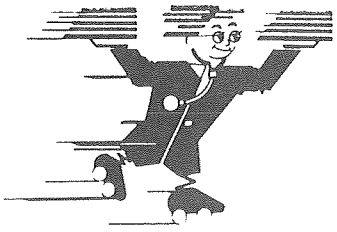
DECEMBER 4, 5 and 6, 1989

PARIS-NORTH EXHIBITION CENTRE

7 THE 7TH EUROPEAN HEALTH RECORD MANAGEMENT CONFERENCE



ABSTRACTS

AN EFFICIENT SOLUTION FOR THE STORAGE AND MANAGEMENT OF CLINICAL DATA: THE MINIMUM DATA BASE

A. GATTAI
President of the Italian Society "Archivi Sanitari Ospedalieri"
Viareggio, Italy

A. BALDINI, A. CAROBBI
Istituto di Elaborazione della Informazione
Consiglio Nazionale delle Ricerche
Pisa, Italy

Abstract

Italian hospital medical documentation is objectively very complex. The complexity is caused not only by the large number of different information fields which must be included in the medical case-histories but also by the numerous additional documents which are normally associated. Unfortunately, there is a considerable lack of homogeneity between the various models used to handle this type of documentation and the different filing systems adopted.

Despite the difficulties involved in selecting the data to be preserved, the medical and legal obligations for the archiving of clinical data must be respected. Consequently, there is a strongly felt need for the creation of a system for the rapid storage and management of such data. The paper describes a system which is being designed and developed for this purpose: the ***Minimum Data Base.***

The first, and probably the most realistic, picture which comes to mind when the subject of "hospital health documentation" is raised in Italy is that of an enormous pile of heaped-up records, consisting principally of documents and other papers bundled into folders, and frequently lacking any chronological order, important information often being mixed randomly together with much less important material. In addition, there is frequently the suspicion that other, equally important, documentation has either not been transcribed or has been lost in midst of the overall disorganization. Furthermore, the relevance of the fact that, whether or not the data which has been collected was complete at the moment of acquisition, it is very unlikely that it can be retrieved later, in a place or at a time different from the moment when it was produced, must not be under-estimated. The responsibility for this situation is hardly ever that of the availability or not of certain tools or instruments but the lack of an efficient organization which would make it possible to select the data to be recorded, to evidence them in the most suitable way, to store them adequately, and finally to reuse them when a case-history must be updated or (a factor which must not be forgotten when dealing with the medical sciences) for study and research purposes.

These negative aspects of the actual situation, regarding clinical data and medical documentation in general, require an in-depth analysis which, in our opinion, must not be limited merely to seeking a solution for

the storage of the data collected, but must be directed above all to analyzing and reformulating the underlying problems.

It is therefore our belief that the whole problem of the archiving and storage of hospital medical documentation must be carefully re-examined in function of an efficient preservation of that information which is considered to be of primary interest. This is of fundamental importance not only for those cases in which the medical history must be re-examined totally or with regard to certain particulars, but also, when particular cases are to be studied for research purposes, statistical analyses, epidemiological situations, and so on.

However, it is also clear that the same problems are found in an even more urgent manner when we look at the medical record which, apart from being the most representative item of hospital medical documentation in general, can also be used for legal, statististical and administrative reasons in addition to strictly medical scopes.

The possibility, however, that a medical record can or should be used in legal medicine cannot change its primary scope which is that of documenting information and data which specifically regard the medical assistance and treatment provided, over a well-defined period of time passed in hospital. For this reason, the language and descriptive style used must be clear and appropriate for communication between all those who are responsible for looking after the patient throughout his stay. In fact, whatever its future use, including eventual production in courts of law as documentary evidence, this can and must never be considered as the main scope of the medical record. Therefore, whatever its legal status, well-defined norms must regulate the language and style of the medical record. In order to favour its efficient compilation, it should be brief, contain all significant details and provide an accurate reconstruction of the medical data to facilitate a later interpretation.

The range covered by the information included in the record and its intrinsic importance is not limited to written data but may well be integrated by graphs, tables and, sometimes, drawings, in order to throw as much light as possible on the condition of the patient and to permit a better interpretation of the data In fact, all that which regards the assistance and treatment of the patient will be faithfully recorded in the medical record from the moment of admission until discharge.

Therefore, if the clinical case-history is to be complete from all points of view, the following requirements must be satisfied:

- it must be exhaustive, i.e. provide a faithful reproduction of the complex hospital activity in all its moments and sectors;
- it must be clear and precise so as to avoid giving rise to doubts concerning the assistance and treatment which has been provided to the patient by the hospital, medical and nursing staff.

It appears thus evident that we cannot continue to allow each hospital or institution a completely free hand in the preparation and compilation of their own personalized medical records; a complete and well defined methodology must be introduced to describe all the elements which contribute to make up the medical services.

