Pure & Appl.Chem., Vol.54, No.11, pp.2059-2062, 1982.
Printed in Great Britain.

0033-4545/82/112059-04$03.00/0
Pergamon Press Ltd.

COMPUTERS IN THE MODERN CLINICAL LABORATORY: INTERFACING AND SAMPLE IDENTIFICATION

HERBERT KELLER

Institut für Klinische Chemie und Haematologie,
Kantonsspital CH-9000 St. Gallen

Abstract - The problem of interfacing can be solved in the modern clinical laboratory thanks to the newly developed microprocessors. Most of the modern analyzers are equipped with microprocessors. Under their control the signals of different sensors are processed. They also control the analytic processes and give error messages if certain limits are exceeded. For on-line connections it is no longer necessary to construct special interface devices for each instrument. The hardware switching algebra is being replaced by software logic. Recently, personal computers have also come into use as interfaces. They may be programmed to fit the special needs of any specific application. In this way the efficiency of the central lab computers increases significantly. The new intelligent interfaces overcome all bottle necks with respect to hard- and software. The logic consequence is the decentralisation of the computer intelligence. In contrast to the progress in the field of interfacing there are no new aspects in the field of sample identification. The currently used techniques have been known for ten years. The majority of labs working with direct sample identification are using barcode-systems. The newly developed machines for sample distribution are not designed for direct, user-readable sample identification. The sequence of samples produced by the machines is the only means of identification. The disadvantages of this philosophy are discussed. Finally the point is made that an individual sample may be recognized by a pattern of test-results thanks to the biochemical individuality. Although this procedure is not promising for routine application it may be useful for exploration of individual cases.

The first computers were implemented in clinical laboratories of the US, Great Britain and Scandinavia in the early sixties (1,2,3). In spite of good experiencies of the pioneers most laboratories hesitated introducing this new kind of tool for laboratory work. In 1973, 10 years ago, Auerbach (4) stated in a report that only 11 % of the hospital laboratories and 6 % of the independent laboratories, responding to their survey, used computers. They were mostly used for clerical tasks and statistical purposes. Only a minority of laboratories (less then 1 % of all responding the questionnaire) indicated that they had test equipment connected direct to the computer, although more than 90 % used automated equipment in clinical chemistry, hematology, and other fields. The data were collected manually and reduced by hand, then they were entered into the computer manually via key-board-terminals or punch-card-readers. Evidently, there existed an enormous void between the practical application and the available technology: the computer served only as a big cardindex with connected typewriter.

However, according to Seligson (4), a computer should fulfil two basic functions:

"- the first is to act as extension of every analytical instrument in the laboratory

- the second is to place the analytical results into files, which can later be put into reports or retrieved for other purposes.

While it all sounds so simple today, it in fact must be difficult because so few, if any, have done this whole job well".

This statement of Seligson was emphasized by Homer Warner (5) in 1979: "... the limiting factor in the growth of computer systems for use in clinical medicine is neither hardware nor software. It is "medical ware", the representation of medical knowledge in the form of explicit decision algorithms that can be executed by the machine...

Evidently the basic problem is: the insufficient and inadequate link between man and machine and the difficult contact between the analyzer and the electronic data processor: In other words, interfacing was the main problem. Today the situation is changed. Most big laboratories in the US and in Western-Europe today use computers, and on-line connections are realized to multichannel analyzers as well as to smaller instruments.

Evidently the problem of interfacing has been generally solved by applying the newly developed microprocessors in clinical chemical instrumentation (6,7,8).

This new kind of electronic device, basing on the "very large integration technology" has been introduced in our laboratories nearly unnoticed. All modern analyzers (e.g. Cobas-Bio, Centrifichem 400, ACP-Eppendorf) are equipped with microprocessors. Under their control, the signals of different sensors (multipliers, thermistors, electrodes, etc.) can be processed inside the instrument; they also control the analytic process and give error messages when certain limits of temperature, concentration etc. are exceeded. The results can be printed out or represented on a display. They can also be stored in a memory and can be recalled from a central processor.

For on-line connection it is no longer necessary to construct a special interface-device for each instrument. This task was very protracted and expensive, because of the multitude of different instruments with different specifications. Today the hardware switching-algebra is replaced by software logics.

