Using health care audit to improve quality of clinical records: the preliminary experience of an Italian Cancer Institute

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Abstract

Introduction. Audit and feedback are recognized as part of a strategy for improving performance and supporting quality and safety in European health care systems. These considerations led the Clinical Management Staff of the "Regina Elena" Italian Cancer Institute to start a project of self-assessment of the quality of clinical records and organizational appropriateness through a retrospective review.

Materials and Methods. The evaluation about appropriateness and congruity concerned both clinical records of 2013 and of 2015. At the end of the assessment of clinical records of each Care Unit, results were shared with medical staff in scheduled audit meetings.

Results. One hundred and thirteen clinical records (19%) did not meet congruity criteria, while 74 (12.6%) resulted as inappropriate. Considering the economic esteem calculated from the difference between Diagnosis Related Groups (DRG) primarily identified as main diagnosis and main surgical intervention or procedure and those modified during the Local Health Unit (LHU) assessment, 2 surgical Care Units produced a high negative difference in terms of economic value with a consequent drop of hospital discharge form (named in Italian "scheda di dimissione ospedaliera", SDO) remuneration, 7 Care Units produced about the same medium difference with almost no change as SDO remuneration. Concerning the quality assessment of clinical records of 2015, the most critical areas were related to medical documents and hospital discharge form compilation. **Conclusions.** Our experience showed the effectiveness of clinical audit in assessing the quality of filling in medical records and the appropriateness of hospital admissions and the acceptability of this tool by clinicians.

INTRODUCTION

Healthcare audit is the audit of current practice *versus* standards in any aspect of health care and includes both clinical and non-clinical audit. Audit, therefore, has a role to play in education and management including activities such as cost effectiveness, quality control, risk and resources management, as an important element of the clinical governance [1].

Healthcare audit is aimed to verify to what degree

Key words

- audit
- clinical records
- quality improvement
- healthcare
- planning

standards for any given healthcare activity are reached, recognize reasons why they are not reached, and identify and implement changes to practice to reach those standards. These standards should be evidence-based and are clinical (e.g. breast cancer management) or non-clinical (e.g. record management) [2].

Audit and feedback are recognized as part of a strategy for improving performance and supporting quality and safety in European health care systems [3, 4]. Additionally, these tactics are seen as principles integrated into the healthcare policies of other countries. In Italy, even though there is not a central committee for healthcare audit, some healthcare organizations created networks for clinical audit involving scientific societies, general practitioners, and regional health authorities [5-11]. The Ministry of Health underlined their importance in a specific document with a "road map" of 10 key aspects for an appropriate audit (*Table 1*) [12].

In this context, the registration on the clinical record of all the activities, processes and events related to an admission is a fundamental moment to assure the transparency and the clarity able to guarantee correct, appropriate and timely decisions of any healthcare professional (HCP) who takes care of a patient during hospitalization. The accurate filling of the clinical record is an assumption of the whole process above described, which brings to the improvement of the quality of admissions and is a duty of every HCP. Furthermore, several studies demonstrated the effectiveness of interventions based on accurate methodologies and with a broad and multidisciplinary participation in order to promote the improvement of health facilities [13, 14].

Finally, the clinical record is an instrument used by external reviewers of Local Health Unit (LHU) who are institutionally in charge of verifying appropriateness and congruity of each admission and of every single day of hospitalization of any single admission in all public hospitals.

In each place where health assistance is provided, reliability, patient's centrality, and especially effectiveness and efficiency are driving values, even more so where cancer patients are treated. The "Regina Elena" National Cancer Institute is one of the most important oncologic hospitals in Italy. Founded in 1939, it is located in Rome and, by virtue of its position, attracts many patients from Southern Italy, reaching high percentages in extra-regional mobility. Its total number of beds is 261, and most of the activities concern three main areas: clinics, research, and education. Its mission is to achieve the excellence in prevention, diagnosis and cure of cancer by means of research in the fields of epidemiology, etiology, neoplastic transformation and progression, and experimental treatments, together with the pledge of the highest standards in a healthcare organization.

In light of the considerations described above, the Clinical Management Staff of the National Italian Cancer Institute "Regina Elena" decided to start a project of self-assessment of the quality of clinical records and organizational appropriateness of inpatient admissions and day hospitals through a retrospective review. The aim of this paper is to define the methodology and the results of the project and the audit activities conducted with Care Units involved, including the clinicians' acceptability.

