

Malpractice and patient safety descriptors: an innovative grid to evaluate the quality of clinical records

*Anna Santa Guzzo¹, Mario Tecca¹, Enrico Marinelli², Caterina Palazzo³, Paolo Ursillo³, Claudio Bontempi³, Arianna Di Nezza⁶, Domenica Patrizia Sposato³, Giuseppe Ferro³, Anna Maria Lombardi³, Amalia Allocca⁴, Maria De Giusti^{3,5}

Affiliations: ¹Risk Manager, Teaching Hospital "Umberto I", Sapienza University of Rome, Italy

² Legal Medicine Department, Sapienza University of Rome, Italy

³ Hygiene Unit, Department of Public Health and Infectious Diseases, Sapienza University of Rome, Italy

⁴ Health Manager, Teaching Hospital "Umberto I", Sapienza University of Rome, Italy

⁵ Roman Academy of Public Health

⁶ Department of Prevention U.O.C. Hygiene and Public Health, ASL Rome 1, Italy

***Corresponding Author:** Anna Santa Guzzo, Risk Manager, Teaching Hospital "Umberto I", Sapienza University of Rome; e-mail: annasanta.guzzo@uniroma1.it; Tel: (+39) 0649979568 - Fax: (+39) 0649979871.

Article history

Received: December 1, 2015

Accepted: December 22, 2015

Published: December 31, 2015

Abstract

Introduction: The medical record contains all the health information related to the patient's clinical condition and its evolution during hospitalization. It was defined by the Italian Ministry of Health in 1992 as "The information tool designed to record all relevant demographic and clinical information about a patient during a single episode of hospitalization". The documents and information in a Medical Record must meet the following criteria: traceability, clarity, accuracy, authenticity, pertinence and completeness. The objectives of our study was to develop a tool capable of assessing the quality of the clinical record and pointed the critical point at the Organizational, Technical - Professional, Managerial level.

Methods: To evaluate the quality of the medical documentation, we created an assessment grid composed of 4 sections with a total of 92 criteria. This grid was tested on 200 medical records that were randomly selected from 25 (18 medical and 7 surgical) wards of a teaching hospital in Rome.

Results: The grid contains 4 sections. The first part regards administrative and clinical data; the second assesses the quality of hospital stay and surgical/invasive procedures; the third part is concerned with the discharge of the patient and the fourth aims to identify the presence of advisory reports given to the patient.

This grid has been validated to verify internal consistency with Cronbach's Alpha = 0,743.

Conclusions: Medical records were analyzed using a validated tool with grids to identify critical issues in care activities. Weaknesses in the system were identified in order to improve planning. The sample testing also in terms of 'self-assessment' represents a tool to introduce activities to improve safety and quality of care, greatly reducing the costs of litigation.

Keywords: malpractice; medical records; risk assessment, quality care.

Introduction

The medical record is a document of primary importance for patients from their admission and beyond in fact contains all the information related to the clinical condition of the patient, its evolution during hospitalization and the patient's personal details. In 1992 it was defined by the Italian Ministry of Health as "The information tool designed to detect all individual relevant demographic and clinical information about a patient during a single episode of hospitalization". The personnel responsible for the compilation of the medical record are identified by Presidential Decrees [1]. Compilation of medical records can also be completed by other ward staff, in accordance with Decree [2], and by nursing staff in accordance with Decree [3]. The importance of this tool's quality has been underlined by many Authors, and stated by the new Code of Medical Deontology [4].

It is fundamental for the follow-up, clinical history and legal protection of patients, their doctors and the hospital. It has specific and strict regulations concerning its compilation and conservation. The appropriate use of the medical record has been the subject of many regulations, some are compulsory, some already implemented and many others are recommended [3,5,6,7].

Nowadays hospital organization where evaluated by the Ministry of Health in economical and quality assurance aspects. The quality of the Medical Record is a standard that has strong implications in the process of hospital accreditation and has a major impact on the rating system of healthcare accredited organizations.

In the 2004-2007 evaluation of accredited hospitals the medical record, in fact, forms part of the assessment:

- Management of Medical Records (who has access, who can annotate, acronyms list);
- Content of medical records (initial assessment, informed consent, discharge letter);
- Critical areas involved are: keeping medical records, management of human resources, management and quality improvement and patient safety [8]. Subsequently, the Joint International Commission, stressed the need for proper completion of medical records stating that they "must contain sufficient information to identify the patient, support the diagnosis, justify the treatment, document the course and results of treatment and promote continuity of care between the various providers of health services" [9].

The lack of clarity and completeness of a medical record is recognized as a medical malpractice.

