ASSESSMENT OF QUALITY CONTROL PROGRAM IN CLINICAL CHEMISTRY LABORATORY

Thesis
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By

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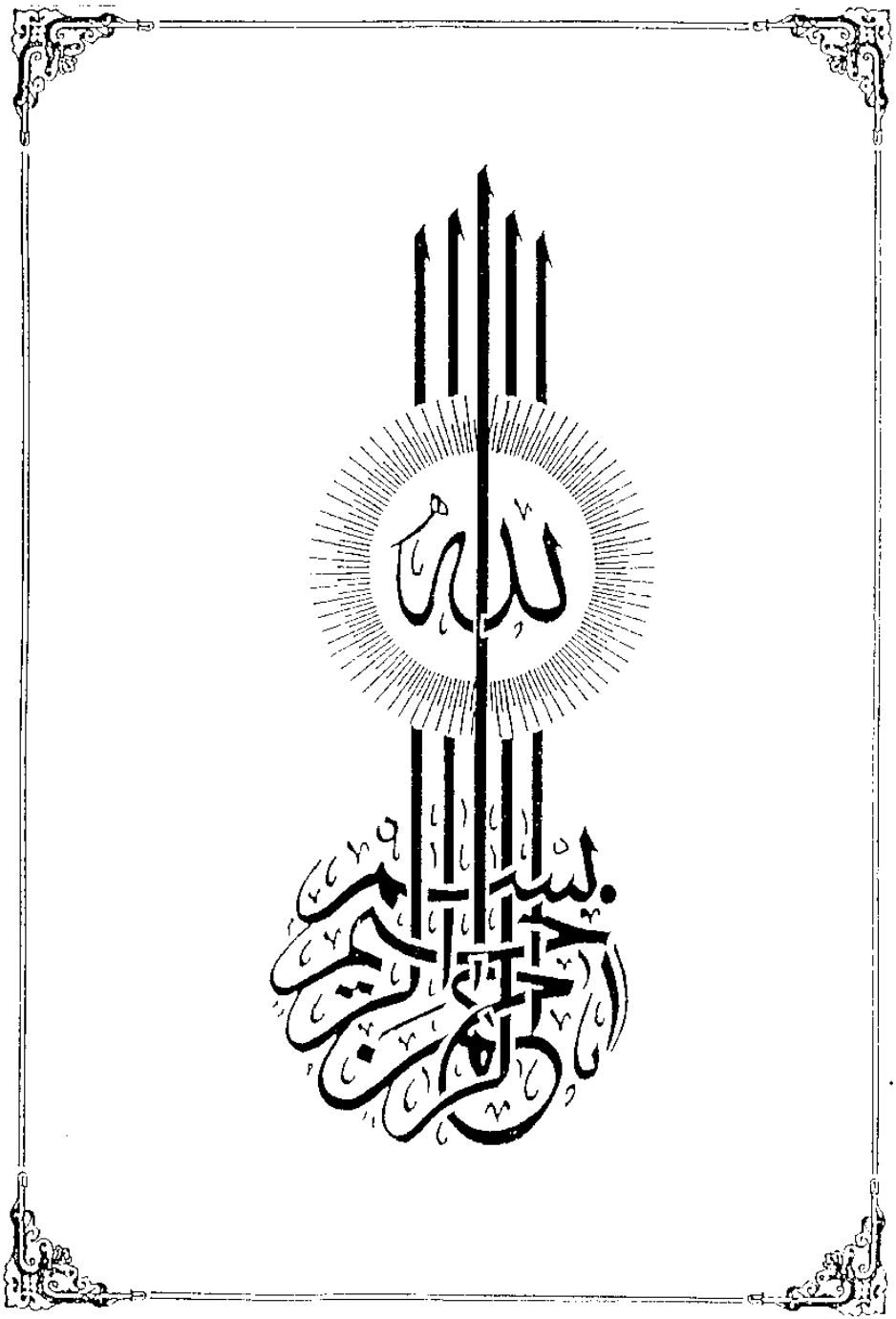

TO
MY WIFE, GINA &
DAUGHTERS DINA & SARAH

General Introduction
And
Aim Of Work

I. GENERAL INTRODUCTION AND AIM OF THE WORK

The laboratory has a responsibility to the patient and physician to supply accurate results. For that aim, laboratory quality assurance program should be designed. Quality assurance is a coordinate process of providing the best possible service to the patient and physician. It includes monitoring and controlling the competence of personnel, quality control materials, methods, reagents, and instruments and the reliable reporting of test results. Some aspects of quality assurance such as quality control and instrument maintenance are highly visible while others are not obvious. A laboratory that neglects some aspects of quality assurance can be compared to a wagon wheel with missing spokes. Both will roll along, doing an adequate job, when the going on is smooth, but when the going becomes rough and difficult, a breakdown will occur. A breakdown in the quality of the laboratory performance will result in wasted effort and resources, and mistakes that threaten the health and treatment of the patient whom the laboratory serves (Stewart, and Koepke, 1987).

Quality assurance is not a single activity nor is it the responsibility of a single individual but must be practiced by every one within the laboratory. It

brings together the various activities in the laboratory that are designed to detect, control and hopefully prevent the occurrence of errors. A good quality assurance program has three major aspects: preventive activities, assessment procedures and corrective actions. Preventive activities are taken to prevent errors and to improve accuracy and precision. Assessment procedures are taken to monitor the analytical process to determine the type and amount of error and the change in accuracy and precision in the process. Corrective actions are taken to correct errors after discovery (Hainline, 1982).

