Quality Assessment of medical records as a tool for Clinical Risk Management: A three year experience of a Teaching Hospital Policlinico Umberto I, Rome

Anna Santa Guzzo[1]*, Mario Tecca[1], Enrico Marinelli[2], Claudio Bontempi[3], Caterina Palazzo[3], Paolo Ursillo[3], Giuseppe Ferro[3], Anna Miani[3], Annunziata Salvati[3], Stefania Catanzaro[3], Massimiliano Chiarini[3], Vittoria Colamesta[3], Domenico Cacchio[3], Domenica Patrizia Sposato[3], Anna Maria Lombardi[3], Maria De Giusti[3]

[1]Quality and Risk Management Unit, Teaching Hospital "Umberto I", "Sapienza" University of Rome
[2]Department of Legal Medicine, "Sapienza" University of Rome
[3]Department of Public Health and Infectious Diseases, "Sapienza" University of Rome

*Corresponding author: Anna Santa Guzzo, Risk Manager, Teaching Hospital "Umberto I", Viale del Policlinico 155, 00161, Rome, IT Phone: +390649979568. Email: annasanta.guzzo@uniroma1.it

Abstract

Introduction: The medical record was defined by the Italian Ministry of Health in 1992 as "the information tool designed to record all relevant demographic and clinical information on a patient during a single hospitalization episode". Retrospective analysis of medical records is a tool for selecting direct and indirect indicators of critical issues (organizational, management and technical). The project's aim being the promotion of an evaluation and self-evaluation process of medical records as a Clinical Risk Management tool to improve the quality of care within hospitals.
Methods: The Authors have retrospectively analysed, using a validated grid, 1,184 medical records of patients admitted to the Teaching Hospital "Umberto I" in Rome during a three-year period (2013-2015). Statistical analysis was performed using SPSS for Windows © 19:00. All duly filled out criteria (92) were examined. "Strengths" and "Weaknesses" were identified through data analysis and Best and Bad Practice were identified based on established criteria.
Conclusion: The data analysis showed marked improvements (statistically significant) in the quality of evaluated clinical documentation and indirectly upon behaviour. However, when examining some sub-criteria, critical issues emerge; these could be subject to future further corrective action.

Keywords: *medical record, malpractice, quality, patient safety, validated grid*

1. Introduction

In 1992, the Italian Ministry of Health defined the medical record as "the information tool designed to record all relevant demographic and clinical information on a patient during a single hospitalization episode".
The medical record allows:
1. The performance assessment (effectiveness and efficiency);
2. Quality control of care;
3. Control of health expenditure.
The documents and information in a medical record must meet the following criteria:
1. Traceability;
2. Clarity;
3. Accuracy;
4. Authenticity;
5. Relevance;

6. Completeness.

Only a complete and accurate documentation can provide a useful source of information for the purposes of quality control and patient safety. Furthermore, it is essential that the documentation is compiled and recorded in a transparent way to protect health professionals from litigation. The lack of clarity and completeness of the medical record is considered medical malpractice.

The quality of the medical record has serious implications in the process of hospital accreditation and has a strong impact on the evaluation system of accredited healthcare organisations. Quality is a criterion for measuring the validity of a product and/or service that meets the needs required by the "client" (UNI EN ISO 9001: 2015).

The medical records and health records are of central importance in Clinical Risk Management through:
- Proactive containment of communication errors and errors in the diagnostic and therapeutic management process;
- A reactive role by providing a source of information for the implementation of corrective measures to improve care pathways.

Retrospective analysis of medical records is a tool for selecting direct and indirect indicators of critical issues (organizational, management, technical and professional). The sample checks provide a vehicle for introducing improvements in the safety and quality of care activities while reducing the cost of litigation (1-16).

2. Context

A project was proposed by the Risk Manager of the Teaching Hospital Umberto I - "Sapienza" University of Rome. The project's aim being the promotion of an evaluation and self-evaluation process of the medical records as a Clinical Risk Management tool, to improve the quality of care within the hospital. This has been strongly supported by the Department of Health.