The increase in the number of claims for medical malpractice is a trend prevalent in many developed countries in recent years, this is a widespread phenomenon which has led to an increase in compensatory damages as a result of an increasingly strong

awareness of the care and treatment a patient should receive [10].

Considering clinical and legal value of the clinical records the Authors have developed a grid to the evaluation medical record quality of a Teaching Hospital in Rome, Italy.

Methods

First of all the Project Team has been nominated by hospital management board involving Risk Manager, Health Manager and Staff belonging to the Hygiene Unit of Department of Public Health and Infectious Diseases of Sapienza University of Rome, Risk Management and Health Management of the Teaching Hospital "Umberto I" of Rome.

In order to develop our study, from April 2013 to November 2014 we performed a systematic review searching observational studies focusing on the quality completion of medical records and the clinical and medical-legal aspects. A structured grid were implemented considering legal and literature evidences.

Systematic Review

The review followed the conceptual framework of the "PRISMA statement for reporting systematic reviews and meta-analyses" [11].

Systematic Review (SR) was conducted using both the PubMed (Medline) and Scopus databases, using the Key words: "healthcare management, medical record, safety care, risk management, legal aspects, quality, malpractice and patient safety descriptors" using the Boolean operator AND-OR. Moreover, in order to find also non indexed articles, we searched for useful "grey literature" using Google and Google Scholar. Inclusion criteria were the following: articles regarding Guidelines or National regulations; including quality evaluation of medical record, showing the evaluation grid. Exclusion criteria were: articles about epidemiological data or referred to electronic medical record.

Grid Building

The Project Team designed a grid (see technical document, Annex 1) including ninety-two criteria identified in scientific literature and legislation structured in four sections:

The first section including a total of twenty-five criteria regarding information about administrative data and the clinical information. This section described Medical History, Physical Examination and some Risk Scores.

The second section including a total of fifty-one criteria evaluating organizational and clinical aspects represented by the accurate and daily updating of Daily Diary, by the presence of a nursing record card, the order sets paper (for medication therapy management) with the annotation about diagnostic procedures, the patient informed consent and Surgical Safety Checklist in case of surgical operation/procedures.

The third section including eleven criteria regarding Discharge Summary.

The fourth section including third criteria evaluating, if present medical advices from different consultants. Regarding clinical value, we have assigned, arbitrarily, values of conformity:

- 1: the criteria is satisfied;
- 3: the criteria is partly satisfied;
- 5: the criteria is not satisfied;
- 0: the criteria cannot be evaluated.

In order to assess a medical legal weighting, we have utilized data base of judgments from the Appeal to the Supreme Court [12,13]. A score from 5 to 1 was given to the “criteria” taking into consideration the percentages of recurrence of the appeal judgments (**Table 1**).

This weighting utilizes a periodic upgrading (every 2 years) on the basis of sentence turn-over.

Table 1. Legal weight (Score from 5 to 1) taking into consideration the percentages of recurrence of each criteria in judgments (Appeal to the Supreme Court).

| Score | Criteria (% of occurrence) |
|-------|----------------------------|
| 5 | > 40% |
| 4 | 30-40% |
| 3 | 20-30% |
| 2 | 10-20% |
| 1 | at least once per year |

This grid was tested on 200 medical records, randomly selected by Galileo Software function, among 25 wards of teaching hospital “Umberto I” in Rome. The staff of Project Team, including 5 physicians and 5 nurses, 1 Decree in Public Health Studies and Prevention and the Risk Manager have been evaluated medical records. Each evaluation has been performed by a couple of researchers and in case of different opinions, Risk Manager resolved formulating the third opinion.

Statistical Analysis

Data input was realized using Microsoft © Excel software. The statistical analysis was performed using SPSS©19.00 for Windows©. This grid has been validated to verify internal consistency with Cronbach's Alpha [14].

Results

Systematic Review

A total of 412 records (282 records from PubMed, 114 records from Scopus and 16 records from references of the paper) were retrieved. The results of SR are shown in **Figure 1**.

After the removal of 11 duplicates and the exclusion of 300 papers that did not meet inclusion criteria, we selected a total of 103 records (101 Full text records assessed for eligibility plus 2 records identified from Reference lists). After the exclusion of 81 papers considering inclusion/exclusion criteria, 22 full texts were included in the SR (**Figure 1**).

The results of SR demonstrated that only a few Italian studies have dealt with the objective of our study.

There is no evidence of comparable methods evaluating quality of medical records in their entirety. Researchers have focused their attention on few aspects of medical records as appropriateness [15]; operating theater [16]; clinical risk management [17,18]; or they focused their attention only on specific issues without specified scores [19].

