Quality assurance in radiotherapy.
How to improve the effectiveness and completeness of an electronic patient’s chart

Maurizio PORTALURI (a), Sergio CASCARO (b), Santa BAMBA (a),
Francesco TRAMACERE (a), Ernesto CASCARO (b), Virginia RECCHIA (c),
Albarosa SANZIO (a), Giorgio PILI (d), Vittorio DIDONNA (d) and Alessandro DISTANTE (b)

(a) Dipartimento di Radioterapia, AUSL BR1, Ospedale Perrino, Brindisi, Italy
(b) Istituto di Clinica Fisiologica, Consiglio Nazionale delle Ricerche, Lecce, Italy
(c) ISBEM, Euro Mediterranean BioMedical Institute, Brindisi, Italy
(d) Medical Physics, AUSL BR1, Ospedale Perrino, Brindisi, Italy

Summary. - A checking form was introduced in order to test the completeness of electronic and paper patient’s charts in a radiotherapy department which had introduced record-and-verify system (RVS) and to improve the staff performance. The chosen items for the electronic chart were 9 and 5 for paper chart. 223 patients were reviewed in two phases. The data analysis was based on a scoring method, attributing a positive score (+1) to the operator’s good behaviour, a negative score (-1) to the lack of data input and a neutral score (0) to the inapplicable situation. The average global score increased from 0.4 to 0.7: in A (lowest complexity) category from 0.37 to 0.64, in B category from 0.4 to 0.89, in C category from 0.48 to 0.61.

Key words: quality assurance, electronic chart, errors, computer control.

Riassunto. - Una scheda di controllo fu introdotta per testare la completezza della cartella clinica elettronica e cartacea in un servizio di radioterapia che adoperava un sistema di registrazione e verifica (RVS) a fini di migliorare l'adattamento al sistema. I parametri esaminati per la cartella elettronica furono 9 e 5 per quella cartacea. Le cartelle riviste in due fasi furono 223. L’analisi dei dati fu basata su un metodo di scoring che dà un punteggio positivo (+1) ad un comportamento positivo dell'operatore, un punteggio negativo (-1) se il dato non è stato immesso e un punteggio neutro (0) se il parametro è inapplicabile. Il punteggio medio globale aumentò da 0.4 a 0.7: nella categoria A (la meno complessa) da 0.37 a 0.64, nella categoria B da 0.4 a 0.89, nella categoria C da 0.48 a 0.61.

Parole chiave: assicurazione di qualità, cartella elettronica, errori, controllo computerizzato.

Introduction

The complexity of three-dimensional conformal radiotherapy (3DCRT), a technique that involves the application of novel imaging techniques in an attempt to maximize radiation delivery to tumor and minimize the impact on surrounding normal tissues, requires more safety and overall control of the treatment because of the great amount of data to transfer from simulation and computerised treatment planning machine to linear accelerators. The traditional method of transferring the planned treatment parameters (number of fields, machine settings, MUs etc.) of a patient to the treatment machine was via the delivery of the patient’s folder containing the plan information by the radiation therapist, who had to insert manually the parameters, for each patient, into the therapy machine at the time of treatment. In 3DCRT “era” all or part of this increased amount of information can be transferred directly to the treatment machine by floppy disk or over a local area network (LAN) in the case of a semi-automated treatment machine, whereas, for a fully automated treatment machine, all necessary information of the patient’s treatment plan can be transferred over a LAN to the control computer.

This is the main reason that could lead to the use of a modern computerized RVS that, once implemented, would allow more controlled delivery of daily
treatments and registration of all field parameters, so that they could be checked whenever needed. RVS is also composed of an electronic clinical chart which comprises two levels of data: technical and clinical data. Incompleteness of technical items stops the subsequent procedures and the treatments, incompleteness of clinical items affects only the immediate knowledge of a patient’s clinical problem and the aim of the treatment. The overall completeness of RVS increases the effectiveness of global medical assistance and avoids lack of clinical information and time-consuming retrieval of data on paper charts (that are still the mandatory part of a clinical documentation in Italy).

Soon after the adoption of RVS the incompleteness of the chart created stops in the flowing of the procedures. Unfilled fields about the intent of the treatment and about the stage and the lack of fundamental clinical data, course prescription, treatment beams definition in the RVS created misunderstandings in the staff and delays in the procedures.

Some documents and signatures lacked in clinical charts and this could have created legal troubles. Some authors have already described advantages [1-3] and mistakes [4-6] connected to the introduction of RVS into 3DCRT treatments but, to our knowledge, no study has focused on completeness of the clinical part of an electronic chart.

