WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTÉ

LAB/WP/80.27

ORIGINAL: ENGLISH

INTERNATIONAL CONFERENCE ON CLINICAL LABORATORIES: PRACTICE, MANAGEMENT AND USE

Brussels, Belgium, 25-28 November 1980

Agenda item IV.E

GOOD LABORATORY PRACTICE: RESEARCH

by

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Research in the field of clinical laboratory practice has tended to concentrate on the development of new or improved laboratory methods and systems, and has neglected the precise study of how, and how much, the great volume of laboratory work actually contributes to patient care. I shall discuss a few areas where research might provide guidance towards better utilization of the laboratory services. It has to be admitted that much of the research must inevitably suffer from the limitation that it is exceedingly difficult to measure the effect that we really wish to study, namely the actual benefit to patients of the application of results from clinical laboratory tests.

Interpretation and use of laboratory reports by clinicians

There have been a few studies of the ways in which clinicians react to the reports they receive from laboratories. We need to know how best such reports are to be set out if they are to convey the meaning intended by the laboratory staff and provide the information the clinician needs or thinks he needs. A study by Ackerman et al. (1979) illustrated ways in which microbiological reports could be misinterpreted, although the style of report that the authors preferred involved in my opinion far too many words. There is, clearly, need for research into the style of reporting, particularly when computerized methods are to be used, as well as some agreement among laboratory workers on nomenclature, abbreviations, units of measurement, and so forth, and into the methods most appropriate for educating clinicians in the interpretation of reports. Skendzel (1978) reported an interesting study in which he asked clinicians to indicate the minimum change in a laboratory value - blood sugar, antibiotic assay, etc. - that would be regarded as significant. The great variation in opinion indicated the need for guidance on the inherent variability of tests, as well as on "normal" values, and their intelligible presentation.

It is well recognized that laboratory results, even when understood, do not always lead to appropriate action by recipients. Spencely and colleagues (1979) found that this was particularly common when the test was done in the first place as part of a "unit policy to screen". Too much should not be made of this because decisions on patient management quite properly rely on a number of considerations, of which a laboratory report may be only one, but there is need for research to identify the tests that make the least useful contribution to patient care, in the hope that their numbers could be reduced.

Indications for requesting laboratory tests

The substantial growth in requests for laboratory tests, which has been seen everywhere and which involves both an increase in the variety of tests and in the number of individual requests, must of course be largely due to the increase in the extent to which such tests can elucidate

diagnosis and guide treatment. There is however a widespread belief that the growth has been "excessive", meaning that more tests are requested than can be justified by the clinical use made of the results. With some national health-care systems, excessive demands for laboratory tests may be in part attributable to the financial gain they bring to the clinicians or laboratory or both, a problem that is compounded if there are opportunities for excessive charging of the already excessive number of requests. In other circumstances, the fear of litigation may generate an overly defensive approach to protect the clinician against any possible accusation of inadequate investigation. But concern for an allegedly "excessive" growth in demand is common also in countries such as the United Kingdom, where neither personal financial gain, nor passionate litigation, is a dominant factor.

A brave attempt to identify the grounds on which microbiological tests were requested of laboratories in five general hospitals was reported by Spencely and colleagues (1979). Some 35% of tests were routine examinations made as a result of the clinical unit's policy, and altogether 20% of the tests were considered to have made no contribution at all to diagnosis, treatment or general management. Unfortunately, as the authors point out, it may not be possible to judge just which 20% will be superfluous at the time of requesting the test.

Routine "screening" is responsible for a greater number of tests in clinical chemistry and probably in haematology than in microbiology, thanks largely to the availability of multi-channel analysers that perform several tests as easily as one. There is clearly scope for a variety of research approaches aiming to define more precisely the appropriate indications for many laboratory tests, in the hope that such definitions can be used to educate students and clinicians into more rational use of the laboratory.

Unnecessary duplication of requests, prompted either by shift systems of working, impatience, confusion, or a desire to be doubly sure, is a potent cause of excess workload and would be worth study to test the effect of different reporting methods, especially the despatch of preliminary reports, if necessary, by telephone. The relevance of various computer reporting systems would also be of interest.

Perhaps advantage could also be taken of the various organizational systems that operate in different countries to determine how much, in fact, different systems affect the demand for laboratory tests. There has been at least one attempt to use economic pressures to limit laboratory requests by allocating a budget to a clinical unit costing its various activities and allowing the clinicians to switch resources from laboratory tests to other activities. This led, temporarily at least, to a reduction in the demand for laboratory tests, as did the necessity of consultant justification of "on call" requests during a period of industrial action. There may be scope for future research along similar lines. Several attempts have been made to control numbers by allocating a monthly "ration" of requests to each clinical unit but, although there are anecdotal accounts of both success and failure of such systems, little of general value seems to have been published.

New and old tests

A significant contribution to the increase in laboratory work stems from the introduction of new tests which could, but often do not, replace tests already in use, some of very doubtful value. Holland and Whitehead (1974) reviewed the need for research into the efficiency, effectiveness and economics of new tests at an early stage in their development. There is however often resistance from clinicians to the abandonment of long-established tests, even if new tests are demonstrably better. Conn (1978) pointed out that part of the education of each clinician is the generation of his own data base, acquired from experience, reading and discussion, and the discarding of obsolete tests requires a modification of this data base. There is clearly scope for research into methods of presentation of laboratory results that minimize this difficulty.