The aim of our study was to develop a tool capable of evaluating the quality of medical records and use the results to:

1. Improve the quality of clinical practice;
2. Reduce adverse events;
3. Reduce litigation;
4. Involve employees in a virtuous path of self-assessment, evaluation and continuous performance improvement.

The project involved the study of a sample of medical records relating to inpatient admissions made at the

Teaching Hospital Umberto I, Rome. The project realisation was developed through the following phases:

1. Survey planning and Working Group definition (WG);
2. Creation of the instrument for assessing the quality of records;
3. Medical records evaluation (Survey, 2013);
4. Data analysis and interpretation;
5. The introduction of corrective action;
6. Monitoring (Survey, 2016);
7. Data execution and report.

3. Methodology

3.1. Planning

At the beginning a multidisciplinary and multi-professional Working Group (WG) was established. Several people were involved in this group: The Risk Manager and his staff, the Director of "Organization and Health Management" and his staff and the Director of the "Legal Medicine" Division and his staff.
Following this, some key roles were defined: The Project Manager (Risk Manager) and other people responsible for project sub-phases were chosen (e.g. randomisation, training, systematic data collection, statistical processing and final reports). Profile evaluators were also identified among the members of the group, both medical and health professions were included; the evaluation team worked under the supervision of the Risk Manager.

Criteria for the selection of the medical records to evaluate were defined (random selection of records of inpatient admissions). The organisational arrangements to perform the retrospective analysis were also defined.
Before creating the detection tool, a bibliographical research of international scientific literature and grey literature was carried out to search for examples of evaluation forms, evaluation grids and/or structured questionnaires effective in evaluating the quality of records and the effects upon staff behaviour. To carry out such a review the conceptual framework for systematic reviews "PRISMA STATEMENT 2009" was followed (17). "The scientific articles were managed through the software JabRef 2.8.1. The research results showed that only a few papers have dealt with the topic and these only in general terms. The systematic review revealed no evidence of validated methods for assessing the quality of medical records. The WG therefore proceeded to structure and validate the grid (18) as follows.
The grid to evaluate the quality of medical records is made up of 4 sections, these are:
1. Patient Admission (items 1-18);
2. Hospitalization (items 19-36);
3. Letter of discharge (item 37);

4. Advisory reports (item 38).

The grid contains 92 items, identified in the scientific literature, current regulations, and Ministerial Recommendations regarding the safety and quality of care. The evaluation grid was tested on 200 medical records resulting more than satisfactory (0.743 Cronbach's alpha).

Each item was assigned a numerical coding to be inserted into an Excel Database, according to compliance or non-compliance with the criterion:

YES: compliance with the criterion = 1;
NO: non-compliance with the criterion = 5;
Rated partially (VP) = Partial compliance with this criterion = 3;
Not Applicable to the rating criteria (NA) = 0.

The data obtained from the evaluation of the records have been included in tables and expressed as a rate of compliant and non-compliant results.

The compliant results include all the answers classified as YES and, if specified, those Partially Evaluated (VP).

The non-compliant results include all the answers classified as NO.

The following cut off were applied:

BEST PRACTICE: criteria with a compliant result rate≥75%,

BAD PRACTICE: criteria with a compliant result rate <75%.

3.2. The Evaluation Team

The evaluators were trained to use the grid by attending a theoretical and practical course lasting eight hours. The training methods included an introductory part, aimed at explaining the aims of the project and the evaluation grid (lectures) and a second part instructing evaluators how to use the grid (practical exercise on medical records).

The assessment of each medical record was carried out by a pair of evaluators and in the case of diverging assessments the decision of the Risk Manager final.

3.3. Data Analysis

The collected data was entered into a spreadsheet (Microsoft Excel © software). Statistical analysis was performed using SPSS for Windows © 19:00. All duly filled out criteria (92) were examined.