The medical and physical staff therefore decided to adopt a daily checking form to evaluate the completeness of the essential information on patients in order to promote a correct behaviour towards the new requests of RVS. The criteria used to choose the necessary data were based on the quality assurance report by national and international radiation oncology organisations [7, 8].

The aim of this study was to evaluate how the adoption of a checking form may change the behaviour of the staff with regard to completeness of electronic and paper clinical charts and whether these changes are durable.

Materials and Methods

Our “digitized” radiotherapy center comprises the following equipment: 2 linear accelerators (Clinac 600C/2100C by Varian, Palo Alto, Ca, USA) both equipped with multileaf collimators 80 leaves (MLC) and Portal Imaging device (Portal Vision), 1 simulator (Ximatron), 1 three-dimensional treatment planning system (TPS) (Nucletron Plato) and 1 Brachytherapy afterloading unit (Gammamed Varian USA) with its treatment planning system (Abacus). All these units, with the exception of brachytherapy, are connected through a LAN (Varian Varis).

RVS implemented in this radiotherapy center is composed of Varis (version 1.4) and Vision (version 6.1) (Varian, Palo Alto, Ca, USA), the former devoted to data, and the latter to images management. The software runs on two Windows NT 4 Server (Microsoft, Redmon, WA, USA), and 9 Windows NT 4 Workstation clients. The first server is aimed at data management through a Sybase Data Base Management System (DBMS) (Sybase, Emeryville, CA, USA). The second server works as a file server for Vision images, and as a DICOM server which receives images coming from external sources.

Varis is divided into 7 sub-modules: “Administration”, for the application management and configuration; “Patient registration”, devoted to patient demographic data and “Schedule” devoted to appointment definition on different department resources (CT, simulator, accelerator, etc.); “Patient’s chart”, where the treatment is recorded in terms of medical and physical data (e.g. diagnosis, stage, pathology, course prescription, radiotherapy intent, treatment field parameters, field scheduling, dose released by each field); “Simulation”, for field parameter acquisition during simulation; “Treatment”, for daily treatment delivery; and “Report” which allows data management.

Before using RVS for the first time, each staff member was given his/her personal user name and password, and strict override rights were set to the technologists for treatment parameters (e.g. jaw position, daily dose).

The application is used daily by the whole staff (physicians, physicists, nurses and technicians alike), and none of them required more than a 10-day training course to be able to use it. The system is built in such a way that, if “course prescription” and “treatment session planning” sections are not completely filled, simulation cannot be performed because type and number of beams are not displayed at the simulator console and cannot be acquired.

The purpose of increasing the completeness of the charts led to the introduction of a working group, composed of five doctors and two physicists, with the aim of discussing errors, lack of information, misunderstandings etc., in order to modify the working behaviour of clinical operators by means of a review of their errors and to improve their performance.

In order to evaluate the attitude of the physicians and physicists to complete the requested items of the system, the working group adopted a checking form (Table 1) in September 2002. In the form we listed the items considered important to be filled in the “Chart” section of RVS, and the documents that should be inserted in the paper chart for archive. The main items for electronic chart were the following: diagnosis, tumor and nodes classification, surgical operation, number of nodes resected, intent, course prescription,
treatment session planning, approved completion (electronic signature at the end of the treatment). The main items for traditional paper chart were: pathologic diagnosis, physical or radiologic examination reports, informed consent, correspondence between MUs in RVS and in calculation report, signatures of the planes by physician and physicist. “Key data” were defined as those which blocked subsequent steps of the procedures.

To evaluate how constant the results obtained during the first employment of the RVS system were, the checking form was administered in three phases: a prospective one before each treatment for 4 months, a second one six months later in a retrospective way for 1 month, and a third one 2 months later for another month.

In the morning briefings, since November 2002 up to March 2003, 100 consecutive charts of patients - who had to perform simulation - were checked by one of the five physicians working in the department, selected to be different from that who accepted the patient. The acceptance physician should have introduced data into Varis “Chart” soon after the first medical examination of the patient according to the internal procedure. The physician in charge of the checking, filled the form according to the criteria explained in the following paragraphs. At the end of each treatment, a physician, not involved in patients’ admittance, checked the completeness of the following items: correspondence of MUs in RVS and in calculation report, signatures of physician and physician on planes, electronic signature at the end of the treatment. In September 2003, during the second phase of the control, the same physician reviewed retrospectively 63 patients with the same checking form both for the electronic items and for the paper ones and other 60 patients in November 2003.

