

Laboratory verification of patient identity

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In considering the installation of a computer-based laboratory report system, what are the legal and professional responsibilities created by such systems? Computer-generated reports and records are acceptable, legally, in place of the original handwritten laboratory request form, but there is nevertheless an increased legal duty, as well as a strong professional responsibility, to see to it that the computer record is correct in every detail. By adoption of proper verification procedures, similar in principle to quality control procedures now regarded as essential in every laboratory, a computer-based record system can be made much more accurate and reliable and far more accessible than the usual manual methods of record-keeping. And this can be done without substantially increasing the burden of laboratory work.

Preliminary studies of laboratory requests coming into our laboratory before installation of a computerized report system showed that over 20 percent of the requests carried patient identification data unacceptable by objective standards of verifiability: this means that patient information was incomplete, so that it could not be verified, or wrong, so that verification would lead to the wrong patient. And in a manual system, there appeared to be no practical way to improve the data. In studying other laboratories we found no reason to believe that our experience was unusual.

Our manual system involved returning the *original request* to the referring physician or other source, with the laboratory report transcribed on to it. This placed the identity of laboratory data in the hands of ward clerks and others outside the control of the laboratory; and for a significant fraction of the laboratory work, left the laboratory without any valid record of the work done on the patient for whom it was done. This was clearly an unsatisfactory state of affairs, although one which was hidden until we began our preliminary analyses for the computer system.

The problem of errors in data input was, in fact, by far the most serious one encountered in the development of our computer report system, and one which was essentially out of control until the completion of the work described in this paper. Beyond a few references to slang expressions (GIGO) this is a topic that is discussed very little in the published literature. A recent well-documented monograph,¹ for example, contains no reference to this topic in index, bibliography, or text. Yet our experience has been that every source of raw data, and every transcription step in the data processing operation, carries an error rate of one to two percent. Furthermore, unless these errors are sought for and corrected, they are additive. Since there may be ten or more identifiable steps involved in ordering a laboratory test on a specific patient, errors accumulate until finally as many as 20 percent of the requests received in the laboratory are unacceptable in some particular of patient or specimen identification. That has in fact been our experience over the last four years, and there has been no significant downward trend in the 20 percent figures during this time.

Part of the reason for this has been the policy, which we adopted at the beginning of our data processing development, of not attempting to make any change in the procedures of data processing used outside the laboratory. Although the problem can, and perhaps should, be considered in its entirety as embracing the whole hospital, to do so immediately involves admissions policy, patient accounting practices, the medical record room, in fact almost every aspect of hospital operation. Faced with that much, we decided it would be better to solve some small definable segment of the problem, and the boundaries of the laboratory seemed a convenient place to draw the line.

In our system, consequently, the hospital staff are still free to make occasional errors in preparing a re-

quest for laboratory service; we have accepted for ourselves the responsibility for finding and correcting all errors before sending out our reports.

The principal object in our error-correcting system is to make sure that laboratory results get back to the correct patient, and to keep one patient from getting another's results. To perform and report an extra or unordered test—this cannot do very much harm; at most it may result in an extra charge on the patient's bill. To miss doing a test which was ordered—this is a situation which very quickly corrects itself by way of an indignant phone call from the physician who ordered the test. But to report results to the wrong patient—this is the ultimate disaster. Such a mistake could be, quite literally, fatal. It could cause a wrong diagnosis to be made or a wrong treatment to be given. Even if the physician receiving the report recognizes that the results reported do not apply to his patient, he will inevitably place all his reports in the suspect category, and will lose all confidence in the computer report system. And of course, there is the question of legal liability for negligent errors.

Our system, therefore, is designed to assure us of 100 percent correctness in the patient identification, and to provide us with an exact record of every input, a separate record of every wrong input, and every step taken to correct the input. The system requirement is satisfied only if there is verification of every input in two independent traces from the original source of the data. This includes both data from outside the laboratory, specifically patient identification, and data generated inside the laboratory, specifically the laboratory result.

Even within the laboratory itself, where the data processing procedures are under our direct supervision, there seems to be no possibility of eliminating errors completely: no degree of motivation or discipline that can be applied will suffice. Outside the laboratory, where conditions are completely beyond our control, not even an attempt can be made. This is a fact of life which justifies the policy decision referred to above. Our objective, then, is to catch the errors and to correct them before the reports leave the laboratory.

