Clinical Data Processing: Concepts in a Pharmaceutical Organization*

By SANDRA PELUS, JOEL L. SHAPIRO, and FRED WIBIRALSKE Lederle Laboratories, a Division of American Cyanamid, Pearl River, N. Y. Received September 25, 1962

Major pharmaceutical companies each year screen thousands of new chemical compounds as well as new dosage forms and combinations of older agents. Clinical trials which provide detailed information on patients treated are an essential part of the drug evaluation procedure. While some trials may include only a few hundred patients, other clinical testing programs may involve over 10,000.

In 1959 Lederle was confronted with a voluminous trial engendered by a promising new antibiotic. Medical Research personnel and information processing specialists at Lederle Laboratories began to pool their ideas on the requirements of a mechanized system geared to process clinical data. An information processing group was created to provide the framework for analyzing the mass of information gathered from a study of this scope.

The four major areas with which this group was concerned were *editing* and *coding*, *storage*, *retrieval*, and *dissemination*.

The accumulation of raw data, the earliest phase of the operation, was performed by other departments of the Medical Research Section. This aspect of the work and the detailed results of the first drug processed through the new system have been described in a paper by Shapiro and Phillips.¹

BEGINNINGS AND EVOLUTION OF A SYSTEM

The antibiotic trial brought about the genesis of the information group, but allowed no period for theoretical experimentation, for a practical system had to be created and in operation within six weeks. It had become apparent that a mechanized system was needed to provide the required information rapidly and accurately, as manual retrieval techniques had proved cumbersome, subject to human error, and unable to provide most correlations within the time allowed.

Nature of Data.—A clinical investigator reports information about his treated patients on a case report form developed for each drug trial. Such a form is designed to obtain all pertinent information: characteristics of the patient, (age, sex, etc.), disease(s) treated, coexistent

disease(s), concomitant therapy, dosage(s) administered, clinical response, side effects, laboratory findings, general observations, and comparisons with other drugs. Several thousand of these detailed reports and hundreds of other types of clinical reports may be received for a drug. In general, each clinical document describes results for one patient.

Application of Data.—Clinical reports act as a source for two basic classes of information: (1) statistical tabulations which present correlations of clinical trial information; (2) specific data which must be readily located in the masses of clinical documents.

Computer vs. Electromechanical Systems.—Because of relatively complex laboratory analyses and other factors, all information from a clinical report could not be contained within the limits of one 80-column punched card. In fact, 3 cards per patient were required on an average. With the available equipment—083 sorter and 077 collator—it had proved difficult to correlate information on one punched card with different types of information on succeeding cards for the same patient. Therefore, it was decided to utilize the IBM 650 computer to store information and provide reports on the antibiotic.

Experience with this equipment proved that the computer could furnish the required correlations among disease, dosage, duration of treatment, cultured microorganisms, side effects, and many other elements. Thus, the data requirements were met by the computer system and evaluation of the antibiotic was expedited.

At the completion of this project, consideration was given to another system, one which would utilize relatively standardized techniques to furnish detailed correlations of data on many different types of drugs undergoing investigation in trials of smaller scale (about 400 patients). Methods based on tabulating equipment—an electromechanical system—would provide required reports for such small trials as well as for larger trials involving simple data. The coding system and report formats were revised, therefore, in order to process several types of drugs within a single conventional system.

The following discussion relates to details and applications of both the computer and electromechanical systems. Aspects of data processing which are similar for both systems are discussed under one heading. Where significant differences are evident, each system is discussed separately.

 $^{^{\}circ}$ Presented before the Division of Chemical Literature. 141st National Meeting of the American Chemical Society, Washington, D. C., March 22, 1962.

¹ J. L. Shapiro and F. M. Phillips, "Demethylchlortetracycline in Clinical Practice," J. Am. Med. Assoc., 176, 596 (1961).

INFORMATION FLOW (INPUT)

Processing Case Reports.—Clinical reports were handled in the same manner for both the computer and electromechanical systems. When reports were received they were duplicated and returned to the investigator. Copies were given an accession number and then were analyzed by medically oriented documentalists. Codes assigned to each item were transcribed onto three basic transmittal or code sheets (A,B,C—Fig. 1) to be used by key punchers for card preparation.