MATERIALS AND METHODS

The project was carried out from July 2015 until December 2015, involving 11 Care Units of the "Regina Elena" National Cancer Institute, whose characteristics are reported in *Table 2*.

The control activities, the retrospective review of clinical records, the writing of related reports and the audits with clinicians were carried out by Clinical Management Staff. The evaluation was carried out in 2 steps: in the first phase, the assessment of a selection of clinical records of 2nd semester 2013 carried out by LHU during 2014 was examined and economically valorised, while in the second phase samples of clinical records concerning discharges of January-October 2015 were analysed through internal controls and compared to results of 2013.

The retrospective evaluation of clinical records carried out by LHU is meant to examine the appropriateness both of single day of admission and of the whole admission, by means of the Italian version of Appropriateness Evaluation Protocol (AEP) [15-17], and also the congruity of hospital discharge form (named in

Table 1

Clinical audit chart (adapted from Italian Ministry of Health [12])

Key aspects	Description
General classification	Specification of general lines, objectives, challenges, risks, scopes of clinical audit and of action plan in the process of improving quality of structures.
Decision-making process	Definition of operating margins and decisions to be taken, after validation by health management.
Group role	Definition of role and responsibility of the leader and of each group member and of relations among group members.
Audit	Definition of participation modality, focusing on skills, trust and responsibility.
Monitoring	Programming of timing, tools and methods of monitoring at different steps.
Accessibility of information	Availability of information needed for carrying out the predetermined activities.
Confidentiality	Awareness of the confidentiality rules for anyone involved in the audit process, according to current legislation.
Communication	Structured communication in order to facilitate participation, involvement and motivation of health care professionals.
Resources	Material (space and equipment) and human resources needed. Information for health management and Care Unit heads about participants and time commitment required.
Behaviour rules	Activities carried out according to specific behaviour requirements and answering requests (deadline, mission, conflict of interest, etc.).

Table 2

Main characteristics of the 11 Care Units involved in the project

Care unit	N° of beds (ordinary ward; day surgery/ day hospital)	Activities
Digestive surgery	10; 0	Surgical treatment of digestive tract cancers.
Hepatic, biliary and pancreatic Surgery	13;0	Surgical treatment of hepatic, biliary and pancreatic cancers.
Plastic and reconstructive surgery	7; 2	In cooperation with breast and soft tissues surgery: reconstructive surgery of breast. In cooperation with otolaryngology: reconstructive surgery of facial and cervical areas. Surgical treatment of cutaneous neoplasms with associated reconstruction.
Thoracic surgery	20; 0	Surgical treatment of pulmonary, thymic, mediastinal, esophageal and tracheal cancers.
Breast and soft tissues surgery	12; 2	Surgical treatment of melanoma, breast cancer and sarcoma.
Gynaecologic surgery	16; 2	Surgical and oncologic treatment of vulvar, vaginal, cervical, endometrial, ovarian, fallopian tube cancers.
Neurosurgery	8; 0	Surgical treatment of brain, spinal cord and peripheral nervous system cancers.
1st Medical oncology	22; 17	Treatment and research about all types of cancers, in particular gastrointestinal, pulmonary, breast, gynaecological and melanoma cancers.
2 nd Medical oncology	22; 15	Treatment and research about all types of cancers.
Otolaryngology and cervico-facial surgery	18; 2	Surgical treatment of: - head and neck cancers, - thyroid cancer, - major and minor salivary glands cancer, - ear cancers, - vocal cords diseases. Prevention, early diagnosis and treatment of oral cavity diseases.
Uroloay	22:1	Surgical treatment of prostate, renal, bladder and urinary tract cancers.

Italian "scheda di dimissione ospedaliera" – SDO), by comparing diagnoses and procedures inserted in each form and all the clinical activities documented in each clinical record. The first step of the project was hence conducted on the basis of assessment of appropriateness and changes in terms of congruity proposed by LHU and, considering diagnosis related group (DRG) respective tariffs for each admission, an economic estimate of the results was then performed.

