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Elements of Good Practice in Decentralized Clinical Laboratories

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ABSTRACT

The possibilities of producing decentralized clinical laboratory data 'nearer the patient' has augmented rapidly during the last decennium due to both simple and sophisticated equipment, often intended to be operated by nonlaboratorians. The theory and practice of quality assurance in its wider sense has not kept pace with this development. The components of Good Laboratory Practice are presented under the headings: type of laboratory work, discipline, management, personnel, premises, safety, equipment, reagents, standard operating procedures, internal quality control, external quality assessment, method, dedicated operating procedure, syllabi, and clinical relevance. The projects currently being established by different national, regional, and international bodies to formulate guidelines should be co-ordinated to avoid duplication and conflict.

INTRODUCTION

During the last decade the combination of chemistry, physics, electronics, and microprocessors has resulted in a vast array of analytical systems ranging from simple dip-sticks to multi-purpose apparatus claiming virtually trouble-free production of paraclinical data by nonlaboratory personnel. Thus, the possibility of providing timely results at the hospital bedside or in the physician's office or in the patient's home has materialized and is being promoted heavily by the manufacturers. While data can easily be produced, their quality and relevance are often less well documented and the nonlaboratorian has difficulties in devising an adequate quality assurance scheme.

As the results of the decentralized analyses are often decisive for the fate of patients, it is high time that the clinical laboratory professions in collaboration with clinicians and manufacturers provide the framework of adequate quality assurance. Currently, several projects are being formulated, notably by the European Committee for Clinical Laboratory Standards (ECCLS), its US sister organization

NCCLS, as well as Canadian and Nordic groups. It is, therefore, relevant to discuss a strategy for such an exercise.

GOOD LABORATORY PRACTICE

The concept of Good Laboratory Practice (GLP) as applied to nonclinical laboratory studies for the testing of chemicals in animal experiments (2, 6) defines the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported. Obviously, analogous guidelines may be formulated for the clinical laboratories - partly from existing texts - with the aim to obtain measurement results sufficiently accurate and precise for the clinical end-purpose and with documentation thereof.

SUBJECTS

The decentralized clinical laboratories comprise a wide spectrum from the highly sophisticated satellite laboratory of a clinical laboratory department via the independent laboratory in a clinical department or group practice, the side-room of a ward, the office of a general practitioner, the bedside in a hospital or patient's home to self-monitoring by the patient anywhere. The later sites, although not proper laboratories, are not the least important and not the easiest to help.

All the different clinical laboratory disciplines - clinical chemistry, haematology, immunology, microbiology, parasitology, cytology, and pathological anatomy - are involved to a varying degree depending on the type of decentralized service. Although the research into systematic quality assurance is quite advanced for the areas heading the list, it is mostly concerned with large series rather than with the occasional analysis.

If decentralized analytical testing - also called SPOT (for Satellite & Physicians Office Testing) - is to be made sufficiently reliable, it seems necessary to formulate a set of guidelines covering various aspects of the work and allowing adaptation to the different types of enterprise.

Management responsibilities should be defined as regards the availability of facilities, equipment, and materials; qualified personnel; provision of standard operating procedures; compliance of personnel with GLP; continuing education and training of personnel.

Personnel responsibilities comprise adherence to instructions and procedures; safe, careful, and adequate working practice; reporting of deviations.

Even if the manager and analyst is one and the same person, he must fulfill the combined requirements mentioned above.

The premises and operational units should have a suitable size, construction,

and location with benches, installations, storage facilities, cleaning routine, suitable waste disposal, and archives.

The safety of personnel relies on written general instructions, safety equipment, specific instructions in individual manuals as well as education and training. In practice this area is too often neglected.

Equipment should have suitable specifications and requirements, a manual in a suitable language, and a location with adequate physical environment; an operating record should be kept.

Reagents of adequate purity; written procedures for production, use, control, and storage; labelling and safety markings; disposal; records of purchase, production, and discard.

Standard operating procedures, approved by management, should use a suitable format (e.g. 4) and nomenclature. The descriptions cover reference materials and reagents; equipment; cleaning facilities; request format and information; patient reception and preparation; specimen collection, labelling, handling, precautions, storage, discard, and transport; analytical procedures; quality assurance; analytical data processing, comments, storage, and retrieval; report format, information, interpretation, and filing; health and safety; contract specifications.

Internal quality control, sometimes erroneously thought of as just a statistical exercise, is founded on the qualifications, education, and training of the personnel; selection of equipment and reagents; standard operating procedures. It requires initial experience with each procedure; calibration; control procedures comprising reagent control, blanks, recovery, replicates, repeaters, and reference material as well as statistical analyses. The latter may be organized locally, professionally, commercially or by governmental authorities. Evidently, it will be difficult to devise a simple, robust, and adequate, yet affordable system for the small size operational unit - but it is imperative to try and to assess its effectiveness.

External quality assessment may be achieved by interlaboratory calibration and testing of different types of reference materials and patient specimens. It may be aided by consultants and governed by regulations and on-site inspection. Sometimes enforcement and sanctions are applied. The organization may be professional, commercial or governmental, and all these types have been established in various countries.

The above subjects lend themselves to guidelines of a general nature. Another and supplementary approach is to formulate detailed GLP according to method, that is principle of measurement, for example gravimetry, volumetry, microscopy, and spectrometry. Many authoritative publications exist in each field, but they may need simplification for the less experienced user.

Finally, each 'analysis' requires a detailed, dedicated operating procedure presenting a selected combination of equipment and analytical protocol.

A comprehensive effort should include syllabi for courses in such subjects as establishing a decentralized analytical service, selecting a method, evaluating a procedure, quality assurance, data management, and safety regulations.

Naturally, the production of superfluous data is not GLP. As an indispensable adjunct, therefore, to the above technical subjects, laboratory management should collaborate with the clinicians to ensure that each particular analytical procedure is capable of providing timely and clinically relevant data at an acceptable price and without undue strain to the patient.

CONCLUSION

The literature on clinical laboratories, their management and procedures is vast. It will be a major task, however, to produce guidelines suitable for the small outfit, even if specialized treatises are beginning to appear (1, 3, 5). The production of useful texts will require a coordinated and collaborative effort by the different groups mentioned in the introduction.

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