Investigation into the actual application of the diagnostic and therapeutic guidelines for colon cancer

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Abstract

Background: In colon cancer, the effectiveness of the cure is largely dependent on the early detection of the pathology. It is therefore useful to investigate the quality prevention programs. As a result, the Italian Healthcare System is increasingly adopting Quality Assurance by implementing diagnostic and therapeutic guidelines.

In this study, a comparison was made between the current pathways undertaken by patients with colon cancer and the prescribed guidelines. The analysis investigates the diagnostic pathways that lead to the discovery of colon cancer, the service center where the pathway started and the therapy regimen administered to treat the cancer.

Methods: The analysis covers all 205,000 patients who accessed one Italian Local Health Agency during the year 2007. In order to fund the costs of the services, the local regional council requested the collection of data from the Agency itself. Starting from this raw data, a data warehouse was built, the required data extracted and, eventually, the actual pathways were created.

Results and conclusions: Only 11.2% of colon cancer patients underwent the sequence of exams recommended by the official guidelines. 54.4% of them only partly followed the sequence of recommended exams. The remaining patients underwent exams that did not comply at all with the guidelines. Furthermore, there is evidence of a lack of prevention for some patients, particularly for those that only discovered the pathology when they arrived at the Emergency Department.

Key words: quality assurance, guidelines, colon cancer, cluster analysis

Introduction

Quality assurance of a healthcare system refers to the systematic monitoring and evaluation of the various aspects of the service in order to comply with quality requirements. The need for a coherent set of Standard Operating Procedures, covering all steps and activities involved in the execution of the service, is largely recognized. The accurate adherence to every step of the procedure is the key for quality assurance (ISO 9001:2008 [1]). Any modification or variation should be thoroughly investigated and the outcomes documented. The most important procedures in the healthcare services are definitely the diagnostic and therapeutic guidelines. They aim at improving the quality of care by providing the best sequence of exams to be undertaken in order to achieve the correct diagnosis rapidly and accurately, and the most effective therapy for the resulting diagnosis [2]. Guidelines are written by regional or national committees and cover a wide range of pathologies. Nevertheless, some studies highlight a scarce or incorrect application of guidelines. The reasons for this include the poor quality, and methodological lack of soundness, of some guidelines, and the insufficient dissemination of best practice guidelines among general practitioners [3-6].

A constant and timely monitoring of the actual application of these guidelines is highly important. Unfortunately, monitoring has to overcome a number of difficulties. While the analysis of the therapy can be accomplished by tracing a statistically significant sample of patients along with their hospitalization process, this is not the case for the analysis of the diagnostic pathways. This analysis requires the selection of certain patients with the same diagnosis, say colon cancer, and tracing these backwards to the diagnostic procedures that led to this diagnosis. The second

difficulty is related to the large number of service centers that perform diagnostic procedures. The whole network of healthcare services (hospitals, healthcare units, pharmacies, medical centers, diagnosis laboratories, general practitioners, …) are involved. Despite these issues, our analysis was made possible and permission was granted to access the data describing the interactions between the (anonymized) patient and the healthcare system, under a strict commitment to privacy. All the data collected came from the database of the Local Health Agency (LHA), located in the Piedmont Region (Italy), in order to guarantee the funding of the running costs to the service centers. In the present research, the data for the identification of the pathways were extracted and combined together. The use of colon cancer guidelines was investigated by comparing the actual pathways with the guidelines. The limit of our approach is that only patients that accessed the public healthcare system could be fully monitored, because the procedures executed in private or extra-regional centers could not be traced. The study focuses on the diagnostic exams executed and on the therapeutic procedures in the actual pathways followed by the considered patients. It does not address the details concerning the execution of every diagnostic or therapeutic procedure. A number of guidelines were analyzed and the sequence of exams and procedures were extracted [7-10]. There is substantial uniformity among all the considered guidelines at a basic level. Differences can be found in the implementation rules for the exams. and in the decisional procedures, but they are not relevant to the present analysis.