Before developing the details of our system it is useful to introduce three terms which may well have been applied by others earlier in this field; they have certainly clarified our thinking and our system.

Audit trail is a printed record, with necessary annotations, of every record entered into the computer, any errors which were found, and the actions taken to correct them. The tendency, all too human, to bury the error once it has been corrected must be strongly resisted. The audit trail is an essential part of the

system; it has both prospective and retrospective functions. It is a necessary record for every input, as from this record alone can one identify later-discovered errors and can know how and where to correct them. It identifies problem areas in the input procedure in the same way that a quality control chart gives warning of procedural error in the laboratory. With the audit trail, any error which does get through the check system, but is later brought to the attention of our staff, can be identified as to occurrence and responsibility. The identification of the source of the error has proved essential in developing psychological defenses within our staff against repetition of the error at a later time. The varieties of error are infinite.

Checking and validation: To distinguish between these processes, which are essentially different, is to provide a logical basis for the design of an error-proof input system. *Checking* is an entirely mechanical process, although it may be very complex. It can be carried out by computer, only providing that a set of logical decision rules can be given. *Validation* is a human process, involving human judgment, which changes as each new experience is assimilated. Checking is always catching up to validation, as the judgment is analyzed and formulated into logical rules, which can be programmed into the computer. Validation is always ahead of checking, as judgment is always being increased by experience.

Checking should be done only by the computer. To give this task to a human is wasteful and inefficient and in the end impossible, because, when boredom and fatigue set in, the rate of human error increases faster than the check errors caught. The computer can perform with unrelenting accuracy any checks of any complexity, once the decision tables are specified with logical precision.

The computer can never replace professional judgment.

A necessary condition of the validation process is that the information to be validated must be *meaningful*. That is to say, the data must not only have meaning in themselves, but they must be presented to the mind in a form which conveys meaning to the validator. It follows that a mere list of numbers cannot be validated (Figure 1); the validation in this case consists of noting that two numbers do not match. Did you, as a careful reader, pick up this point?

One final feature which we believe contributes substantially to the efficiency and completeness of our system: each step is conceptually separate and distinct from the others. This is a principle taught by experience in programming a computer. In practice, it means that we demand of computer or of operator only one type

of checking or validation at a time. It enables us to see, not only that a given step depends on the successful completion of a precedent step, but, more importantly, that in many places, the system allows of parallel paths through to the final error-corrected report.

In summary, our system is built upon the following rules:

1. The computer is always right.
2. The input is wrong until confirmed by checking or validation.
3. Checking is done by computer.
4. Validation must be meaningful.
5. Two independent sources are required for checking or validation.
6. One thing at a time.

With a basis thus established, we are now ready for the development of a system for controlling input errors. In accordance with standard literary conventions of scientific publication,² we shall omit any description of the initial fumbblings, outright mistakes, false trails, and utter disasters which we encountered during the first three years of this project. Starting from scratch, our system has now been in full successful operation for nearly a year. We shall describe it as an orderly logical progression of ideas and events. Like most successful systems, it looks very easy now. Had we known just how to do it, it would have taken us three months instead of three years.

In describing our input validation system, the following outline will be useful:

1. Enter census information
- * 2. Verify census file
3. Enter test requests
4. Print work documents for laboratory
- * 5. Verify
6. Key punch lab results
- * 7. Verify test runs
8. Print patient reports
- * 9. Validate reports.

As this outline shows, most of the steps in our overall procedure can be carried out in parallel. While we insist that every entry of data into the system be independently verified, we also recognize that most of the information is correct as it goes in. Therefore, we go ahead and use the input in our laboratory system before

ACCESSION NUMBER	CENSUS NUMBER	REQUEST NUMBER
801	312486	312486
802	236925	236925
803	318470	381470
804	334862	334862

Figure 1—Validity check of patient identification numbers

it has been verified or corrected, but always under conditions which do not permit the release of unverified or uncorrected data, and which do permit the exact and secure correction of any errors before they can possibly damage the system.