The coding system had to meet three requirements: (1) Most information retrieved had to be highly specific and representative of the investigator's original statements, yet free of redundancies and inaccuracies in terminology. (2) Codes had to facilitate the presentation of information in a logical and orderly sequence within the final tables. (3) Codes had to be consistent from one drug trial to the next for ease in coding and retrieval.

Coding.—In the computer system, because of its capacity, no serious restrictions were placed upon the amount and type of codes. Digital rather than alphabetical codes were used, however, because of certain limitations in storing alphabetical information. Each transmittal sheet and the resulting punched cards were of identical design. One vertical column on the transmittal sheet corresponded to one column of a punched card and one horizontal line of information produced a single punched card.

In the *electromechanical* system all information categories were limited to one 80-column punched card; therefore, the types of codes and code lengths were restricted (Fig. 2).

Codes assigned to types of information supplied fell into the following broad categories:

1. Serial Codes.—Numbers assigned in sequence to alphabetically or systematically listed items, such as names of investigators, laboratory tests, competitive drugs. These codes provided logical listings of specific items when produced by mechanized techniques.

Examples:

An investigator whose last name begins with "A," for instance, might be coded 0100 and one with "Z," 9500. In the anti-inflammatory drug category (600–800), acetylsalicylic acid is 605, prednisone, 700 and triamcinolone, 790.

2. Range Codes.—Single-digit codes which provide useful categories for specific information such as weight and age.

Example:

A patient weighing 150 pounds is coded as 7 (126-175 lb.).

3. Direct Code.—A single digit in a specific column with a specific meaning.

Example:

In an over-all evaluation of treatment, a clinical investigator will check either: excellent, good, fair, poor, worse, etc. on the report form. This is coded as l in a column for "excellent," of 2 ("good"), 3 ("fair"), etc.

4. Alphameric Codes.—In coding disease entities and side effects, it is important to convey the investigator's

original diagnosis accurately. Rather than precise diseases or syndromes, in some cases symptoms must also be coded, Edition is employed occasionally to convert synonyms and obsolete terms into standard nomenclature. Also, similar diagnoses may be grouped into a single authoritative term for retrieval efficiency. In the computer project, the International Classification of Diseases (IC) provided a convenient source of headings.

5. Specific Data.—Quantitative information which is coded exactly as it is reported. Grams may be converted to milligrams, or weeks to days for consistency, but this is the only type of conversion made.

Example

A tranquilizer given at a dose of 250 mg. 4 times daily for 5 weeks is coded as 0250 in dosage column, 4 in frequency column and 035 in duration column.

IC codes were not found suitable for the electromechanical system. Instead, machine-produced reports were selectively fashioned by creating codes based on alphabetical position or the desired classifications. Thus, each diagnosis and side effect encountered in a drug study was assigned a serial alphameric code based on its alphabetical position in a master list of diagnoses compiled from all drug trials. A code for the associated body system was also assigned. This code revision provided disease and side effect tabulations in the desired sequence.

The disease and side effect file, which is continually being expanded, now numbers 2500 terms.

INFORMATION RETRIEVAL (OUTPUT)

Computer System.—Two computer programs were written. The first program (card to tape) was used to build a tape file of clinical reports. The second program (standard report punchout) selected data from the tape record and combined and incorporated them into report designs. Information from as many as 15 cards per patient was edited and placed into a magnetic tape record. Six primary correlations on six punched card decks were prepared by the 650-computer and printed into six reports by the 407-printer. Sequences and controls within each report were varied to highlight relationships in the data. Additional calculations (percentages, averages, etc.) and final tabulations were prepared manually. (See information flow chart, Fig. 3). The decks consisted of a basic card for each patient with additional cards for multiple data, i.e., more than one disease, dose, or organism, etc., per patient. During computer processing, statistical counts were made of age-sex distribution, dosages, cumulative dose administered, diseases reported, and other items of significance.

The Card to Tape Program.—This program built the tape file from the transmittal sheet entries containing information categories shown in Fig. 1. The first card for each patient was punched from transmittal sheet A. (Each case report required at least one transmittal sheet A card.) The process was continued with any multiple data cards for sheet A. Cards for transmittal sheets B and C—optional and punched as needed—with their multiples, were added. The cards were sorted to transmittal sheet sequence by investigator patient code.