The idea behind this evaluation method is to reveal every action done by the physician, grouped in three main behavioural categories: a) positive attitude referring to the presence of the specific parameter; b) negative attitude referring to the absence of the specific parameter; c) neutral attitude referring to the NA case. At this point, action must be intended as “recorded action” that can be founded in RVS in term of completeness of all parameters defined in the Quality Manual as shown in Table 1. In order to analyse the considerable amount of data and reach a reasonable conclusion on the Learning Curve of the radiotherapy team, all along the observation period, a scoring approach was introduced and used. All the data analysis was based on a scoring algorithm, simply consisting in attributing a positive score (+1) to a good behaviour of the operator corresponding then to the a) aforementioned behavioural category, a negative score (-1) to the lack of data input, corresponding then to the b) previously indicated behavioural category, and finally a neutral score (0) to the NA situation. Since the number of patients, for obvious reasons, was not constant during the period of observation, the global score was normalised to the total number of clinical cases observed, that gives a total score ranging from -1 to 1 for every investigated parameter. As explained before, the criteria were oriented to display the general tendency on the part of the personnel to fill in patients’ charts efficiently, so a score equal to zero means that 50% of the checked data is correctly present and 50% is absent, i.e. if we consider a sample of 10 checked cases, we can have a non-normalized score of 10 (all present), 0 (5 present and 5 absent) or -10 (all absent) as extreme situations, that when normalized the score will be 1, 0 or -1.

We gave all parameters the same relevance due to the adoption of uniform criteria of selection [6]. As a consequence, also “key data” got the same weight of the other parameters even if they are “key” to gain access to subsequent procedures of RVS.

The evaluation and analysis were based on three different categories of treatment complexity degree defined by the Working Group of Italian Institute of Health (ISS) [9] A, B, C going from the less complex to the most complex oncology treatments respectively.

Table 1. - Radiation oncology data chosen for the study

<table>
<thead>
<tr>
<th>Data available on the electronic chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician’ initials</td>
</tr>
<tr>
<td>Istatan category (A, B, C)</td>
</tr>
<tr>
<td>ICD-9 diagnosis</td>
</tr>
<tr>
<td>T</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>Intervention</td>
</tr>
<tr>
<td>Number of lymph nodes</td>
</tr>
<tr>
<td>Intent</td>
</tr>
<tr>
<td>Objective exam/CT</td>
</tr>
<tr>
<td>Key data</td>
</tr>
<tr>
<td>Congruity M.U. plan-varis</td>
</tr>
<tr>
<td>Treatment session plan</td>
</tr>
<tr>
<td>Approved</td>
</tr>
<tr>
<td>Completed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data available on paper chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology report</td>
</tr>
<tr>
<td>MD signature of plan</td>
</tr>
<tr>
<td>Phys signature of plan</td>
</tr>
<tr>
<td>Informed consent</td>
</tr>
</tbody>
</table>
A category comprises treatments with simulation and dose calculation along the beam, B category requires bi-dimensional dose distribution on one CT slice, C category includes 3DCRT. The number of cases for each complexity category is 49 for A category, 86 for B category, and 88 for C category.

Results

Figures from 1 to 4 report the results of score computation. For A category, the starting and final score was 0.37 and 0.64 respectively, showing a continuous increase for every subsequent month, but not for January and August, the typical months for summer vacation in Italy, where there is a tougher rotation of the personnel with a clear consequence of reduction of the archival completeness level for the simplest therapy category.

In Fig. 2 the score variation for B category is depicted. Also in this case we observed a constant increase of the score with time, going from 0.4 for the first month to the 0.89 for the last month. We observed as for the A category results, a reduction of the score in the months of January and August, even if not as evident as the one in Fig. 1.

In Fig. 3, the score variation for C category (the most difficult one) is given. In this case, the score went from 0.48 to 0.61, observing a maximum score after five months followed by a reduction.

Finally, in Fig. 4 the average global score variation is depicted in a histogram, giving clearly indication of the increase of the score that went from 0.4 to 0.7 with a maximum of 0.85 in March, at the end of prospective checking phase.

Pathological report presence score increased from 0.20 at the beginning up to 0.90 in March and decreased to 0.20 at the end of the study. Only in B category we observed a final increase up to 0.60. Signature of physician and physicist after few months increased steadily up to 1 and 0.90 respectively in all the complexity category. Informed consent passed from -0.20 up to 0.70 (from -1 up to 0.20 in A category, from 0.10 up to 1 in B category, from -0.30 up to 1 in C category).