The system starts with the control of patient identification information, which includes name, hospital unit record number, date of admission, hospital location, age and genetic data, physician, and hospital service assigned. The nominal source of this information is the patient himself, but in accordance with our principle of independent verification, we require two independent traces back to the original source. Fortunately, the hospital operating system does provide two: one from admission desk through hospital accounting office to patient census, and one from admission desk through the patient's chart and his charge plate.* From the first of these we receive a punched-card deck on Monday containing a complete record on each patient in the house, and update decks each day containing patient admissions, transfers, and discharges. From the second we receive an imprinted laboratory request slip.

Although the data entry starts with the patient at the admission desk, the error entry may begin long before, when a patient number, properly belonging to one patient, is improperly assigned to another. Under an old system, formerly used in this hospital, this particular error was to be corrected if, and as soon as, it was discovered. A new commercial accounting system** recently installed by the hospital has the astonishing feature of *forbidding* any correction of this error. Our experience to date has been too short to demonstrate what effect this rule will have on our system, but it is evident that it will make some of the medical records actively misleading for retrospective studies.

* Our hospital uses a charge plate imprinter system with embossed plastic plates like credit cards, but *without* machine-readable features.

** SHAS, supplied by International Business Machines Corp.

ACCESSION NUMBER	CENSUS NAME	REQUEST NAME
801	TARBELL SUSA	TARBELL SUSAN A.
802	GRICE GEORGE	GRICE G. D.
803	QUIGLEY RALP	JAFFE CHARLES
804		EATON ANDREW

Figure 2—Validity check of patient names

In any case, we accept the census and update decks as input data requiring correction. Our experience has been that one to two percent of the records in each new deck are in error. This is substantially lower than the error rate which would be expected on the basis of the number of steps intervening between the data source and the final record, indicating that substantial efforts at error correction are being made all along the line. Nevertheless, we make a final purge.

We maintain, in our computer, a file of patient identification comprising the current house list plus records of all patients who were in the house at any time in the last two weeks.† This file contains about 2000 names. Our first operation is to combine the current file with the new deck, sort it, and delete all duplicate records from the internal computer file. The cards containing the duplicate records are also ejected from the card file by the computer. An audit trail is generated by printing all the records deleted. This is, of course, a checking operation, not a validating one, and requires only a minute or two of computing and printing time each day.

The duplicate list printed usually contains less than twenty names. These are subjected to a validation by the computer staff. This process may include anything from correction of an obvious misspelling of a patient name to a direct inspection of the original admitting record, according to the judgment of the operator. Most discrepancies are cleared up by a telephone call. The corrected records are re-entered and the process is repeated. Usually the first repetition confirms the accuracy of the corrected census.

It is important to keep in mind just what the accuracy of the corrected census comprises. We have, in effect, a census file in which we are certain that each patient has been assigned a unique hospital unit record number. Each patient record has been compared with every other record, both current and recent past admissions. Every discrepancy has been removed, except one. The exception is the patient who has the same unit record number as some other patient who had been admitted at some more distant past time. This

exception makes the record doubtful, to that extent, for retrospective studies. It could be removed by enlarging our file storage to cover all past admissions, but this does not seem worthwhile. Even with this exception, we are sure that no laboratory results can be sent to the wrong patient under the control of a wrong patient number.

The next major operation in our system is to enter the laboratory test requests into the computer. The laboratory receives requests in the form of the usual 3-part request form, on which the patient identification is imprinted from the charge plate and the tests selected are indicated by handwritten marks. The request is assigned an accession number, and 6-digit patient number, the particular tests required, and the accession number are transcribed by key-punching on a punch-card* which is used to enter the request into the computer. Note that this is the minimal information which must be entered: the accession number, the patient identification number, and the test requested. If every one of these passes the tests which are now to be applied, the request is accepted without further entry; if any one fails, corrections must be made and additional information must be supplied.

As the test requests are entered into the computer, an audit list is printed, showing the accession number and the patient number. At the same time, the patient number is checked against the census file, and if the patient number is found in the file the corresponding name is printed also; if the patient number is not found, no name is printed (Fig. 2). Usually two to ten percent of the entries are missing a name. These are filled in, often by calling the source of the specimen, so that each entry in the entire entry list has an associated name. The list is then validated by direct comparison of the list, name-by-name, with the names on the request slips. This process is not as burdensome or as time-consuming as it sounds, because the validation is comparing two lists of meaningful names (most names convey some sense of familiarity to a literate person, and even the unusual name is meaningful *ipso facto*) and the two lists are in the same order. The validation is highly significant, since the computer-generated name list comes from the census file, while the name on the request slip comes from the patient's hospital chart or charge plate, or—in a fair proportion of the cases—as a handwritten entry on the request slip. Judgment is required to decide when the two apparently similar names are to be accepted as identical.