This trend is accelerated thanks to the availability of low-price personal computers in our laboratories (9).

Personal computers are ubiquitous in our daily lives. It is expected that in this year the sales of these computers will surpass sales of analytical instrumentation (15×10^8 to 13×10^8 US $). Cheeper units with improved performance are appearing and systems with colour graphics have been available for some time. Because of the low prices it was natural to use personal computers as interfaces. Some laboratories took advantage of these possibilities and modified these to their purpose. In the meantime personal computers as parts of industrial systems for laboratories are on the market.

This new kind of interface can be programmed to fit any special needs of specific applications. Until a few years ago only three or four multichannel analyzers could be connected on-line to the usual laboratory computer, because of its limited capacity. Not rarely did the voluminous and complex data-flow overcharge the system. At the same time a break-down of the CPU had disastrous consequences for the analytical operations of the laboratory.

The intelligent interfaces effortlessly overcome all the bottle-necks with respect to hard- and software. The logical consequence is the decentralisation of the computer intelligence. The demands for the efficiency of the CPU can be lowered, especially concerning the velocity of processing. The safety of the system increases significantly. A break-down of the CPU does not cause a loss of data, becuase of the stand-alone-nature of the interfaces. Their stored data can be separately recalled from their memories. In this way the user has sufficient time reserve for repairs of the CPU.

If, on the other hand, an interface breaks down, then it can be immediately replaced by another one. In modern systems one can quite freely exchange all the available interfaces, and (after reprogramming them e.g. by magnetic tape), the system will work well.

In contrast to the progress of data recording and processing there are no new aspects in the field of sample identification (10). The currently used techniques of identification have been known for ten years. This is true for the intellectual aspects as well as for the technology. The majority of the labo-

ratories working with machine-readible systems use barcode systems. These devices nevertheless have important disadvantages:

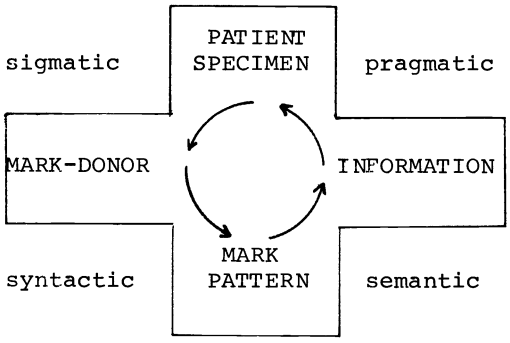
- the prices are relatively high
- the labels are too large for microliter tubes
- the code cannot be read directly by the user

A certain progress was reached in the production of the barcode labels: Many modern printers are able to print labels in barcode. Meanwhile some barcode scanners with a Ruby-laser for reading without contact are on the market. Barcode systems have been fitted into large analyzers e.g. "Prisma" (Clinicon) and "Parallel" (American Monitor).

The direct marking of specimen containers and process-tubes as developed by Siemens and Eppendorf has been unsuccessful.

Summarizing we can state that the stand of the art of sample identification is the same as ten years ago.

Semiotic relationship for any identification system is characterized as follows:



First there is a relationship between the patient and the one, who assigns the "symbol" of identification (e.g. on I-number or other). This relationship is a "sigmatic" one, which means that it implies a connection between a certain symbol and what is denoted by this symbol. Generally a certain "code" is used i.e. an instruction of translation. The translation is a selection of signs from other signs and has to be "syntactically" correct. The pattern of marks yields an information to whom it may concern; that is the "semantic" relation. At last the information must be useful with respect to the patient, this means, it must contribute to the intended goal of the whole identification process, adapted to the needs of the patient. This is called the "pragmatic" aspect of the identification systems.

Sample identification plays an important role on six phases of the laboratory work:

- accession of specimens
- distribution of specimens
- work benches or analyzers, respectively
- collection of different test results
- production of the laboratory report, including
- controls of quality and plausibility.