Grid validation

The Project Team implemented and validated the grid, above described, and it verified internal consistency with Cronbach's Alpha [14]; the result was 0.743 (optimal value 0.7).

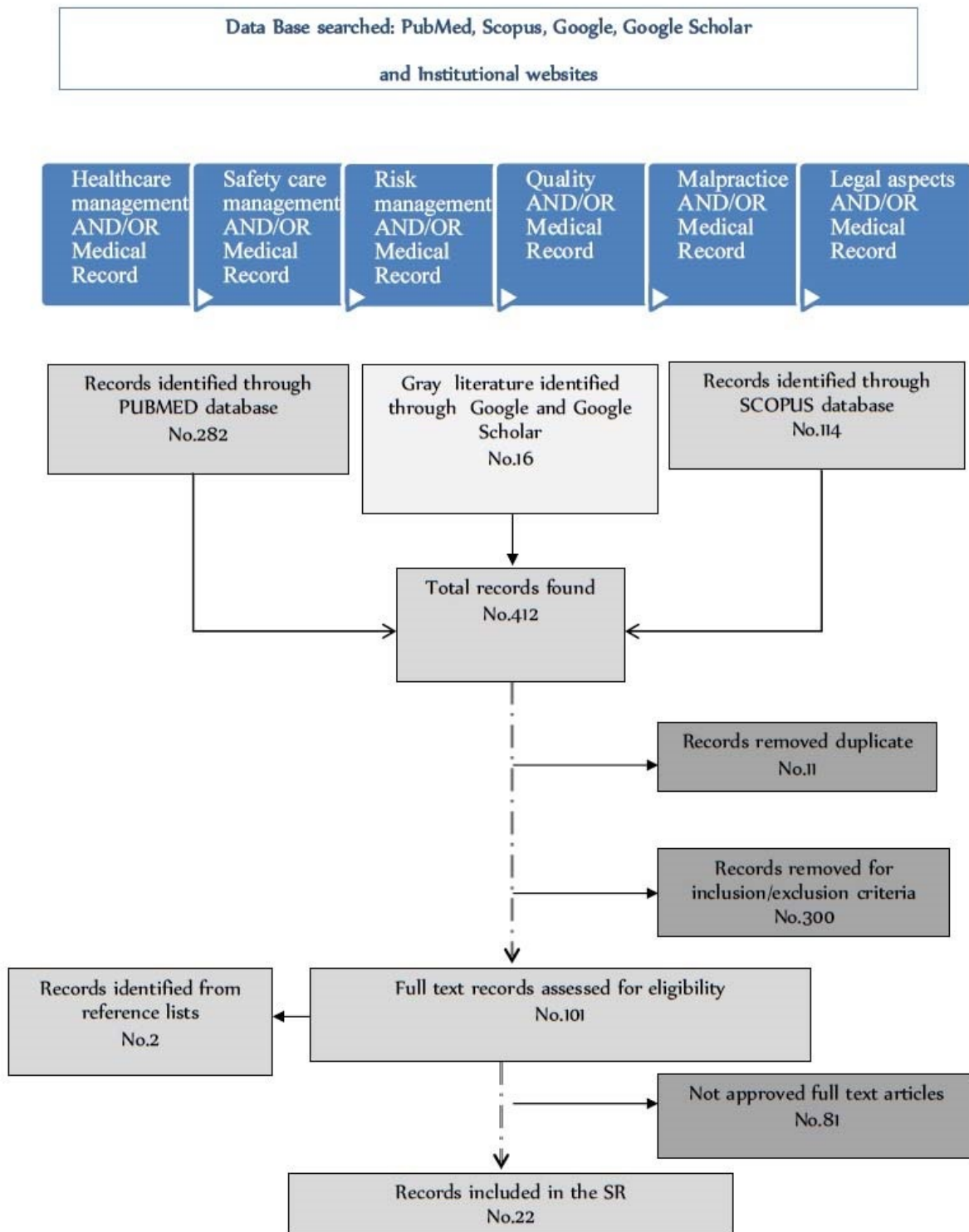


Figure 1. Flow chart of the systematic review.

Discussion

In 2009, local health administration unit (USL) 5 of Pisa (Tuscany) started a project of evaluation and improvement of clinical records, they conducted an evaluation followed by audit and comparison in order to heighten the awareness of health structures towards this goal. Early results show improvements in awareness and perception of critical situations, which can only be achieved easily with a full understanding of the profile of clinical record [19]. A medical grid was devised to verify the quality of medical records.

The *Hospital Quality & Safety Committee of The Society of Hospital Medicine* has developed a checklist for the process and of the most important elements required for an optimal discharge. The errors in discharge letter increase the risk of re-hospitalization by six fold [20].