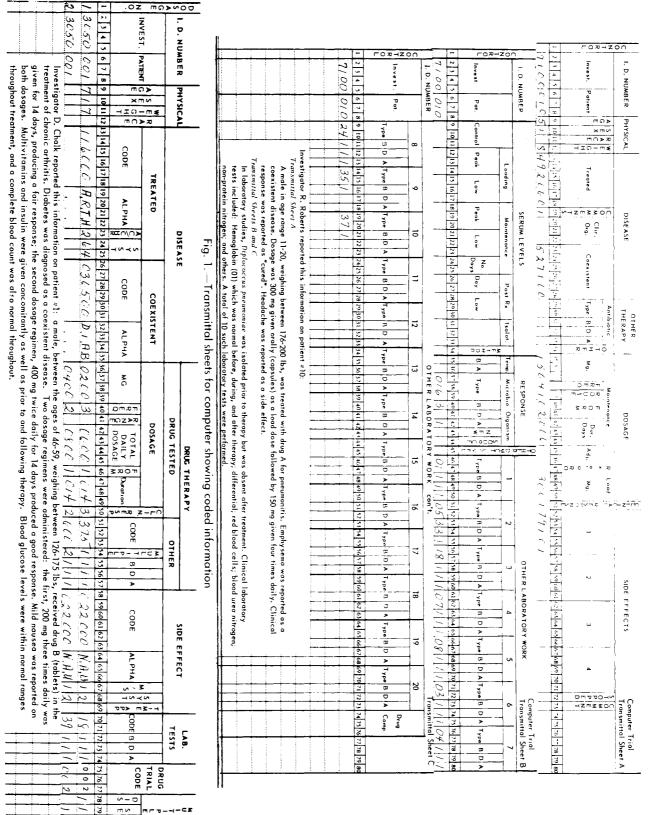


Fig. 2.—Transmittal sheets for electromechanical trial showing coded information

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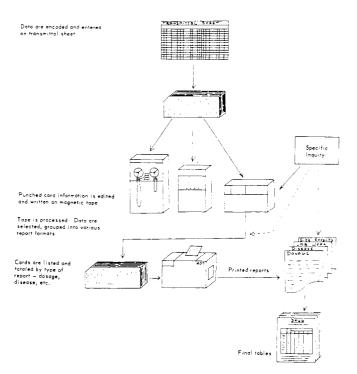


Fig. 3.—Clinical data processing flow chart computer system

The program was designed to read and edit the cards, checking for duplicate investigator patient codes, incomplete records, missing cards and errors in the control sequence, while rejecting erroneous cards. Processing, illustrated in Fig. 4, consisted of accumulating all cards punched for each patient and incorporating them into a record for each patient. Daily and cumulative dosages

administered were calculated at this stage. After the last card for a patient was read, the complete patient summary was written as a 450-character tape record. This sequence was repeated for each new patient, while control counts were maintained of the number of patients and dosages.

Standard Report Punchout Program.—This program was designed to select specified items from the patient case report tape, then group the data into standard formats, and punch cards for the detailed reports.

Cards for dosage and disease reports were punched for each patient record existing on tape. Side effects, laboratory test results, microbiological responses and serum level cards were punched only for those records containing such information. Statistical counts of the age–sex distribution of the patients reported, the number of patients receiving multiple doses, the number of diseases reported for each patient, and the total dose received by each patient were maintained during the run and punched out at its conclusion.