Special problems of identification arise on the level of distribution. In the last three years new machines for sample distribution have been developed. They are all computer controlled, some by personal computers. All these systems are stand-alone-devices, which may be connected to a central processor, but not necessarily depencing on the CPU. None of these machines are designed for direct, user readable sample identification. The sequence of the samples, produced by the distribution machine is the only means of identification. The future will show how safe this way of identification is.

In any case, all the following phases of the analytical process must be performed with the same correctness as the distribution on the rotors, sample plates, sample chains etc. The given sequence has to be strictly adhered to and the resulting data must be transferred in the same order, unchanged and unmultilated. Because there is no control possible after the distribution, the "tunnel-effect" thus increases extremely (11).

During the last years it has been pointed out (12) that with all methods of identification it is not the material of the patient that is identified with respect to its source but the sample container and/or a sequence of containers. The source of the material and the corresponding analytical results can only be related by a reconstruction process. Thus the weakest link in the identification chain is revealed: the unequivocal identification of the patient and the reliable initial transfer of the patient identification to the specimen-container. None of the suggestions for the improvement of the reliability of this decisive step e.g. an identification carrier, permanently associated with each patient, has found wider application (see 9). Whenever the taking or collection of samples is not performed by laboratory personal, all further efforts to ensure correct identification are fraught, from the outset, with an incalculable factor of uncertainity.

Nevertheless the safe identification does not solely depend on labels, marking-machines or decoders: because of the biochemical individuality of each person it is, in principal, possible to recognize a specimen by a biochemical test-pattern as by a fingerprint. This has been first demonstrated by Young et.al. (13). These authors have recently demonstrated that the identity is reflected by multivariate data of biochemical test profiles. The profiles of individual samples were graphically displayed as computer drawn faces. The authors conclude their experience as follows: "... discriminant functions can be used to detect mislabelled specimens ... potentially in the clinical laboratory or ... misidentified samples from patients ...".

Obviously this will not be a way for routine use, but for the exploration of a single case it may be useful.

Another way of identifying a set of data are the so-called delta-check methods. The longitudinal collection of data may be checked for plausibility. Mislabeled results will be detected if they differ greatly from those recorded earlier. The method however is not very effective as Sheiner et.al. (14) have shown. A delta-check method controlled by a computer discovered only 50% of the mislabeled specimens. On the other hand only 10% of the data suspected of being mislabeled were in fact wrongly identified. Maybe this rate could markedly be improved by additionally given clinical data for the delta check.

The interrelationships between individuality and sickness, signs and identifications seem to be well worth reflecting on further.

REFERENCES

1. A.E. Rappoport, W.D. Gennaro and W.J. Constandse, Hosp.Progr., 50, 114-124 (1969)
2. T.P. Whitehead, H.E. Bock and M. Eggstein, Hrsg, Diagnostik-Informations-system, Springer, Berlin (1970), p.: 192-197
3. W. Schneider, H.E. Bock and M. Eggstein, Hrsg., Diagnostik-Informations-system, Springer, Berlin (1970), p.: 189-191
4. D. Seligson, D. Enlander, Ed., Computers in Laboratory Medicine, Academic Press, New York (1975), p.: 166-182
5. H.R. Warner, Computer-assisted Medical Decision-Making, Academic Press, New York (1979)
6. B. Mollerus and R. Hügel, GIT-Labor-Med. 1, 309-310 (1981)
7. K. Spiegel and H.J. Engelhardt, GIT-Labor-Med. 4, 105-112 (1981)
8. R. Heidrich, R.D. Schmid and G. Weidemann, GIT-Labor-Med. 4, 453-458 (1981)
9. R.W. Arendt, J.Autom.Chem. 3, 167 (1981)
10. H. Keller, J.Autom.Chem. 3, 196-198 (1981)
11. H. Keller and R. Richterich, Exc.Med., Amsterdam, Internat.Congr.Series Nr. 285, 183-189 (1972)
12. H. Keller, J.Clin.Chem.Clin.Biochem. 17, 57-64 (1979)
13. A.E. Robertson, A.C.van Steirteghem, J.E. Byrkit and D.S. Young, Clin.Chem.26, 30-36(1980)
14. L.B. Sheiner, L.A. Wheeler and J.K. Moore, Clin.Chem. 25, 2034-2037 (1979)