Globally ICD-9 filling passed from 0.45 up to 0.90, intent of treatment from 0.90 up to 1, while T classification decreased from 0.75 to 0.55, N from 0.80 to 0.55, objective exam/CT from 0.55 to 0.20 with much lower scores in between extreme data analysis. Operation passed from 0.10 to 0.40 with score higher than 0.60 in five but nine months. Lowest results were recorded in A category patients but much better in B category where all items but one (N classification) reached the maximum score. Among C category patients, all the items but one (objective exam/CT) were at maximum score at the beginning and kept this performance up to the end of the study except in N classification which registered lower scores in August and January.

Course prescription was complete from 0.90 up to 1, treatment session planning from 0.90 up to 1, congruity of MU at the beginning was always 1, “approved” and “completed” fields passed from -0.25 to 0.75. These trends were confirmed in each category of patients.

Because surprisingly C category showed itself to get less constant level of completeness after prospective phase (Fig. 4), the performance of each item was examined. With regard to the worse ones, “objective exam/CT” started at 0.33 finished at -0.2 with 1.0 score in March; “Number of nodes” started at 1, and dropped down to 0.33 and to -1.0 in the second and third checking phases; “pathological report” started with 0.33 and finished with 0.20 although it was almost always over 0.5. “Intervention” started at 1 and dropped down to 0 score with only other two months with score less than 0.5.

Fig. 1 - Score variation during the observation months for the A category cases.

Fig. 2 - Score variation during the observation months for the B category cases.
Recent developments in radiotherapy technology have created new possibilities of cure but the superior performance of modern equipment cannot be exploited unless a high degree of accuracy and reliability in dose delivery is reached which is only possible through quality assurance programmes.

This implies that both the parameters related to the patients (diagnosis, decision, indication of treatment, follow up) and also procedures related to technical aspects of administering the treatment should be subjected to careful quality control.

The European Society for Therapeutic Radiology and Oncology (ESTRO) [8] addressed an advisory report to the European Union Commission for “Europe against cancer programme” where patient data item was included under process control heading. It included patient history, previous treatment, diagnostic work up, pathological diagnosis, report, TNM classification, target volume definition, intent of treatment, information regarding disease stage, prognosis and treatment sequels, all details relating to patients measurements. In the heading “Control of quality system” the establishment of regular reviews and audits of both the implementation and effectiveness of quality system was recommended.

The Italian National Institute of Health [7] encouraged the development of a voluntary program of accreditation by defining and testing appropriate evaluating indicators. Among 13 indicators, completeness of clinical chart was defined. A form was suggested containing identification number, registration data completeness, risk factors and co-morbidity, anamnestic data, previous therapies, TNM, radiotherapy prescription, informed consent.

The introduction of information technology in medicine permitted to manage complex treatments and to share data and images among operators. The analysis of large series of minor medication errors indicated that most of them could be addressed by better medical information [10].

Computerised physician order entry systems - that incorporate clinical decision support - can substantially reduce medical error rates as well as improve the quality and efficiency of medication use [11].

Many papers refer to RVS implementation. They focused mostly on the reduction of errors and misconceptions or on the minor number of therapists operating each linear accelerator [1].

The creation of an electronic chart for use with computer-controlled conformational therapy involves the integration of treatment planning, treatment delivery procedures and dose and prescription information [2].

Fraas et al. [12] found 20 patient/chart errors but detected 152 (13%) errors during a 15 month period of analysis which are one eighth of overall rate (0.13%) registered in their computer controlled department. These patient/chart errors regarded incorrect choice of patient or plane and prescription related problems.

RVS or computer control system will certainly decrease the number and severity of treatment delivery errors, but the use of automated or semi-automated system makes the entire treatment planning and delivery process much more susceptible to systematic errors [12].

In centres using RVS, 15% of errors could be related in a substantive way to the use of this system [13].

Macklis et al. [13] proposed a useful taxonomy of radiotherapeutic errors: questions of appropriateness of clinical decision in treatment plan design; physical inaccuracies and calibration problems, reliability of imaging techniques, patient immobilisation constraints and anatomic uncertainties in day-to-day treatment volume positioning and registration; lack of treatment homogeneity within the chosen target volume; adverse treatment outcomes and errors in treatment implementation.
Patton et al. [14] also reported 3.3% of harmless error of 1,163 radiation therapy courses administered during the evaluation period and 0.04% of patients treatments were related to the functions of the department RVS.

Schwartz et al. showed a learning curve in the use of RVS by which the number of overrides significantly decreased during the first month of experience [15].

Limited experience or excessive confidence in the system increase the frequency of errors in a study where the verification function of the RVS was suppressed [4].