The results were reported in a summary table, showing the criterion rate as a percentage of the total number of evaluated medical records. "Not applicable" answers were excluded from the descriptive analysis. All results were shown in **Annex 1 and Tables 1-5**.

4. Results

518 medical records of inpatient admissions were assessed and evaluated in 2013. These records represented 0.9% of all medical records relating to inpatient admissions in the year under review, of which 237 were from the medical area and 281 from the surgical area. The survey was conducted from August to December and involved 120 wards.

4.1. 2013 Survey

The examination of data, relative to the 518 evaluated medical records, showed a marked compliance for almost all of the analysed criteria. In fact, 61/92 (66,3%) criteria are considered "Best Practice", amounting to a compliance percentage well over 75%. In contrast, 31/92 (33,7%) of the criteria report a compliance percentage well below 75%, thus placing them in the "Bad Practice" category.

Data analysis using established criteria on Best and Bad Practice were used to identify "Strengths" **(Table 1)** and "Weaknesses" **(Table 2)**.

- **The strengths:** some of them, are shown in **Table 1**, and these include: "Patient assessment carried out within 24 hours of admission" (90.5%), "Allergies almost always reported" (87.6%), "Updated Clinical Diary" (87.3%), "Consent to anaesthesia for surgery present and signed" (94.1%), "Consent to surgery present and signed" (96.3%), "The Anaesthesia documentation is present" (80.3%), "Good quality of the discharge letter" (80.2%).

- **The weaknesses:** some of them are shown in **Table 2** and include: "Chronological Order" 20.8% compliance, "Falls Risk assessment" 11.4% compliance, "Pain assessment" 4.8% compliance, "Nursing Card" 6.8% compliance, "Unique Therapy Record (UTR)" 22.9% compliance and "Operating Theatre security check-list" 0.7% compliance.

Some weaknesses were expected because some activities (e.g. OT Checklist, Nursing Card) had still not been introduced in a systematic and structured manner throughout the hospital.

Table 1: Results of 2013 Survey STRENGHT POINTS (Compliance ≥75%).

CRITERION	PERCENTAGE %	
	YES	NO
Was the evaluation of the patient carried out within 24 hours of their admission? (always)	90,5	9,5
Does the file contain information about allergies?	87,6	12,4
Is the daily diary present? (always)	87,3	12,7
Is an informed consent form for anesthetic present? (if a surgical procedure was undertaken)	94,1	5,9
Is the informed consent of the patient for the surgical procedure present?	96,3	3,7
Is the anesthesia documentation or file present or attached?	80,3	19,7
Is the discharge letter present? (always)	80,2	19,8

Table 2: Results of 2013 Survey: WEAKNESS POINTS (Compliance ≤75%).

CRITERION	PERCENTAGE %	
	YES	NO
Is the file organized chronologically? (always)	20,8	79,2
The fall risk: was the patient evacuate according to the Conley Scale within 72 hours of admission (when applicable*)	11,4	88,6
Is pain intensity assessed in the file? (only if the evaluation of pain scale is present)	4,8	95,2
Is the nursing card present in the clinical file?	6,8	93,2
Is the unique therapy record present?	22,9	77,1
Is an operating theatre security checklist present?	0,7	99,3

Legend:*patient over 65 years old and/or when it is satisfied at least one of the three WHO parameters.

4.1.1. Introduction of Corrective Interventions

In light of the results obtained, the hospital planned and undertook specific corrective action regarding staff training, as well as, interventions to some organizational aspects, as shown below:

4.1.1.1. Training

- Basic course on care safety;
- Advanced course on care safety;
- Course/training on "Quality of health record";
- Course on "The safety manual in the operating theatre";
- Course on "Non-Technical Skills "in the operating theatre";
- Course/training on "Pain Management and Assessment";
- Course on "The Nursing Card";
- Course on "The operator patient communication";
- Conference entitled "Patient Safety Day".