The guidelines for the diagnosis of colon cancer consider colonoscopy as the "gold standard" exam. There are a number of alternative diagnostic procedures defined using the ICD 9-CM (International Classification of Diseases, 9th revision, Clinical Modification [11]). They can be summarized as follows (see also Figure 1):

1. General physical examination (ICD 9-CM procedure code: 89.7) or Interview and evaluation, described as brief (89.01)
2. Colonoscopy (ICD 9-CM procedure code: 45.23) /Flexible Sigmoidoscopy (45.24) followed by a Double-contrast barium enema (87.64) / Computed tomographic colonography (V 76.51)
3. Closed biopsy (45.25)
4. Diagnostic ultrasound of abdomen (88.76.1)

Regarding the therapeutic section of the guidelines, they present a number of alternative surgical procedures that are reported in Table 1 (the correctness of the adopted procedure is not addressed by the present study).

Methods

The study starts from the analysis of all the Hospital Discharge Records for the year 2007 in the considered LHA. In order to extract which patients were affected by colon cancer, the research focused on the ICD-9 CM diagnostic codes [12] present in the Hospital Discharge Records (see Table 1). All the identified patients (134 people since February 2007) were traced both backward and forward. Therefore, the set of patients considered represents, not only a sample, but also the whole population of colon cancer sufferers in one LHA during that year. The patients discharged from the Hospitals in January were ignored because it was impossible to trace their diagnostic exams, which were

Figure 1. Block diagram representing the procedures indicated in the guidelines for colon cancer diagnosis.

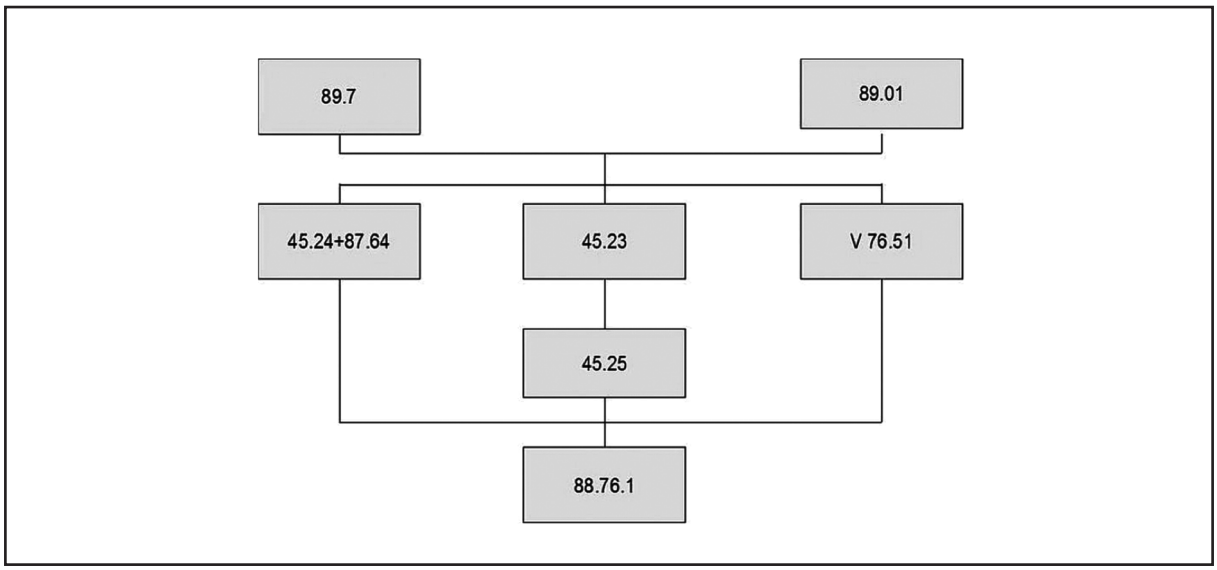


Table 1. The ICD 9-CM Procedure codes corresponding to the surgical interventions recommended in patients with colon cancer and the ICD 9-CM diagnosis codes reported on the Hospital Discharge Record that led to identify patients with colon cancer.