Note that this process does not require any operator checking or verifying of the six-digit patient number,

† We would like to go back further, but our file space is limited and the indicated interval covers a sufficiently high fraction of our needs.

* The mechanics of this transcription will be described in a separate report.

since the validation could fail to turn up an error only in the unlucky coincidence that (1) an incorrect patient number exactly matched a patient number in the census file, and (2) the name in the file, in turn, was identical with the name of the actual patient. Since the patient number is six digits, the chance of the first is on the order of one in a million, and considering the statistical distribution of names, the chance of the second must be one in a thousand: the combined chance of one in a billion is acceptable. At least, this mischance has not shown up yet.

At this point we can be certain that within the above probability, each test request is correctly and unambiguously matched with some individual patient in the hospital, and that the three-digit accession number or the six-digit patient identification number, either one, will unambiguously lead us to the correct inpatient.

As the requests accumulate in the day's run, and interspersed with the above-described verifying activities, we also print, by computer, a series of test checklists of accession numbers arranged by the laboratory work-station which is to handle them. Also, laboratory personnel have been carrying forward preliminary processing on the specimens received. The test checklist is compared, by laboratory personnel, with the specimens being processed, and any discrepancies are reported to the computer staff for correction as necessary. This is the first of several verifications made of the tests ordered on each request. The source document for this information is the test request itself, supplemented by telephone calls from the patient areas, adding to, altering, or cancelling the list of tests requested. Because very little machine checking is possible, and a great deal of human checking and

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033 1376703 RAV6 GOLDNER EUG      563 24 02 W M
    376703 RAV6 GOLDNER EUG
034 1376704 RAV6 DUBROW SOL       622 58 05 W M
    376704 RAV6 DUBROW SOL
038 2336838 WD N MOLDEN MARGA     028 36 28 N F
    336838 WD N MOLDEN MARG
041 1317132 MAL4 RAYNOR JOHN      799 61 01 W M
    317132 MAL4 RAYNOR JOHN
043 1366042 GIBS DEEGAN EDWIN     725 53 03 W M
    366042 GIBS DEEGAN EDWI
052 1329766 NEUR THOMAS JESSI     028 51 20 N F
    329766 NEUR THOMAS JESS
**** CENSUS ENTRY HAS THE SAME NUMBER BUT NOT THE SAME NAME ****
055 1346710 MAL4 FREIDMAN LEO     434 55 01 W M
    346710 MAL4 FRIEDMAN LE
057 1178790 WHI7 LEHR ETHEL

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Figure 3—Audit trail: duplicate census entries

12/03/70 ACC	PATIENT NAME	NUMBER	CLASS
316		376799	1
317	FELDMAN EVA	365248	1
318	URBAN MITCH	376713	1
319	POMANO PASCA	000000	4
320	FREEMAN SOP	374916	1
321	MARTIN PERCU	000000	4
322	CALAB ALLEN	000000	4
323	SYLVIA BEARM	000000	4
324	VANKOUWENBER	376664	1
325	WOODARD MIN	115048	2
326	BASCH SADIE	113689	1
327	HENRY RALPH	000000	4
328	KROUSE LEONA	000000	4
329	TARASON EVA	000000	3

Schoffnit, Gladys # 376711
Called Mr. Smith, admissions.
Two history numbers in the house are the same.
Changed Schoffnit number to 376711

DATE 12/3 TIME 12:00 SIGNATURE *Earg*

Figure 4—Audit trail: verification of patient identity

human verification is required, more human effort, perhaps, is expended in keeping this list correct than in getting the patient identification correct. We regard this as principally a public relations effort, since an extra test or a missing test on a patient's specimen cannot have very serious consequences. Nevertheless, we do what we can.

All the while, preparations are being made for printing the daily worksheets for the laboratory personnel, one of the two main tasks of our computer system. These worksheets carry complete information about every patient specimen—name, number, hospital location, hospital service assigned, doctor code, age, sex, and genetic information. We expect the laboratory personnel who are professionally trained at all levels from staff physician to technician, to notice this information, to take a personal interest in the people for whom they are helping to provide medical care, and to notify the computer staff of any technical or data processing discrepancies they may pick up. It is largely due to their alert interest that the last one-tenth percent of errors is corrected which make the difference between success and failure.