About the second step of the project, clinical records of 2015 to be included in the analysis regarded both hospitalizations and day hospitals (DH) of patients already discharged. The selection of clinical records to be controlled was carried out on the basis of the following criteria reported in the SDO:

- primary diagnosis of unspecified cancers or not related to the specialty of the selected Care Unit;
- surgical intervention not performed;
- primary diagnosis not in relationship with main surgical intervention;
- complications of surgical interventions;
- chemotherapies with length of stay of 3 days;
- secondary diagnosis that would better be placed as primary.

About this last criterion, the verification was carried out thanks to the use of software $(3M^{TM} PARM)$

[18]) which analyses the SDO, detects and suggests the changes needed to improve coding and often the weight of the DRG.

The quality assessment of clinical records of 2015 was performed by means of a 20-item evaluation grid, adapted from a 16-item one used in another experience about clinical records quality conducted in a hospital in Florence, Italy [19]. The four additional items were about the performing of pre-hospitalization, the presence of the admission note, the presence of the histological report and the completeness and signature of the anesthesiology record. These items were added as they were considered important from the clinical quality viewpoint: the pre-hospitalization performed for patients undergoing surgery leads to a reduction in hospital stay and avoids unnecessary admissions, the admission note is compulsory for a patient's hospitalization and gives early information about personal data and first supposed diagnosis, and the histological report gives the final and confirmed diagnosis, being thus a primary part of the clinical record when a biopsy or a surgical intervention is performed, as well as the anaesthesiologic record.

Data from records were compared to the assessment grid. The 20 items under investigation, reported in *Table* 3, could have only one answer in a dichotomous (yes/ no) form. When the item was not applicable (e.g. ab-

Table 3

The 20-item evaluation grid used for the assessment of clinical records

Item	Possible answers
Presence of diagnosis	Yes/No
Complete medical history	Yes/No
Comprehensive medical examination	Yes/No
Clarity of writing and updating of clinical notes	Yes/No
Possibility of recomposing diagnostic-therapeutic process	Yes/No
Informed consent for diagnostic and therapeutic treatment (invasive diagnostic exams, surgical interventions, anaesthesia, transfusions) signed and fully completed	Yes/No
Therapies performed	Yes/No
Description of surgical intervention performed	Yes/No/NA
Presence of detection of vital signs	Yes/No
Presence of detection of pain (VAS)	Yes/No
Indication of identity of people to be given information about patient's health	Yes/No
Readability of writing	Yes/No
Name of the health care professional who attended the health service	Yes/No
Consent to treatment in case of minor or incompetent subject	Yes/No/NA
Hospital discharge letter fully completed and signed	Yes/No
Hospital discharge form correctly and fully completed	Yes/No
Pre-hospitalization performed	Yes/No
Admission note present	Yes/No
Histological report present	Yes/No/NA
Anaesthesiology record fully completed and signed	Yes/No/NA

NA: not applicable

sence of histological report as no surgery or biopsy were performed), the answer marked as NA (not applicable). The results were subsequently presented in single Care Unit audits and were designed according to the indications given by the Italian and English Ministry of Health to share the methodology and the results with all the involved professionals (doctors and nurses) and to discuss together improvement strategies [12].

At the end of the evaluation of clinical records of each Care Unit, all the results of both 2013 and 2015 were shared with medical staff in scheduled meetings structured according to the audit modality, with participants actively discussing critical issues and proposing improvements. Audits were structured according to the four steps model proposed by the Ministry of Health (preparation, implementation, improvement activities, evaluation of results/re-audit) [12], in order to ensure analysis of strengths and weaknesses through the systematic comparison with set benchmarks and objectives. In particular, during discussions areas of common weaknesses and gaps among Care Units were tried to be identified, in order to further define actions to be implemented at the institutional and/or individual Care Unit. Moreover, an effort was made trying to determine if problems found were due to individual (habits, knowledge about AEP and ICD9 rules, etc.), organizational (lack of coordination between Care Units, lack of time, etc.) or structural (lack of surgical material, blood, etc.) causes.

RESULTS

LHU assessment examined a total of 801 clinical records. About congruity, 113 clinical records (19%) did not meet criteria. Main causes of non-congruity of SDO were the following:

- use of V code ("history of neoplasm") instead of neoplasm-specific code in the primary diagnosis field when a radicalization surgery was performed;
- use of neoplasm code instead of complication code in the primary diagnosis field when a complication was treated;
- use of specific code of a plastic surgery procedure instead of V52 code ("Fitting and adjustment of prosthetic device") when a lipo-filling or similar interventions were performed;
- use of 25.2 ("Partial glossectomy") or 29.39 ("Other excision or destruction of lesion or tissue of pharynx") code instead of 25.01 ("Closed [needle] biopsy of tongue");
- malignancies coded in primary diagnosis not confirmed by histological.