ICD 9-CM Procedure Code	*Procedure Description*
45.49	Other destruction of lesion of large intestine
45.71	Multiple segmental resection of large intestine
45.72	Cecectomy
45.73	Right hemicolectomy
45.74	Resection of transverse colon
45.75	Left hemicolectomy
45.76	Sigmoidectomy
45.79	Other partial excision of large intestine
ICD 9-CM Diagnosis Code	***Diagnosis Description***
153.0	Hepatic flexure
153.1	Transverse colon
153.2	descending colon (left colon)
153.3	Sigmoid colon
153.4	Cecum (ileocecal valve)
153.6	Ascending colon (right colon)
153.7	Splenic flexure
153.8	Other specified sites of large intestine
153.9	Colon, unspecified

partly executed in the year 2006 when no data was available. Backward tracing aimed at extracting the diagnostic exams that led to the final diagnosis, and consequently the diagnostic pathways, was carried out. Forward tracing was applied for investigating the chosen therapy, thus checking the correctness of the diagnosis. Two difficulties were encountered during the backward tracing. Firstly, problems emerged when obtaining the information about visits and exams executed by a large number of the different service centers, spread around the territory and distributed over a large time span. Secondly, filtering the access records of the healthcare system that were not related to the considered pathology, as patients could also access the healthcare systems for other needs.

The solution exploits the large amount of non organized data available in the Regional Administrations. These Administrations collect information about the services performed in the different centers for administrative use. In the present research, a unique database is built by collecting the data needed for the sequence extraction after format conversions. All the tables are loaded onto the same Mysql database by writing a php routine that allowed the automatic import of each record in its destination table,

Table 2. The operative table, or rather, the list of procedures supplied to patients by the healthcare system before the diagnosis of colon cancer.

PatientID	*Procedure date*	*Procedure code*	*Type of supplier*
134	2007/11/11	89.01	Emergency Department
135	2007/03/02	45.25	Ambulatory Care Centre
….	….	….	….

which had previously been loaded onto the database [13]. Following this, an effective and efficient patient-centred data warehouse was built. It allowed us to perform a cross analysis among different types and sources of data. An operative table was built by extracting and manipulating data from the group of inpatients described by the ICD 9-CM diagnosis code for colon cancer. Obviously, patients with colon cancer diagnosis that did not access hospitals were missed because the associated code is reported only on the Hospital Discharge Records. At the next stage, the ambulatory care procedures delivered to the identified patients before the hospital admission date were extracted. The procedures not correlated to the pathology were filtered. Eventually the interventions executed during hospitalization that produced the colon cancer code were extracted. An example of the operations extracted is shown in the table as follows (Table 2).

The Operative table is only a long list of procedures. This list makes it possible to study the frequency of the application of a single procedure, but doesn't make it possible to state that the procedure belongs to a pathway. In order to find the diagnostic pathways, the procedures had to be grouped together using the Hierarchical Agglomerative Cluster Analysis [14]. Cluster Analysis groups together the procedures by minimizing a similarity measure among the single procedures. The similarity is calculated by using some attributes of the data. The attributes of a procedure are its occurrence in the pathway of every patient. The attributes are represented by means of dichotomous variables, i.e. variables that can assume only the values 1 or 0. The similarity between pathways is measured introducing a distance function. The standard Euclidean distance is not appropriate for measuring the similarity in the correlations among procedures because it can not be used with dichotomous variables. For the research aims, a more suitable function was the Jaccard distance, that calculates the percentage of attributes that differ between two objects [15]. The clustering was carried out on the 24 most frequent procedures that emerged. Hierarchical Clustering is the most appropriate technique for working with ordinal metrics. It creates a cluster tree, which is not a single set of clusters, but rather a multi-level hierarchy, where clusters at one level are joined to clusters at the next highest level. The decision of the most appropriate level of clustering is found by choosing the threshold of the inconsistency coefficient for each link of the hierarchical cluster tree. The 'nearest neighbour' or *single linkage* technique was chosen from the agglomerative techniques available. In the *single linkage*, two clusters are joined together on the basis of the minimum distance between the two nearest elements. This technique is seldom applied because it has the drawback of creating elongated clusters (in a spatial visualization of the distance measure), i.e. long chains of procedures, each one differing from the successive one only in a few attributes. In this study, this fact is not a defect because it is reasonable to expect that every procedure is the starting point for the following one.