4.1.1.2. Organization

- Review and monitoring of the hospital procedures for falls prevention;
- Introduction of the Hospital Unique Therapy Record (UTR) and related procedures;
- Introduction of the use of the hospital UTR in budget targets;
- Introduction of staff participation in hospital courses on patient safety in budget targets;
- Introduction of the operating theatre checklist and related procedures;
- Introduction of the operating theatre checklist in budget targets;
- Introduction of the hospital pain assessment card;
- Introduction of pain assessment in budget targets;

- Creation of the hospital Network of Facilitators for Clinical Risk Management;
- Testing and approval of the Nursing Card template;
- Gradual introduction of Nursing Cards to homogeneous areas;
- Re-organisation of the Health Department for the proper keeping of medical records.

4.2. Survey 2016

A second survey was conducted from January 2016 to monitor and verify the effectiveness of interventions and/or measures taken in light of problems that emerged in the 2013 Survey and to verify proposed solutions.

The evaluated clinical records, regarding the last quarter of 2015, were 666 in total, of which 327 where from the medical area and 339 from the surgical area, corresponding to 1% of the ordinary admissions in Teaching Hospital Policlinico Umberto I. The sample complied simultaneously with the regional project that was developed by the Lazio Region in partnership with the Teaching Hospital "Umberto I".

The examination of data, relative to the 518 evaluated medical records, showed a marked improvement for almost all of the analysed criteria. In fact, 64/92 (70%) criteria are considered "Best Practice", amounting to a compliance percentage well over 75%. In contrast, 28/92 (30%) of the criteria report a compliance percentage well below 75%, thus placing them in the "Bad Practice" category.

-The Strengths: some of them, are shown in **Table 3**, are represented by: "Patient assessment within 24 hours of admission" (99.2%); "Allergies almost always reported" (84.5%); "Updated Clinical Diary" (96.7%); "Consent for blood transfusion: present and signed" (92.9); "Consent for surgery: present and signed" (97.4%); Consent for invasive procedure: present and signed "(99.6%); "Good quality of the letter of discharge" (81.2%).

- The Weaknesses: some of them are shown in **Table 4** and include: "Privacy policy document: present and signed" (33.4%); "Chronological Order of documents in the Medical Record" (8.9%); "The falls risk assessment" (50.8%); "Pain assessment (25.4%), "Nursing Card" (8.9%), "Fluid balance assessment: present" (40.2%).

Table 3: Results of 2016 Survey: STRENGHT POINTS (Compliance ≥75%).

CRITERION	PERCENTAGE %	
	YES	NO
Was the evaluation of the patient carried out within 24 hours of their admission? (always)	99,2	0,8
Does the file contain information about allergies?	84,5	15,5
Is the daily diary present?	96,7	3,3
Is the patient's informed consent specific for a transfusion present? (at least a copy	92,9	7,1
Is the informed consent of the patient for the surgical procedure present?	97,4	2,6
Is the signature of the patient present on the informed consent form for an invasive procedure? (if an invasive procedure was undertaken)	98,1	1,9
Is the discharge letter present? (always)	81,2	18,8

Table 4: Results of 2016 Survey: WEAKNESS POINTS (Compliance ≤75%).

CRITERION	PERCENTAGE %	
	YES	NO
Is present the privacy form (signed and dated always)?	33,4	66,6
Is the file organized chronologically? (always)	8,9	91,1
The fall risk: was the patient evacuate according to the Conley Scale *within 72 hours of admission?	50,8	49,2
Is pain intensity assessed in the file? (only if the evaluation of pain scale is present)	25,4	74,6
Is the nursing card present in the clinical file?	8,9	91,1
Is there an evaluation of the water balance? (at least one day)	40,2	59,8

Legend:*patient over 65 years old and/or when it is satisfied at least one of the three WHO parameters.

4.3. Comparative Analysis Survey 2013-2016

In the first survey (2013), strengths and weaknesses emerged; the latter were subject to corrective action implemented during the period 2013-2016. To verify the effectiveness of the implemented measures (in the second Survey, 2016), special attention was paid to the previously emerged critical elements relating to: "Chronological order", "Falls risk assessment", "UTR", "Check-list for Operating Theatre", "Pain assessment " and "Nursing Card".