About appropriateness, 74 clinical records (12.6%) resulted as inappropriate, specifically 66 ordinary and 8 DH. Main causes of inappropriateness of admissions were the following:

• several days of length of stay with only the day of surgical intervention recognized as appropriate because of lack of transcription of care practices on clinical records, or inconsistency of hospital care support during the days following surgery;

- surgical procedures which could be carried out in DH or outpatient setting because anatomically limited or of short duration;
- no PRUO (Protocol for Hospital Use Revision) inclusion criteria for hospitalizations of surgical Care Units aimed to express a diagnosis, with SDO producing medical DRG;
- ordinary medical admissions aimed to new assessment and staging of patients in surgical Care Units.

Considering the economic esteem calculated from the difference between DRGs primarily identified as main diagnosis and main surgical intervention or procedure and those modified during the LHU assessment, 2 surgical Care Units produced a high negative difference in terms of economic value with a consequent drop of SDO remuneration, 7 Care Units produced about the same medium difference with almost no change as SDO remuneration, and 2 Care Units had a positive difference with a profit in terms of SDO remuneration.

Concerning the quality assessment of the clinical records sampled of 2015, the most critical areas were related to medical documents and SDO compilation. In particular, in all the clinical records assessed, the following were frequently missing (*Table 4*):

• discharge time (90%);

• physician's stamp and signature in medical history

and/or physical examination (80%);

- physician's signature in the hospital discharge letter (77%);
- completeness and/or signing of informed consent (50%);
- completeness of clinical diary for each day of hospitalization (50%);
- medical history and/or physical examination not correctly reported (48%);
- anesthesiologic record not signed (45%);
- information in clinical diary not readable (31%).

About compilation of SDO and congruity, substantial differences among Care Units were observed. All the critical issues found by LHU in 2013 were unfortunately found again, together with the frequent use of codes describing neoplasms of uncertain behaviour.

Regarding to appropriateness, the most frequent oversights were the presence of medical admissions in surgical Care Units, long waiting for movement to long term care structures, days with insufficient clinical assistance, administration of chemotherapy on the day of discharge.

About computerization of medical documents, the level was low, with only 4 Care Units compiling the history and physical examination electronically. Notwithstanding, almost all the Care Units made use of computerized discharge letter, operating report and documents regarding the informed consent.

Table 4

Most frequently missing items of the clinical records assessed, sorted by care units and total percentages

	Care Units									Total		
Items	Gastrointestinal surgery (22)	Hepatic, biliary and pancreatic surgery (22)	Thoracic surgery (37)	Gynaecologic Surgery (30)	2 nd Medical oncology (33)	Urology (46)	Plastic and reconstructive Surgery (50)	Breast and soft tissues surgery (17)	Neurosurgery (9)	1ª Medical oncology (20)	Otolaryngology and cervico-facial surgery (10)	296
Discharge time	19	20	35	28	31	42	46	16	6	13	9	89.53%
Physician's stamp and signature in medical history and/or physical examination	14	19	28	24	25	41	42	14	5	18	7	80.07%
Physician's signature in the hospital discharge letter	15	11	32	27	29	33	37	15	4	17	7	76.69%
Completeness and/ or signing of informed consent	9	9	18	19	17	21	29	8	2	10	5	49.66%
Completeness of clinical diary for each day of hospitalization	11	11	17	19	18	19	28	11	2	8	5	50.34%
Medical history and/or physical examination not correctly reported	14	13	18	13	16	19	21	10	4	7	7	47.97%
Anesthesiologic record not signed	7	8	20	11	25	21	17	11	5	6	3	45.27%
Information in clinical	8	9	10	10	б	20	11	7	2	5	4	31.08%

In relation to audits, physicians of every Care Unit took part to meetings scheduled for the end of July to November 2015. Meetings were arranged by the Clinical Management Staff at the end of the evaluation of clinical records one by one with each Care Unit. Physicians welcomed the project positively, but relevant differences among physicians were observed in relation to attitude showed during audits. Most of the participants agreed in recognizing the importance of audits for the improvement of their activities, but a few considered them needless, underlining the bureaucratic and administrative nature of the initiative. Some physicians also showed the need for further meeting moments in order to find an answer to doubts related to the appropriateness and practical filling of SDO. At the end of each audit, a list of critical issues related to the quality and appropriateness and suggestions to address their improvement were summarized and sent in a written communication for each Care Unit.