Results

Cluster analysis produced the dendrogram illustrated in Figure 2. The threshold value used to group the procedures was set to 0.5 in the linkage distance that is a measure of the degree of dissimilarity. The choice of the threshold value is a matter of preference but, in this case, values higher than 0.5 would have forced us to group procedures which were too different. The choice of the threshold value determines the number and the composition of the clusters. For graphical reasons the procedures were renamed.

Figure 2. The dendrogram of the hierarchical cluster analysis that group procedures provided to colon cancer affected patients. The horizontal line is the threshold value under which the groups of procedures are consistent.

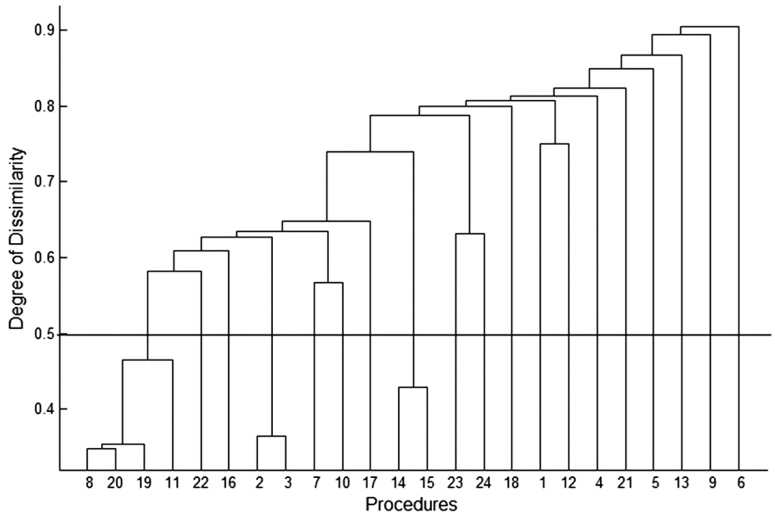


Table 3. Correspondences between the renamed procedure codes in the dendrogram and the ICD 9-CM ones.

N	*ICD 9-CM*	*N*	*ICD 9-CM*	*N*	*ICD 9-CM*
1	45.13	***9***	88.01.5	***17***	89.01
2	45.23	***10***	88.01.6	***18***	89.03
3	45.25	***11***	88.19	***19***	89.52
4	45.42	***12***	88.72.6	***20***	89.7
5	87.03	***13***	88.73.5	***21***	96.59
6	87.24	***14***	88.74.1	***22***	99.25.1
7	87.41.1	***15***	88.75.1	***23***	99.93
8	87.44.1	***16***	88.76.1	***24***	99.93.1

The corresponding ICD 9-CM procedure codes and the new numbering is given in Table 3.

From the dendrogram of Figure 2, it is apparent that a very small number of procedures can be grouped together in a pathway, with a safe consistency value. There are only three clusters with more than one element (procedure). They consists of cluster A (8, 20, 19, 11), cluster B (2, 3) and cluster C (14, 15). All the other elements can be joined together only by accepting very high inconsistency values. The elements of the dendrogram not belonging to the three clusters represent procedures that are stand alone and cannot be inserted within any pathway.

For the sake of clarity, the meaning of the service numbering in the three identified clusters is repeated below:

- Cluster A: Routine chest X-Ray (8) + General physical examination (20) + Electrocardiogram (19) + Other x-ray of abdomen (11).
- Cluster B: Colonoscopy (2) + Closed Biopsy (3) (the official guideline).
- Cluster C: C.A.T. scan of thorax (14) + C.A.T. scan of abdomen (15).