Data analysis shows a statistically significant improvement in 5 of 6 critical issues (**Table 5**) as shown below:

- "The falls risk assessment from 11.4% to 50.8%;
- "Pain assessment" from 4.8% to 25.4%;
- "Nursing Card" from 6.8% to 8.9%;
- "UTR" from 22.9% to 90.5%;
- "Operating Theatre Checklist" from 0.7% to 78.7%.

As for "Chronological order of the documents in the medical record", a decrease of compliance was detected since the previous survey; in fact, while in 2013, the detected percentage was equal to 20.8%; in 2016 compliance was only 8,9%. It therefore remains a critical issue.

Table 5: Significant differences rating of "WEAKNESSES" among 2013 AND 2016 Surveys, using chi-square test.

CRITERION	PERCENTAGE YES		Asymp. Sig. (2-sided)
	Survey,2013	Survey,2016	2013-2016
Is the file organized chronologically? (always)	20,8	8,9	,000
The fall risk: was the patient evacuate according to the Conley Scale within 72 hours of admission (when applicable*)	11,4	50,8	,000
Is pain intensity assessed in the file? (only if the evaluation of pain scale is present)	4,8	25,4	,000
If the nursing card is present is it annotated for each day in hospital?	6,8	8,9	,184
Is the unique therapy record present?	22,9	90,5	,000
Is an operating theatre security checklist present?	0,7	78,7	,000

Legend:*patient over 65 years old and/or when it is satisfied at least one of the three WHO.

5. Conclusion and Discussion

The action taken to remove/contain the critical issues identified in the 2013 Survey, considering the data obtained from the assessment of the medical records relating to the 2016 Survey, have proven effective with regard to:

➤ "The fall risk assessment": the result achieved was satisfactory although it will be reassessed after reviewing hospital documentation in light of a new regional policy;

➤ "Pain assessment: the result showed an encouraging outcome, although not meeting the regulatory requirements currently in force; various health professionals showed that the card currently in use is not considered to be user friendly by the nursing team, therefore it requires review;

➤ "Nursing Card": the data found in the 2016 Survey, compared to the 2013 Survey showed a statistically significant improvement; however, compliance is expected to further increase in 2017, the year in which not only training (theoretical and on the job) will be completed but, as scheduled, the introduction and full implementation of the nursing record will involve all the concerned operational wards;

➤ "UTR": the activities carried out for the purpose of using the tool are well-structured and well-established;

➤ "Operating Teatre Check List": statistically significant improvements have been achieved since the introduction of this tool. These achievements will be consolidated over time following the completion of ongoing specific training on the safety of care and on "Non-Technical Skills" that are fundamental and support action to improve the safety of care and the adherence to specific procedures by operating theatre staff;

➤ "Chronological Order": this criterion requires further and more structured improvement activities aimed at "cultural change" of professionals who currently perceive the chronological order as a purely "bureaucratic" issue, neglecting the safety of care and forensic implications;

➤ "Privacy": this criterion, like chronological order, is a critical issue, which needs corrective action through working on "cultural change" of professionals.

The data analysis showed marked improvements (statistically significant) in the quality of evaluated clinical documentation and indirectly of behaviour. However, when considering some sub-criteria, critical issues emerge; these issues once hospital priorities have been considered, could be subject to further corrective action in the future.

5.1. The Strong Point: Lazio Region Project

Assessing the quality of clinical documentation, tested with success by the Teaching Hospital Policlinico Umberto I, has attracted the attention and interest of the legislators of the Lazio Region, which in 2015, prepared in partnership with the teaching hospital Umberto I "Sapienza" University of Rome, a regional project, in order to survey the quality of health records of each regional single hospital.

The statistical measurement concerned all individual items, on a regional basis and on an individual hospital basis, facilitate internal and competitive benchmarking.