The medical record cannot be regarded as a set of totally pre-established elements; it is used to document hospital activity which is in continual evolution and is a practical tool which can and must be adapted to the concrete possibilities of those operating in the field. For these reasons, improvised documents must be replaced by a pre-defined and standardized record, which on the one hand is of easy compilation, while on the other represents succinctly the essential elements of hospital treatment. At this

point, we have to decide whether it is better to prepare a single, comprehensive medical record to which separate sheets can be added to cover each specialist field or to create a separate medical record for each different hospital activity.

Without doubt, in consideration of the characteristics and the evolution of hospital treatment which is increasingly tending towards specialization, the type of medical record which would best meet these requirements would appear to be a separate record for each specialist branch of medicine, standardardized over the entire national territory. The medical record must, however, satisfy all the demands for activity and efficiency which are made on the health service; while remaining precise and succinct it must not assume the dimensions of a note book or an even larger volume. It must be as synthetic as possible so that, at any moment, a general overall check-up on the course of the illness can be made and while at the same time it can fulfil all the functions which from time to time may be requested of the medical record: archiving, issuing of authorized copies, re-use for a subsequent admission, study and research, etc.

From a medical record organized in this way on a well-defined and precise structure, which can be easily transformed to a computational representation and thus be used for statistical analyses and epidemiological investigations, it would be quite easy to create a minimum data base, both nationally and internationally, once agreement was obtained on which data should be stored, and which instead ignored as not being strictly pertinent.

If, yesterday, this problem was confined to the single hospital, today it is extended to the regional and national level, and in the near future (1992), we envisage it interesting a much wider area, not only Europe but further afield. In view of this situation, it is clear that we must act immediately and not await the course of events passively in the illusion that we can continue in the same way as we have gone on so far. Neither must we expect the new technologies to smooth the path and resolve organizational defects by themselves.

In this regard, we must not forget that the project, begun in Italy in 1978, to regulate the National Health Service proposed the introduction of a number of important innovations aimed at providing the country with a modern and efficient public health service, e.g. personal health books and record cards, particular record cards for subjects at risk, various specific records to document the activities of the general practitioner and the basic health services. However, so far, not all these services have been realized at the practical level.

Even the European Community (EC) has given attention to the problem, attempting to define the "minimum medical record" as the smallest possible set of basic standardized information capable of covering a large number of data. If such information could be extracted in a summary, compiled in hospital, when the patient is discharged it could offer a wide range of applications through a minimum of basic information. The aim would be to define a minimum set of information on clinical cases, in order to be able to determine general norms for Europe for the development of epidemiological information at the level of the EC.

We have no information on how medical cards are managed in the rest of the European Community countries, but we are certainly aware of the fact that in Italy there have only been sporadic attempts at uniformity in certain sectors at the local level (in some Hospital and Local Health Authorities) and the results of these initiatives, even if locally acclaimed, leave us somewhat perplexed with respect to their improvisation.

It is also true that in a number of international conferences held in Italy on this subject (see for example APIM88, Florence, 26-29 October 1988) increasing attention has been given to projects such as the EC "Advanced Informatics in Medicine" project, or to the formulation of guide-lines by the World Health Organization for various types of classification and encoding activities. But this does not mean that, in actual fact, data and questionnaires, information and databases, the medical record and its storage have been standardized. On the contrary, we have received the clear impression that such discussions have encouraged the promotion of spontaneous initiatives, generally assisted and made more interesting by the application of the computer, to the various fields of medicine. However, even if, on the one hand certain standards are respected or imposed by the use of the computer, on the other such projects cannot be generalized or extended either because of the type of computer, system or language used, or because of the way that particular branch of medicine.is organized.

All this leads us to predict that, rather than a common "minimum data base" for different branches of medicine valid over a wide area, we are moving towards the creation of an large number of "minimum data bases", each one constructed without taking into consideration in any way the needs of the others. This is because there is no supervising authority to set down rules which govern the choices and applications to be made.

Perhaps these impressions are influenced by the pessimism of one who, for many years now, has listened to the proposal and formulation of all too many projects and has participated, more or less convinced, in meetings and round tables where these topics have been discussed and where over enthusiastic solutions have been proposed without any real verification or even a serious and coodinated attempt at realization.

In our opinion, we have allowed ourselves to be lead astray by the computer, idealizing it as a tool capable of resolving problems which have not only been formulated incorrectly from the conceptual viewpoint but also in the planning of analyses. The data collected and inserted in the medical record are too numerous and vary too much with regard to their degree of importance to be able to think that it is possible to store them all, generically, with the hope of retrieving them in the same form and the same way, and using them in many different applications. It is clearly necessary to pass through a stage of careful and studied evaluation in order to discard information which is "superfluous" or at least considered as such, summarizing some and evaluating the effective importance of others. In our opinion, it is on these last three points which it is necessary to concentrate all our efforts, employing the forces of both those who have already made attempts in this direction and others who, even if they have no direct experience in the field, are aware of the necessity of this work, as they are daily involved in hospital activities. But, above all, we must emphasize how important it is to have a single body which is responsible for coordinating all these efforts, and for controlling that no project is undertaken in which the standards which have been agreed on are not followed. This will certainly lead to considerable benefits not only from the administrative point of view but also from the economic, health, legal and research viewpoints.