Additional information to improve the understanding of the phenomenon are provided by the pie chart in Figure 3. In the figure, the percentage of patients that followed the guidelines, or the alternative pathway consisting of a C.A.T. scan followed by a diagnostic ultrasound and other kinds of procedures are represented. It is apparent that very few patients follow the actual recommended guidelines. A larger number followed the alternative pathway, which is considered to be less accurate for the diagnostic purpose. The vast majority did not follow either of the two pathways. Indeed, 54% of patients followed the sequence of suggested

Figure 3. The percentage of patients that followed the guidelines, the alternative pathway consisting of a C.A.T. scan followed by a diagnostic ultrasound and the other kinds of procedures.

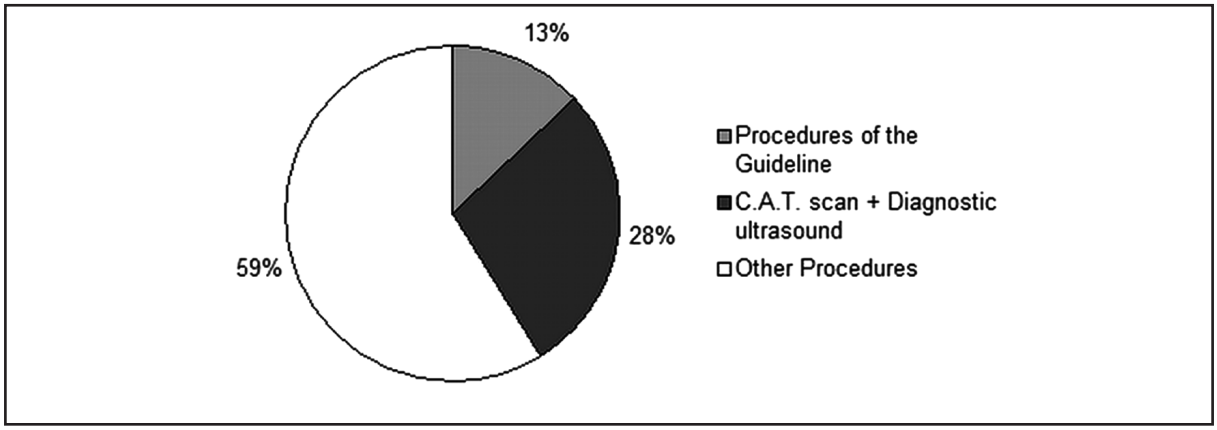
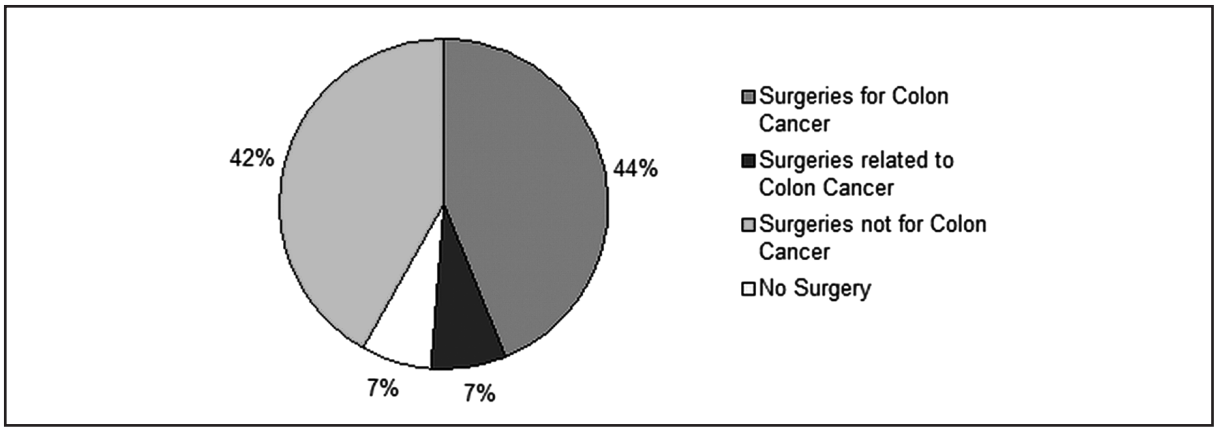