The sequence for processing data in the punchout program was developed as follows: (1) A dosage card was first punched for each patient. Multiple dosage schedules were controlled by a dosage control number punched in the card. (2) For the disease report, a card was punched for each primary disease reported. When multiple dosage schedules had been administered to a patient, a new series of disease cards was punched and identified by the dosage number. (3) A card was punched for each side effect reported. A side effect was related to a specific dosage, in turn identified by its control number. (4) A card was punched for each pathogenic organism reported. Responses to the various dosages were punched into separate cards. (5) For laboratory work a card was punched for each test reported. The result of the test—its numerical

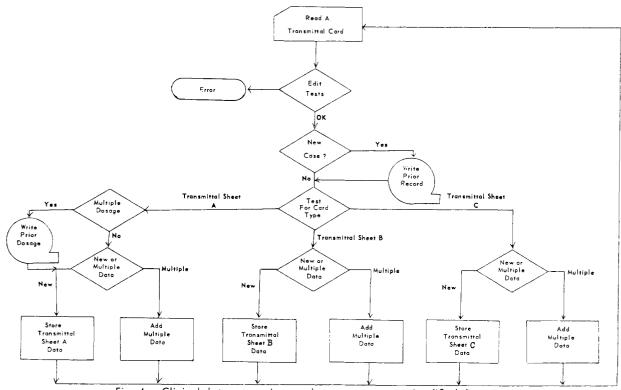


Fig. 4.—Clinical data processing-card to tape program simplified diagram

value coded as normal, abnormal high, or abnormal low—was correlated with various phases of the treatment. (6) Serum levels for each dosage (where reported) were punched into cards. (7) The sequence was repeated for each patient record.

Electromechanical System.—As in the computer program, coded information from transmittal sheets was punched into cards and verified. Cards were sorted into investigator-patient sequence and a list was printed to serve as a basic reference source where all of the information coded for a specific patient could be found. Before the detailed tabular reports could be run, however, preliminary processing was required to prepare a complete patient deck, since only the first card coded for a patient contained basic information (age, weight, sex, primary disease). As shown in Fig. 5, the first card for each patient was sorted out and matched with cards containing multiple items for that patient. Such multiple cards contained only new data and the investigator-patient identification without the basic patient codes. In several reproducing steps the basic information from the first card was punched into those cards containing multiples (disease, dosage), thus completing the deck. Cards were sorted into report sequence and a report was run.

MACHINE-GENERATED REPORTS AND FINAL TABULATIONS

Reports produced by both the computer and the electromechanical systems provided relatively complete summaries of drug activity. The types of reports generated by these systems during a typical drug evaluation are listed below in six information categories.

Reports Prepared For Drug Evalution.

1. Disease

- a. Disease in Alphabetical Sequence—Correlated with dose, frequency, duration and clinical response
- Disease Listed by System—Correlated with dose frequency, duration and clinical response
- Primary Disease Listed by System—Correlated with first dosage, frequency, duration and clinical response (for a patient count)
- d. Primary Disease—Listed by age and sex, correlated with clinical response
- e. Coexistent Disease—Correlated with primary disease treated, clinical response and side effects

2. Dosage

- First Dosage, Disease—Correlated with frequency, duration, clinical response
- Maintenance Dosage—Correlated with frequency, disease, duration, clinical response
- c. Total Daily Dosage—Correlated with duration, clinical
- d. Total Daily Dosage—Correlated with age, duration, clinical response

3. Side Effects

- a. Side Effects—Listed in investigator-patient sequence
- b. Side Effects-Listed in alphabetical sequence
- Side Effects—Listed in alphabetical sequence and correlated with total daily dosage
- d. Side Effects—Listed by system correlated with total daily dosage
- e. Side Effects—Correlated with disease treated
- f. Side Effects-Correlated with age and sex

4. Other Therapy Administered

- a. Other Therapy—Type of drug correlated with results before, during and after test drug administration; comparison with test drug
- b. Type of Other Therapy—Correlated with disease treated and clinical response

5. Laboratory Tests

 Type of Test—Correlated with results before, during and after therapy

6. Microörganisms Cultured

- a. Microörganisms Cultured—Correlated with disease treated and clinical response
- b. Microorganisms Cultured—Correlated with results of culture before, during and after therapy

These reports are used in most drug evaluations. However, some may be omitted or varied depending on the characteristics of the drug on trial. An example of a typical disease report is shown in Fig. 6, which illustrates correlation of cases of anxiety with total daily dosage, clinical response, and side effects. Totals which are printed across the page are taken for each clinical response, each change in dosage, each disease, and each side effect.

The table superimposed on the report shows how information has been selected and arranged in final form. Tables of this type are used for distribution since machine reports, which contain coded information, are frequently bulky and difficult to handle, and thus are not suitable for dissemination.