In clinical laboratory "Quality Assurance" is often confused with "Quality Control". Quality control involves the use of control samples to monitor the precision and accuracy of a test procedure. The control sample is processed along with patient samples and the result is interpreted as either acceptable or unacceptable by comparison to expected values. Statistical rules or control charts and graphs are applied to determine the amount and type of error in the procedure. Quality control is an important part of the quality assurance program.

The aim of this work is:

1) To review the different components of quality assurance program.
2) To study the different quality control techniques.
3) To choose the most suitable technique or techniques for our hospital.

Review Of Literature

II. REVIEW OF LITERATURE

All laboratory testing can be divided into three phases: pre-analytical, analytical and post-analytical. By far, the analytical phase is given the best attention, with a lot of money and effort being spent on prodigious instrumentation designed to produce results quickly and cost effectively. The post- analytical phase also has received a great deal of attention recently, as laboratory computers are assuming more and more of the burden of reporting results in a rapid and accurate fashion (Landenson, 1975).

A) Pre-analytical variables:-

The pre-analytical phase of laboratory testing is the interval between the clinicians orders of a laboratory test until the specimen is prepared for analysis. Monitoring the pre-analytical phase requires the coordination of many individuals and hospital departments, who must recognize the importance of their efforts in performing and maintaining a high quality service. The pre-analytical phase includes patient preparation, sample collection and handling the specimen for testing (Fody, 1987).

1. Patient preparation:

Laboratory tests are affected by many factors related to patient preparation. Therefore, proper patient preparation is essential for the test result to be meaningful. The laboratory must define the instructions and procedures for patient preparation and sample acquisition (Westgard and Klee, 1987). The most pronounced factors that may affect patient results are age, sex and race of patient, previous diet, diurnal variation, posture, physical activity, caffeine intake, tobacco smoking and drug intake.

a- Age, sex and race:

Age, sex and race are important information that should be written on the request form. There are many analytes that show great differences in the normal range as regards age, sex and race. Interpretation of these results is quite difficult if such information is not known. For example, creatine kinase enzyme (CK) activity is about three times the adult values in normal newborn babies. There is also sex and race difference in CK activity, it is higher in males and in black people (Lang and Wurzburg, 1982). Alkaline phosphatase enzyme (ALP) is another example which shows

much greater activities in children and adolescents than in adults. The reference ranges for inorganic phosphate vary greatly with age. It is highest in infants up to six months decreasing till puberty with no sex difference. It reaches its lowest levels after puberty with levels slightly higher in females (Keating et al., 1969).

b- Meals:

The concentration of certain plasma constituents is affected by ingestion of meals (Caraway, 1962). These changes are dependent upon the type and quantity of food ingested as well as the timing of the venipuncture in relation to meals. The largest increase in serum concentrations or activities occurs for glucose and triglycerides and in ALP in certain individuals. A fatty meal will cause great increase in triglycerides while a carbohydrate-rich meal will increase serum glucose. The increase in ALP is mainly in the intestinal isoenzyme activity and is more pronounced in patients who are Lewis- positive secretors and have blood group O or B (Statland et al., 1973). After a fatty meal, triglycerides may rise more than tenfolds, and will need 12 hours to return to base line values. A carbohydrate load elevates blood glucose

rapidly, with levels returning to base line in about three hours (Statland and Winkel, 1977).

The effect of meals may be long lasting. Ingestion of protein rich meal may increase blood urea nitrogen which lasts for 48 hours. Cholesterol levels generally reflect long term dietary trends and are little affected by recent meals. However, this is not true for all patients (Fody, 1987). When oral glucose tolerance test is requested, a patient should have a regular balanced diet for at least three days before the test (Klimt et al., 1969). In estimating quantitative fecal fat, Bin et al. in 1983, recommended that the patient should be on a diet containing 100-150 grams of fat per day for three days prior to the test.

c- Prolonged fasting:

On the other hand, prolonged fasting (more than 24 hours) may lead to unexpected laboratory results. In such a condition, decrease in levels of C3, albumin, prealbumin, and transferrin have been documented (Bloomer et al., 1971, and Olusi et al., 1975). Prolonged fasting has been also associated with elevations in serum bilirubin concentration, that may reach 240% of the basal level, after 48 hours of fasting (Barrett, 1971). Stout et al. in 1976, monitored

the concentrations of plasma lipids in nine healthy volunteers who underwent a 72 hours total fasting with dramatic increase in the concentrations of plasma triglycerides, glycerol, and free fatty acids without a significant change in the concentration of serum cholesterol.

d- Exercise:

Physical activity has a number of effects on blood analytes. Mild exercise causes an increase in blood glucose, which is often followed by increase in cortisol and insulin (Fody, 1983). It also increases creatinine clearance and causes lymphocytosis (Kachadorian and Johnson, 1971). Severe physical activity can also affect laboratory results. Most dramatic changes occur in enzymes specially those associated with muscle, as CK, lactate dehydrogenase (LD) and aspartate aminotransferase (AST). King and Statland in 1976, studied the time course of enzyme elevation following an hour of moderate exercise. CK was more than double its base line values, peaking approximately 11 hours later. Lesser increases were noted for AST, LD and ALP. It is to be noted that well trained athletes have less exercise-induced enzyme elevations than untrained ones.