Figure 4. Percentage of patients that underwent the different types of surgical interventions.



exams only in part. It should be noted that one exam suggested in the guidelines (colonoscopy) is deemed effective, but requires more time and is quite painful. It is therefore not surprising that patients preferred alternative exams. Another important question regards the effectiveness of the prevention programs. Current Italian guidelines recommend two screening tests: FOBT (Faecal Occult Blood Tests), executed every year on subjects aged 50-69, or alternatively FS (Flexible Sigmoidoscopy), executed with a frequency of at least 10 years in subjects aged over 58 or 60. As a consequence, several Italian programs have recommend FOBT as a screening test [16]. Unfortunately, in the extracted group of patients (134 patients), only 15 people performed the FOBT exam and nobody underwent the FS. They correspond to 11% of the total patients. This result shows that the screening tests had frequently been neglected. This assertion is confirmed by the considerable number of people that went to the Emergency Departments as part of their diagnostic / therapeutic pathway: 69 of the 134. Among them, 12 patients had their first visit in the Emergency Deparment. Both the number of FOBT and the number of accesses to Emergency Departments indicates that prevention activities cover a limited subset of the total population. A further consideration could be to investigate the correct diagnosis of colon cancer in cases where diagnostic guidelines were not followed. In this case, it is difficult to give a clear answer based on only data from this investigation that cosidered the log files in the database. The pie chart shown in Figure 4 is nevertheless significant. It represents the different types of surgical interventions the patients underwent after colon cancer diagnosis. There was a significant number of patients with surgical intervention codes, registered on the Hospital Discharge Records, that were not related to colon cancer. There were also a large number (42%) of patients who did not undergo any surgery despite the diagnosis of colon cancer. There are three possible explanations for this result. Firstly patients who were non operable (e.g. too old for surgery or in the final stage of cancer), secondly a wrong diagnosis could have been made and finally surgery may have been performed in an extra-regional hospital or in a private clinic (not recorded in the database). The

last explanation is impossible to gauge, due to the high costs of private surgery and the limited use of private health insurance in Italy, though it is possible to assume that it may not account for such a large number of patients. The advanced age of the patient and erroneous diagnosis are therefore the most probable explanations.

Discussion

This study highlights important results and could be used to assess the application of the colon cancer diagnostic and treatment guidelines. Only 13% of identified patients followed the pathway described by guidelines. This is probably due to the long waiting times and long waiting lists for colonoscopy. The remaining patients probably migrated elsewhere to private clinics or extra-regional service centres for diagnostic and / or therapeutic procedures. It is worth noting that the possibility for a patient to avoid a queue by turning to a different service center reduces the effectiveness of waiting times and waiting lists as performance indexes. To illustrate the problem it is worth comparing two service centers. In the first, the patient cannot leave the queue until he/she is served (conservative service). In the second, the patient can leave the queue when the queue length exceeds a given threshold (blocking). The second case is a simplification of the current health organization in Italy. Whenever the waiting time is too long, patients accept to pay for private services even though they have the right to receive them for free from the public healthcare system. Following the queueing theory, the two systems behave differently. The second service center (with blocking) outperforms the first in terms of the number of people waiting in the system (they are less). However, there is a slightly reduced throughput rate in this type of system (number of patients served in the unit time). A side effect of a queue with blocking is that its waiting length (and with some approximation the waiting time, too) never exceeds a determined value, giving the wrong impression that the queue is short because the service center is efficient. The other important subject to address is that 9% of the patients first discovered the presence of colon cancer at the Emergency Department and 89% of them did not undergo the FOBT or other screening activities. These results can be considered as inefficiency indexes of the prevention process. It is difficult to put the whole blame on the healthcare system. Prevention is heavily dependent on the cultural attitudes of the population. The success of a prevention program is correlated to the initial attitude of a population towards this kind of subject. Educational interventions, and good practice dissemination programs, can improve the situation but only over the long term.

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