Future plans, which include the use of the 1401 computer, should serve to accelerate searching even further. More sophisticated and readily intelligible tables will be produced by utilizing the newly acquired 1401 computer, which will reduce the serious time lag between machine-produced reports and finished tables for distribution.

DISCUSSION

Clinical data processing has many applications which transcend those already described in this presentation. The programs described were originally based on the need for rapid processing and analysis of clinical material to expedite evaluation of experimental drugs by the medical research staff. The ramifications of this objective have been very broad and vitally important to the medical profession.

Advantages of Coded Data.—After receiving the final reports, medical research management determines whether the drug studied warrants introduction to the market. If the decision is affirmative, a new phase begins for the medical information group. When a drug begins to be widely used, questions are likely to arise among physicians who administer it. Previously unreported side effects may be observed or new therapeutic uses indicated. Such findings create new questions which are reported back to the Company and in turn relayed to the medical information staff. Specific searches through the processed data either secure the answers or indicate the need for further clinical investigation. Some relatively uncomplicated questions can be answered almost immediately, without resorting to machine searching, through visual checking of the mechanically produced reports which serve

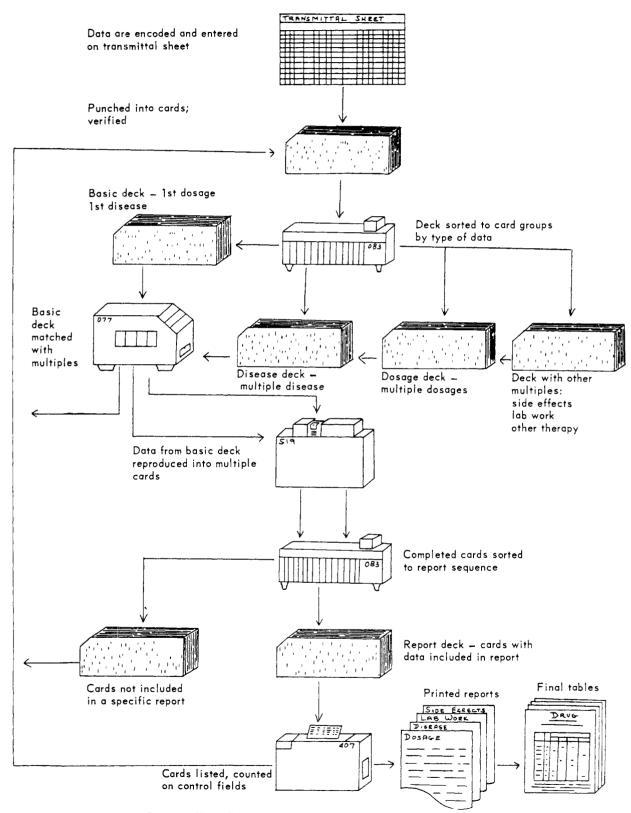


Fig. 5.—Clinical data processing flow chart electromechanical system

as indexes. More difficult questions can be answered within hours by searching the file contained in punched cards or magnetic tape. Highly complex relationships may require more time.

Post-marketing searches usually fall into three major categories, as shown below. Typical questions are listed in each category.

- Specific correlations of information on patients treated with the drug:
 - a. Correlate clinical response to antibiotic therapy with drug-resistant microörganisms cultured.
 - Correlate time of appearance of side effects with daily dosage and with duration of administration.
- 2. Listing and counting:
 - a. Count patients receiving a drug for ophthalmic use in the treatment of bacterial infection—list by type of preparation.

- b. Count patients for whom liver function studies were performed during treatment—list those with values deviating from "normals."
- 3. Location of documents:
 - a. Children with behavior disorders receiving the drug.
 - b. Patients receiving a drug at high dosage for long periods.

Some Roadblocks.—Although both of these systems are now operational and reliable, they were not always so. There were many obstacles and revelations along the way. A brief analysis of some of the problems may be valuable to others interested in developing their own systems. For instance, the computer program at first seemed to lend itself to the concept of one inclusive master report from which all statistical tabulations and correlations could be drawn. However, in practice it was found that usually only three types of relationships could be analyzed in a

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Fig. 6.—Disease listed by system correlated with total daily dosage, duration and clinical response

report. Interpretation was clouded by the addition of more correlations. Now several reports are produced to highlight fundamental associations of data, such as disease-response or dose-side effects correlations.