Rapid methods have been the subject of considerable study, especially in microbiology, where traditional tests often take 24-48 hours or more for completion. Many of these new rapid methods provide good reliable tests but they are commonly labour intensive, and research is needed to discover the right place for the use of rapid methods as a contribution to better

patient care: how often does the fact that the result is available sooner actually mean that the management decisions are made earlier? This will surely depend not only on the test concerned and the management consequences but critically on the time of day, in relation to all other activities, at which the result is available. Results will need to be of outstanding importance to have any rapid influence on management if they arrive after the working day is over.

In addition to increasing numbers of tests, there has often been the opportunity of increasing the precision of the individual tests, or increasing the detail of the tests; in microbiology this often involves a finer and finer distinction of microbial species, subspecies, types and subtypes, or expressing sensitivity tests in MIC's instead of Sensitive/Resistant, in biochemistry a more precise or more reproducible quantitative result. There is a real need for guidance on the appropriate indications for the varying degrees of precision and this ought to be based on some operational research. Lindberg and Watson (1974) reported some theoretical analyses of the effect of increasing precision of diagnostic tests, which indicated that the benefit, in terms of decreased missed diagnosis, was critically dependent on the relative frequency in the population studied of subjects with the diagnostic criterion sought. Increase in precision of the test might or might not provide better diagnosis. Lindberg and Watson's model was grossly oversimplified but the principle is highly relevant and too little studied.

Rationalization of laboratory services

The introduction of automated and mechanical methods for chemical and haematological analyses, coupled with a belief that laboratories with a large workload are more cost-effective than those with a small load, have led to the closure of many small laboratories and the concentration of the work in fewer large centres. In England there was a 43% decline in the number of "small" laboratories between 1966 and 1974, and an increase of 44% in the number of large laboratories (Buttolph, 1977). A few research studies of actual or proposed rationalization schemes have been published. Nussbaum and others (1977) claimed that the introduction of computers and of a partially centralized organization for biochemistry and haematology in two hospitals in Seattle was responsible for an observed decrease in the real cost of tests, a decrease not observed in microbiology which was excluded from the scheme. Other schemes claimed to decrease costs have been reported by Brain et al. (1976), Katz et al. (1973) and Goldberg and Mitchell (1970).

The real cost of a laboratory test is very difficult to determine if everything is to be included, from collection of specimen to return, interpretation and clinical application of the results, so the cost-saving attributable to centralization cannot be asserted with any great confidence. Moreover, there are penalties arising from the separation of the pathologist from some or all of the clinicians to whom he should relate. This must lead to less efficient utilization of the laboratory results and might well result in an actual increase in the numbers of tests requested. The overall effect of rationalization of laboratory services is thus a further area demanding operational research.

The pattern of professional staffing of clinical laboratories varies greatly in different countries, and within one country in laboratories of different size, type of funding and so forth. These patterns are determined by history, availability of individuals with appropriate qualifications, and local prejudices. It would be of great interest if appropriate research methods could be developed to study the influence of different patterns of professional staffing on the running costs of the laboratory, the relative use made of the laboratory by clinicians, and, if possible, its overall effectiveness in contributing to patient care.

Operational research

Virtually all the research studies referred to in the preceding paragraphs can be regarded as aspects of operational research. A major problem in all research on the functioning of clinical laboratories is the difficulty of measuring the output of the laboratory in clinically relevant terms. Much effort has been put into methods for measuring workload on the basis of technician - and machine - time in carrying out the tests, but good clinical laboratory practice

demands interpretation as well as estimation. The overall effectiveness of the laboratory in providing support to clinicians also requires prior judgement on the selection of tests and active development of methods for ensuring utilization of results. There is a real need for further research into methods by which all aspects of laboratory activity can be measured, so that different clinical laboratory systems could be properly evaluated.

REFERENCES

Ackerman, V. P., Pritchard, R. C., Groot Obbink, D. J., Bradbury, R. and Lee, A. Consumer survey on microbiology reports.
Lancet, 1979, 1, 199-202.

Brain, M. C., Haggar, R. A., Moore, S. and Cameron, R. W.
The Hamilton district program in laboratory medicine: a progress report on integration.
Canad. med. Ass. J., 1976, 114, 721-6.

Buttolph, M. A. National Health Service Laboratories in England, 1966-74.
J. clin. Path., 1977, 30, 1103-9.

Conn, R. B. Clinical laboratories. Profit center, production industry or patient-care resource?
New Engl. J. Med., 1978, 298, 422-7.

Goldberg, I. J. L. and Mitchell, F. L. Clinical biochemistry in the hospital laboratory services.
Lancet, 1970, 2, 1240-3.

Holland, W. W. and Whitehead, T. P.
Value of new laboratory tests in diagnosis and treatment.
Lancet, 1974, 2, 391-4.

Katz, S. H., Diamond, B., Prier, J. E., Lukaszczyk, T. A. and Kegerreis, J. B.
Regionalization of laboratory services.
Health Lab. Sci., 1973, 10, 287-293.

Lindberg, D. A. B. and Watson, R. Imprecision of laboratory determinations and diagnostic accuracy: theoretical considerations.
Methods of information in medicine, 1974, 13, 151-8.

Nussbaum, B., Minckler, T., Roby, R. and Ackerman, E.
Economic impact of a computer-based centralized organization in a clinical laboratory.
Amer. J. clin. Path., 1977, 67, 149-158.

Skendzel, L. P. How physicians use laboratory tests.
J. Amer. med. Ass., 1978, 239, 1077-80.

Spencely, M., Parker, M. J., Dewar, R. A. D. and Miller, D. L.
The clinical value of microbiological laboratory investigations.
Journal of Infection, 1979, 1, 23-36.

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