the regression model used in our study, the size of the impact of the CG dimensions above on the overall medical record quality seems low in terms of clinical relevance. Nevertheless, considering that quality of medical care is affected by a number of variables, including medical record quality, our results should be read from a comprehensive point of view as the contribution of each variable is synergistic [27]. In this perspective, even results describing small effects gain importance in relation to the overall healthcare quality.

The CG domain of risk management turned out to be inversely associated with the quality of records. Risk management is a direct tool for the exploration, assessment and therefore reduction of harm within a healthcare organization [28]. It is generally linked with other initiatives aimed to quality development, and this objective is usually targeted by different instruments which act in a coordinated way. The heterogeneous nature of CG assessment tools (and of their domains) makes it difficult to shape them for every specific setting, such as the one related to the quality of clinical records. We believe that in our investigation, the apparent contrast between CG's risk management domain and the quality of medical records could be explained by the intrinsic nature of CG frameworks and the tool adopted in the model of our study, assessing the quality in an overall context rather than in the specific field of medical records.

Limits of this study are attributed to the psychometric properties of OPTIGOV. Although the results of its application within several Italian Hospitals lead to hypothesize the validity and reliability of the methodology, carrying out of further studies would be advisable in order to confirm these properties. However, the previous applications of OPTIGOV showed its potential to produce a realistic representation of the CG implementation level of a hospital, highlighting both criticisms and transferable best practices and providing concrete plans for organizational change and quality improvement [9]. Furthermore, both OPTIGOV and quality evaluation of medical records are based on the detection of process indicators which can be considered a proxy measure of overall quality in healthcare.

Further studies would be useful to investigate the effectiveness of specific CG tools and processes in influencing the quality of medical records, particularly referring not only to accountability, clinical audit and risk management, but also the application of targeted training programs for healthcare professionals.

CONCLUSION

This study confirms that CG influences healthcare quality, even in terms of quality of medical records. CG plays a central role in driving quality improvement and advocates the systematic, structured and integrated implementation of standardized and repeatable tools to assess and promote healthcare quality improvement.

A systematic implementation of such an approach within healthcare organizations is strongly recommended.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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