6. Regulation

- D. L. vo 257/91; G.U. n.ro 191 del 16 agosto 1991.
- DPR 128/69 e 129/69 o Articolo 24 del D.M. 05.08.77.
- D. L. vo 42/99; G.U. n.ro 50 del 02 marzo 1999.
- Determinazione 25 ottobre 2016, n.G12356 (Approvazione del "Piano Regionale per la prevenzione delle cadute dei pazienti").
- Legge 15 marzo 2010, n. 38 Disposizioni per garantire l'accesso alle cure palliative e alla terapia del dolore. (G.U. Serie Generale, n. 65 del 19 marzo 2010).
- Linee Guida 17 Giugno 1992 "La Compilazione, La Codifica e la Gestione della Scheda di Dimissione Ospedaliera Istituita Ex Dm 28.12.1991"
- Manuale per la Sicurezza in sala operatoria: Raccomandazioni e Checklist del Ministero (operating room safety), 2009. www.salute.gov.it/imgs/C_17_pubblicazioni_1 119.
- Raccomandazione per la prevenzione della morte, coma o grave danno derivati da errori in terapia Farmacologica. Raccomandazione n. 7, Marzo 2008. Ministero della Salute.
- Raccomandazione per la corretta identificazione

dei pazienti, del sito chirurgico e della procedura. Raccomandazione n. 3, Marzo 2008. Ministero della Salute.

- 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.
- 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_1 688.
- UNI EN ISO 9001:2015 "Sistemi di gestione per la qualità".

7. References

1. 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.
2. 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.
3. 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.
4. Negrini G, La Pietra L. Cartella di ricovero: alcune osservazioni critiche sulle funzioni della cartella di ricovero e sul suo contenuto - Tecnica ospedaliera, 2007, 2:28-33.
5. Negrini G, La Pietra L. Conservazione di documenti sanitari in ospedale -Quaderni AIDOS, 2006, 1.
6. Negrini G. Ripensando alla cartella clinica ospedaliera. Gli ospedali della vita,1998, 103-112.
7. Nonis M. et al. Cartella Clinica e qualità dell'assistenza. Presente, passato e futuro - Il Pensiero Scientifico Editore, 1998.
8. Ramos-Cuadra A, Marión-Buen J, García M. Use of the appropriateness evaluation protocol: The role of medical record quality: The effect of completeness of Medical Record on the Determination of Appropriateness of Hospital Days. International Journal for Quality in Health Care (1995); 7 (3): 267-275.
9. Joint International Commission Accreditation Standards for Hospitals, 4th Ed, IL: Oakbrook Terrace; 2010.
10. Joint International Commission Accreditation 2004-2007.
11. Peter D. Stetson, Frances P. Morrison, et al. Preliminary Development Of The Physician Documentation Quality Instrument. 2008. J Am Med Inform Assoc.15:534–541. Qualità e Risk Management 12.
12. Vincent C. Clinical risk management. BMJ press, London, 2001.
13. Bucci O. La cartella clinica. Profili strumentali, gestionali, giuridici ed archivistici. Maggioli, Rimini 1999.
14. Bianchin C. La lettera di dimissione: rilevanza e requisiti di contenuto. Decidere In Medicina. Professione & Clinical Governance. Agosto 2013; Anno XIII n. 4.
15. De Giusti M, Boccia A. La qualità in sanità: elementi di legislazione. Elementi di diritto per le Professioni Sanitarie. Esculapio Ed. Milano 2012: 17-40.
16. Del Vecchio S. et al. La cartella clinica e la cartella infermieristica - CGEMS,Torino 2006.
17. 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.
18. Guzzo AS, Tecca M, Marinelli E et al. Malpractice and patient safety descriptors: an innovative grid to evaluate the quality of clinical records. Senses Sci 2015; 2 (4):120-125 doi: 10.14616/sands- 2015-4-120125
19. www.cortedicassazione.it
20. www.italgiure.giustizia.it
21. www.ania.it