At this point, and in light of the hypothesis for a standardized medical record suggested several years ago, we should like to suggest the creation of a "minimum data base" as a first approach towards dealing with the problems which have been presented above.

Having discussed this subject on many occasions, we are perfectly aware of the difficulties implied by this hypothesis, but on the other hand, it

seems even more absurd to be aware of the existence of a problem and not to have the courage to tackle it, in this way, permitting the problem to become even more complex. We are thus making a concrete proposal which, although it is certainly open to criticism, we hope can serve to stimulate the treatment and production of documents which are too frequently forgotten. This proposal is based on certain considerations which make it possible for us to tackle the problem within realistic limits and which are summarized in the following points:

1) it must be possible to summarize each medical record into certain essential information fields which we identify as the "minimum data base";
2) at the moment, each minimum data base representing, the single medical records, should be stored on electronic support;
3) all medical records referring to the same patient must have the same identification number and indication of the year, (e.g. 21714/89);
4) the structure of the "minimum data base" must be standardized over the whole national territory.

A second series of elements which interest this proposal regards the type of standardization: it is necessary to identify those sectors whose presence is essential in the "minimum data base". According to us, these sectors are the following:

1) Heading
2) Anagraphic data
3) Anamnesis/Personal history
4) Objective Examination
5) Clinical case-history
6) Discharge data

It is clear that each of these sectors must have a brief, well-defined and standardized content, and they must be compiled using generally recognized guide-lines.

We hope that the example which we give here can provide a basis on which the scientific community, both medical and not, can, or better still should, concentrate its efforts towards our common, and long dreamed objective. We should like, however, to repeat here a concept which, appears obvious as it has been stressed several times but, if we look at the present situation in Italy, does not seem so. In order to obtain a "minimum data base" we must first achieve a minimum level of uniformity and standardization of the medical records both in their form and their content.

HOSPITAL _____

Department or Service _____

CASE HISTORY-SHEET No. |_|_|_|_|_|_|_| |_|_|

Date of Admission |_|_| |_|_| |_|_|_|_|

ANAGRAPHIC DATA

Surname and First Name(s) _____

Sex |M| |F| Date of Birth |_|_| |_|_| |_|_|_|_|

Place of Birth _____

Blood Group |0| |A| |B| |A B| Rh Factor |+| |-|

Profession _____

Address _____

City _____ ZIP |_|_|_|_|_|

Tax Code |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

A N A M N E S I S

Family Data

Father Age |_|_|
State of Health _____
Mother Age |_|_|
State of Health _____
No. of Siblings |_|_|_____
No. of Children |_|_|_____
Age of Spouse |_|_|
State of Health _____

Social and Environmental Data

Home _____
Work Environment _____
Social Relationship _____

Personal Physiological Data

Menopause/Andropause _____
Alcohol _____
Drugs _____
Disability _____

Past Pathological Data

Surgical Operations _____
Traumas and Accidents _____
Past Deseases _____
Allergies and Intolerances _____
Risk Factors _____

Recent Pathological Data

Diagnosis on Admission _____
Symptoms _____
Therapy _____
Exams _____

OBJECTIVE EVALUATION

General Notes _____

_____

_____

Specific Observations _____

_____

_____

Specialists Consulted _____

_____

_____

DISCHARGE

Date |_|_| |_|_| |_|_|_|_|

Diagnosis on Discharge _____

Results:

Cured |_| Improved |_|

Stationary |_| Worsened |_|

Deceased |_| Date of Decease |_|_| |_|_| |_|_|_|_|

Postmortem Examination |No| |Yes|

Diagnosis _____

Signed by _____

References

A. Baldini, A. Gattai
Indagine conoscitiva sull'informatica negli ospedali italiani.
Ospedali d'Italia, Aug. No. 8, 1975, pp. 11-52.

A. Baldini, A. Gattai
Considerazioni generali sulle cartelle cliniche ospedaliere e sulla loro gestione.
Bollettino dell'Accademia Medica Pistoiese F. Pacini, XLVII, 1976.

A. Baldini, A. Gattai, A. Perini Carobbi
Analisi comparativa di cartelle cliniche per una ipotesi di standardizzazione: parte anagrafica.
I SIASO National Congress, Montecatini Terme, 29-30 Oct. 1976.
L'Ospedale, Sup. No. 1, XXXII, pp. 34-40.

A. Baldini, A. Gattai, A. Perini Carobbi
Proposte analitiche per un'ipotesi di uniformazione delle cartelle cliniche ospedaliere.
SIASO "Convegno di Studio", Montecatini Terme, 6 May 1978.

A. Baldini, A. Gattai, A. Carobbi
Analisi comparativa di cartelle cliniche per una ipotesi di standardizzazione: diario clinico, inserti mobili e dimissione.
Comunit e Salute, No. 4, 1981, pp. 66-81.

A. Baldini, A. Carobbi
Problematiche inerenti l'organizzazione e la gestione computerizzata delle cartelle cliniche ospedaliere.
III SIASO National Congress, Pisa 20 May 1988, pp. 51-93.