Among main problems found, individual poor perception of suboptimal quality of their documentation in the clinical records was noticed by physicians, while from an organizational viewpoint the most frequent critical issues were the preoperative waiting longer than 1 day, the low use of pre-hospitalization, the lack of coordination with the Intensive Care Unit for staying after surgery, the limited perception of inappropriateness of admission.

DISCUSSION

The project described in this paper confirmed that clinical audit can be of valuable support to programs aimed at improving the quality of healthcare and its delivery. The assessment modality used was acceptable for the measurement of minimum quality of clinical records and of organizational appropriateness of admissions. Audit as well has proven to be an effective methodology for the introduction of this modality, ensuring its acceptability by most physicians and thus creating a basis for a rapid and quantifiable improvement. In order to effectively measure this last and to verify if critical issues noticed were overcome, a re-audit performed in following months should be needed, and it is what the Clinical Management Staff already planned as a six-monthly activity from this experience on. Results about the quality of clinical records are consistent with those described in previous Italian studies [20, 21], in particular with reference to the problems about the compilation of clinical diary and traceability of physicians' signatures. Many of the found hitches could be overcome in quite simple ways: about individual aspects, a suggestion could be to implement knowledge about ICD9CM and Regional Guidelines coding, to use a readable writing and to report every health service effectively provided to each patient on the clinical diary. Considering the organization of care, solutions proposed could be:

- to encourage the use of day service in order to find the right diagnostic classification of patients and take the following appropriate clinical pathway of care thus avoiding inappropriate hospital admissions;
- to favor the use of pre-hospitalization for planned

surgery, avoiding admissions of patients for several days before surgery only for routine tests, which can be performed during pre-hospitalization;

• implement admissions of patients in low assistance care regimens when possible (DH and outpatient).

Results above discussed should be consolidated through the 5 main practical actions shown in *Figure 1* [22].

The available evidence suggests that audit and feedback may be effective in improving professional practice but that the effects are generally small to moderate. Nonetheless, depending on the context, such small effects, particularly if shown to be cost-effective, may still be regarded as worthwhile [3]. The initiative shown in this paper was not evaluated by a structured costeffectiveness analysis, but only by a rapid appraisal derived from the estimate of the difference between DRGs modified during the LHU assessment. The only additional economic resource employed was the contract of a freelance consultant working on other projects as well.

Considering that benefits are most likely to occur where the existing practice is furthest away from what is desired and when feedback is more intensive [3], the experience described in this research could have a positive impact on achieving long-term results. Apparently, the impact of audit and feedback conducted, with or without any additional interventions such as reminders, economic incentives, and quality-improvement tools, will be monitored routinely by auditing practice after the described intervention.

Considering the strengths of this manuscript, the following things should be noted:

- the use of a structured and objective instrument as the 20-item grid used for the assessment of clinical records, with only a dichotomic modality of answer, allowed for a clear evaluation without possible qualitative bias of judgment and made for a rapid performance on a high number of records;
- the collaborative involvement of many physicians and their motivation to analyse problems and items;
- the aim for transparency and accountability were the primary points for the promotion of this project.

Among the weaknesses, the lack of set standards about the number of inappropriate admissions for each Care Unit, especially because of the oncologic specialty feature of the Institute where the project was conducted, and the consequent difficulty in setting up quantitative indicators for the assessment should be noticed.

CONCLUSIONS

A clinical audit is a useful tool for continuous quality improvement and the pursuit of clinical governance in healthcare organizations by monitoring the results of clinical activities.

The experience described in this manuscript shows a) the effectiveness of clinical audit in assessing both the quality of filling in medical records and the appropriateness of hospital admissions; b) the acceptability of this tool by clinicians in the first round of audits performed.

Only the systematic and structured implementation

of a clinical audit will consent to realizing the cultural change of the organization and the consequent achievement of lasting results.

Conflict of interest statement

There are no potential conflicts of interest or any fi-

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nancial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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