Another, and not completely solved problem, involved the handling of multiple items for a patient. One patient may have received four dosage regimens for two unassociated diseases, one of which may not have responded satisfactorily. He may also have experienced different side effects at different dosage levels. Processing such multiple items by mechanized reproducing techniques has proved cumbersome in the electromechanical system. To eliminate much of the gang-punching operation, a revision is now underway to place greater emphasis on keypunching.

It would have been most desirable to obtain all calculations through the computer program. However, because of limitations in storage and varying sequences of data, calculations (averages, percentages) were performed manually. Also, the urgency of the project did not permit analysis of the exact groupings and correlations required in the final reports. As a result these calculations were performed manually as a final step in tabulating.

Decoding machine-produced reports in order to provide meaningful tables was also time consuming and arduous at first. Mechanical decoding with the use of "header" or title punched cards has helped to ease this burden. In designing a code system, therefore, consideration should be given to providing alphabetical information, mnemonic codes, and specific data wherever possible.

SUMMARY

Processing of clinical information at Lederle Laboratories has been advanced by the development of two systems—computer and electromechanical—which permit more rapid and comprehensive analysis of clinical reports on patients receiving new drugs.

Each system offers decided advantages over manual methods previously used. Although differing in certain details and techniques, the major objectives are the same:

- Process clinical information rapidly and comprehensively.
- Provide management with analyses of clinical trials for final evaluation of new drugs.
- Provide the medical profession with immediate answers to specific questions on Lederle drugs.

Both systems provide means to these goals.

The computer system demonstrated its effectiveness in analyzing large trials containing many complex variables. On magnetic tape any portion of the clinical reports can be combined or compared with any other data in the tape record. Many intricate correlations are possible. Required processing is accomplished at high speeds. Storage problems are eased. Once a clinical report becomes part of a tape record, it remains undisturbed, regardless of how many times it is processed, providing a source which is always available for additional searching in its original form. A card file, on the other hand, frequently must be re-sorted to its original sequence.

The electromechanical system, which utilizes simpler machines, also has advantages. Small or relatively uncomplicated studies of many drugs can be successfully processed on less expensive equipment. This system, although somewhat awkward for complicated correlations, requires less technical knowledge and less advanced scheduling, both of which are restrictions imposed by high-speed computers.

The systems which have been described represent an evolution toward an ideal model. Future developments in processing clinical data at Lederle will provide for routine transmission of information on all clinically tested agents into a standardized information system based on high speed computers. Medical research will establish standards and specifications to achieve automatic evaluation of drug safety and efficacy and a central storehouse of data in punched cards and magnetic tapes to provide periodical analyses of clinical trial results.

These programs with continuing refinements will serve to accelerate the flow of information on new drugs, from basic research and clinical testing to the endpoint—the practicing physician.

MS CURRICULUM IN INFORMATION SCIENCE

A new information science curriculum leading to the degree of master of science (information science) will be inaugurated in the Spring term (April 1) at the Graduate School of Library Science at Drexel Institute of Technology in Philadelphia. The curriculum is the first of its kind in the nation.

For many years, Drexel's library school, the third oldest and one of the largest in the country, has educated large numbers of special librarians. Now, the school has enlarged its service to the industrial community and will be educating not only librarians but other professional staff members for science information centers.

The curriculum and faculty are provided jointly with the Colleges of Engineering and Business Administration and department of English. Subject areas of concentration include instrumentation and computers, science bibliography, publication, management, and science. Research will be an important part of the student's work and a thesis will be required. Students will be given work experience in information centers. Their course work will be taken in the evenings at the air-conditioned Drexel Library Center and in other buildings on the Drexel campus.

To be eligible for admission, a student should have an undergraduate bachelor's degree, a science or technology major, and a B academic average. Admission information and a list of courses can be procured from Mrs. Beatrice Davis, director of students, Graduate School of Library Science, Drexel Institute of Technology, Philadelphia 4, Pa