Also in a study regarding errors in treatment course or completeness of non-electronic treatment chart, errors in compilation phase resulted higher (10.5%) with respect to execution (0.58%) and in registration phase (2.9%) [16].

The aim of this study was to check the compliance of the medical and physical staff with electronic chart and the possibility of improvement of paper chart completeness. We also tried and did measurement of completeness by means of a score system. We observed that introducing a form as a checking method can affect in some way the behaviour of the staff. Completeness score passed from 0.39 to 0.70 globally and the presence of some items was surely improved as informed consent, “approved” and “completed” electronic filling, intent of therapy, doctor’s signature of treatment plan, ICD-9 indication. The performance of some items were high at the beginning (course prescription, treatment session planning, physician’s signature and congruity of monitor units on paper and on RVS) because the former two items are preliminary to subsequent procedures and their incompleteness created disclaims and misunderstandings in the staff. Furthermore, with regard to physician’s signature and congruity of MU items, we decided that radiation technologists had to control if they are present in the charts.

We did not observe marked and durable improvement of completeness with regard to objective exam or CT report notation, N classification, indication of number of resected and positive nodes, surgery description and pathological report presence. The introduction of these items in RVS depends on physician who accepts the patients and transfer the data from paper into electronic chart. The lack of this type of information does not stop subsequent procedures in RVS and can be detected only by checking activity. In fact, the best performance of the staff was obtained in March at the end of the prospective use of the checking form (Fig. 3 and 4) and decreased soon after. N classification does not imply only a transferring activity of data but requires that the physician should make a clear summary of the data at her/his disposal. In the system is mandatory the filling of “stage” field and the physician prefers to fill this one rather than T and N items. Because C category is composed mostly of prostate cancer patients the incompleteness of N items in this complexity category depends on the fact that in current practice we usually use stage classification in this cancer site rather than TNM. Lack of information about lymph nodes depends on the fact that prostate cancer patients present CT scans mostly with negative nodes. CT scans rarely produce information about extracapsular extension and the department policy in this cancer site, almost always oriented towards local conformational irradiation, could have discouraged a more accurate reporting of these items into electronic chart. Absence of pathological report in some charts when instead it was necessary may be explained a) by the use to summarise it in clinical discharge letter from other specialists, b) by the use of some patients’ relatives to hide diagnosis showing no pathological report during the first visit but successively. This shortage is not detected in B category treatment which is compounded mostly by breast cancer patients. This kind of patient referred to our department is generally well documented by surgeons and specific N stage may change treatment plan prescription. Incomplete description of surgery could depend on the “free hand” type of recording and the physician’s preference for pre-coded “intent” item which includes the clear notation of “postoperative”.

The explanation of different effects on different items can be explained by the relevance of these items in order to subsequent procedure and by the simplicity of transferring into electronic chart. The first type of items have already been discussed in great detail. In the case of “intent of care” and ICD-9 introduction, the physician is guided by pre-coded answers and this facility helps the completeness. As to electronic filling of “approved” and “completed” field, we immediately planned to insert the data before archiving paper charts, thus creating a kind of “check point”. In addition we decided that nursing personnel had to control the completeness of informed consent before simulation procedure.

Less complex treatments (e.g. palliative treatments) show lower completeness. In this category of patients the completeness performance was worse during summer months due to a more acute shortage of personnel.

Because low performances depend on lack of human control, we decided to check the most deficient items during the morning discussion of the cases studied for simulation.

According to the adopted scoring system, which expresses a tendency of completeness rather than its percentage, we considered positively the reached level of completeness of electronic and paper chart and estimated
useful the experience of introducing a checking form in order to ameliorate the compliance of the staff with RVS and their attention to completeness issue. Global reduction of score performance after the spike of the first checking phase did not reach anyway the level of the starting score which is lower. This reduction could be coherent with the general behaviour of the learning curves.

Conclusions

We realised a quality assurance activity aimed at checking radiation oncologists’s attitude towards RVS and completeness of the clinical chart. The adoption of a checking form improved the performance of the medical and physical staff and kept it at a level higher than the starting one in the majority of the items. The study revealed that completeness of information about the patients can be obtained only if a) it is strictly preliminary to other procedures so as to stop subsequent activities of the staff, if b) a control system, represented by a checking activity of a different operator, is adopted towards some necessary actions that the radiation oncologist should take or if c) data input is simple and preferably pre-coded by the system. The study confirms the importance of human factor with regard to possible errors also in presence of automated system of medical procedure management and shows the effectiveness of quality control activities in improving the efficiency of medical staff behaviours.

Acknowledgments

We thank Rosita Maglie who translated in English this article.

REFERENCES