A high quality discharge letter is generally recognized to be essential for the promotion of health and patient safety especially after the discharge. The Joint Commission has established that every discharge letter must contain: the motivations of hospitalization, the most significant results, procedures and treatments, conditions of the patient at the moment of discharge, the instructions provided to the patient and the signature of the referring doctor.

Regarding informed consent, the Italian Law considers that its omission or incompleteness could be contestable as a violation of the patient's ability to freely determine the outcome of treatment, regardless whether the outcome is positive or negative. The legibility of handwriting, as well as representing an index of valid organizational management, could have a clinical and medical- legal aspect (writing, theory of proof nearness negative-element) [13].

Conclusions

Weak points of this study are referred to the lack of references in the international scientific literature, an experience-based method. Other limits can be associated to a temporal inertia and to a Medicine of jurisprudential observance, that must be derived from a correct procedure of law, international and corporate Guidelines.

Strengths of the study are as follows. The method is able to identify corrective measures in the compilation of clinical records based on non auto-referential criteria; the tool could allow a more accurate mapping of the critical

factors that facilitate the occurrence of errors and adverse events in single operative units and the identification of improvements in primary intervention.

This method support the Top management selecting the corrective actions oriented to the Organization as well as the Line management selecting the corrective actions oriented to the specific critical point of the context.

The evaluation grid used here was found to be effective, especially when considering that the retrospective analysis of medical records is a tool for selection of descriptors of direct and indirect problems: Organizational, Technical and Professional, Managerial. The sample testing also in terms of 'self-assessment' represent a tool to introduce activities to improve safety and quality of care, greatly reducing the costs of litigation.

References

1. DPR 128/69 and 129/69 or Article 24 of D.M. 05.08.77.
2. D. L. vo 257/91; G.U. n.ro 191 del 16 agosto 1991.
3. D. L. vo 42/99; G.U. n.ro 50 del 02 marzo 1999.
4. Zagra M, Favitta R; Minutella V, et al. "La qualità della documentazione sanitaria come strumento di governo clinico in emergenza-urgenza". *Decidere in Medicina* Year 10, Number 2, Apr 2010.
5. Raccomandazione per la prevenzione e la gestione della caduta del paziente nelle strutture Sanitarie. Raccomandazione n. 13, novembre 2011 (aggiornata al 1 dicembre 2011). Ministero della Salute.
6. Raccomandazione per la prevenzione della morte, coma o grave danno derivati da errori in terapia Farmacologica. Raccomandazione n. 7, Marzo 2008. Ministero della Salute.
7. Raccomandazione per la corretta identificazione dei pazienti, del sito chirurgico e della procedura. Raccomandazione n. 3, Marzo 2008. Ministero della Salute.
8. Joint International Commission Accreditation 2004-2007.
9. Joint International Commission. Accreditation Standards for Hospitals, 4th Ed, IL: Oakbrook Terrace; 2010.
10. Ania Report, 2012.
11. Liberati, Altman DG, Tetzlaff J et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation

- and elaboration. J CLIN EPIDEMI. 2009 Oct; 62(10):e1-34.
12. www.cortedicassazione.it
 13. www.italgiure.giustizia.it
 14. Cronbach LJ. Coefficient Alpha and internal structure of tests. *Psychometrika*. 1951; 16:297-334.
 15. Poppa G La Torre, G, Mannocci A et al. Appropriateness of admission and stay in obstetrics wards: a new tool assessing unnecessary days of hospital care. *JPH - Year 7*. 2009; Volume 6, Number 4.
 16. Manuale per la Sicurezza in sala operatoria: Raccomandazioni e Checklist del ministero (operating room safety), 2009. www.salute.gov.it/imgs/C_17_pubblicazioni_1119.
 17. Sicurezza dei pazienti e gestione del rischio clinico:

Manuale per la formazione degli operatori sanitari del ministero, 2012 www.salute.gov.it/imgs/C_17_pubblicazioni_1688.
 18. De Giusti M, Boccia A. La qualità in sanità: elementi di legislazione. In Boccia A, Capparelli A, Celletti P, De Giusti M, Fubelli A, Larosa B, La Torre G, Sabbatella A. *Elementi di diritto per le Professioni Sanitarie*. Esculapio Ed. Milano 2012: 17-40.
 19. Terranova G, Scarselli MG, Nardi L. “La valutazione delle cartelle cliniche: attività strategica per garantire qualità, appropriatezza e sicurezza delle cure”. *Toscana Medica*.2012; n.ro 10.
 20. Bianchin C. La lettera di dimissione: rilevanza e requisiti di contenuto. *Decidere in Medicina. Professione & Clinical Governance*. Agosto 2013; Anno XIII n. 4.