Among the subsidiary but useful records which the system generates in this period, which occupies the first two or three hours of the working day, are the master accession list, arranged in numerical accession order, and the alphabetic list of patients. Both of these carry the complete lists of tests entered for each patient. The alphabetic list is highly useful in answering telephone inquiries from the house staff who want to know if they "forgot to order" and like excuses. The provision of this service by the computer has undoubtedly reduced the number of "stat" requests received during the day.

Enough has been said already to illustrate our general approach to input, so that only a brief summary of our input verification of results is necessary. Here we

have two distinct problems: (a) the correct transcription of the results from laboratory to computer and (b) the medical significance of the results as reported.

(a) As to the first, we have had no direct personal experience yet with direct on-line acquisition of data from the laboratory analyzers. Our observation of such systems installed in other laboratories leads us to believe that on-line direct data acquisition will raise just as many problems as it solves. In our system, the laboratory technician key-punches her own results direct from her original record. The key-punched cards are checked by another technician or operator. After the key-punched results are entered, the computer prints a reconstruction of the laboratory record, which is used for a second check against the original record. This reconstruction not only affords a second check on the numerical results reported, but especially calls attention to (1) extra results reported which were apparently not called for on the original test requests, and (2) results missing on tests which were originally entered into the computer.

(b) Still more important, however, and one of the principal benefits to be sought from a computer-based report system, is a professional evaluation of the medical validity of the laboratory results reported. In the days before the overwhelming expansion of volume in the laboratory work, every result reported from our laboratory was personally examined by the chief of the laboratory. This protected the laboratory from many embarrassing mistakes and made the results, even with the crude and unspecific tests of those days, more significant medically in many cases than the excessive number of tests which are indiscriminately reported today. It is now humanly impossible for the chief, or even any reasonable number of assistants, to examine attentively and with judgment all the results which are reported on hospital patients today. We need some sifting procedure to separate the laboratory results which are obviously reasonable, or for which no informed judgment is possible, from those which require and would benefit from the attention of an experienced clinical pathologist. No one, for example, can make anything out of a single blood sugar determination on a patient for whom no previous laboratory work has been reported. There is no value in taking up the time and attention of the professional staff on such a report. If, however, the computer is programmed to bring together all the patient's results and to print out, for human attention, the blood sugar which is dubious when compared to other values for that patient, much valuable time could be saved for more productive use. We are just beginning to see the benefits of this approach; it does not properly belong in a discussion of input error checking.

The cost. The elaborate scheme proposed above for human and machine verification of computer data may seem all out of proportion to the benefits it produces. We do not deem it so, even though we cannot estimate either the cost of one negligent error in a laboratory or the added cost of preventing it. But more than this, the verification procedure actually costs us very little. We have run our computerized report system for several years with 98 percent accuracy and some—occasionally extreme—dissatisfaction on the part of the final users of it, i.e., the medical staff. We now run at better than 99.9 percent accuracy in patient identification with no increase in costs. The explanation is that in any clinical laboratory system there are periods of great activity and periods of comparative quiet; the human effort required by the above system of verification can easily fit into the quiet periods. The procedures usually need not be carried out a predetermined time, either in relation to the clock or in relation to the system procedures, so long as they are completed before the first external report is generated. The verification procedures are each one simple in themselves, and they use printed lists and batches of source documents which are in simple orderly relationship to each other, so that there is not a lot of frantic back-and-forth searching involved. Each error that is detected can be pinpointed as to source, occurrence, and effect, and the fear of unknown and unknowable responsibilities has been dissipated. The staff has confidence in the system. It is this fact alone which makes our system a practicable one.

In recent months, following circulation of this paper in preliminary form, the level of input accuracy has risen appreciably. *Post hoc ergo propter hoc.* We have noticed that when the input is 100 percent accurate, our verification system reduces to nothing more than reading each laboratory request slip twice: once when it is transcribed for keypunching and again with the validation list produced by computer. This does not seem unduly burdensome. In pharmacy practice, each prescription is read three times—once when picking up the stock bottle, second when counting out the pills, and third when returning the stock bottle to the shelf. We should do no less than twice in laboratory processing.

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