

ETHICAL VALUES IN MEDICAL DIAGNOSTICS

A CASE STUDY OF NORTH DELHI PATHOLOGY CLINIC

Mukul Singh

MEDICINE is not only science but a learned noble profession as well, deeply rooted in a number of sciences and charged with the obligation to apply them for the benefit of human society. The very presence of this serving profession is to benefit others. The responsibility of medicine are three fold:

- (1) to generate scientific knowledge and to disseminate it to others,
- (2) to use the knowledge for betterment of the community at large, and
- (3) to judge the moral and ethical propriety of each activity connected with health care and medical up-keep (Smith 1982).

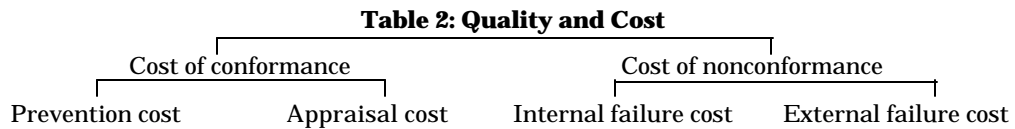
The application of profession to the service of the mankind necessitates the live functioning of professional body which plans, organizes, directs, controls, co-ordinates and monitors the professional conduct of its practicing members such as Medical Council of India (MCI) in case of medical profession, and Bar Council of India in case of legal profession. To judge a medical activity morally requires a diverse form of skills, social responsibility and emotional churning, as practice of medicine is an art which is far more than application of scientific principles to a particular biologic aberrations. It requires a guarded scientific calculation, keeping at the back of mind all the stress, anxiety, and tension which can alter the state of disease and the course of treatment. A medical Professional does not provide sword against the disease but treats a person as a whole. Medical Profession should not be equated with business as it is based on specialized knowledge requiring a very careful and delicate application. It lies in a grey zone between profession and business where even a slightest skewness may cost human life and lead to professional dissatisfaction.

Medical diagnosis is a developing process. The new advancement in medical technology have added new dimensions in diagnostic procedures which beside having high index of accuracy has also raised the cost of medical service. There is often a debate as to what is the reasonable fee for diagnosis to be charged from the patient who wants to undergo reliable and dependable diagnostic report before undergoing treatment and to monitor the progress of the treatment. To some, it appears that the diagnostic charges are too high, others feel that the charges are reasonable keeping in view the quality of service. In this background it is pertinent to highlight the factors which go into the determination of diagnostic fee as explained in the Table 1.

Table1: Financial Factors affecting balance between medical diagnostics and ethics

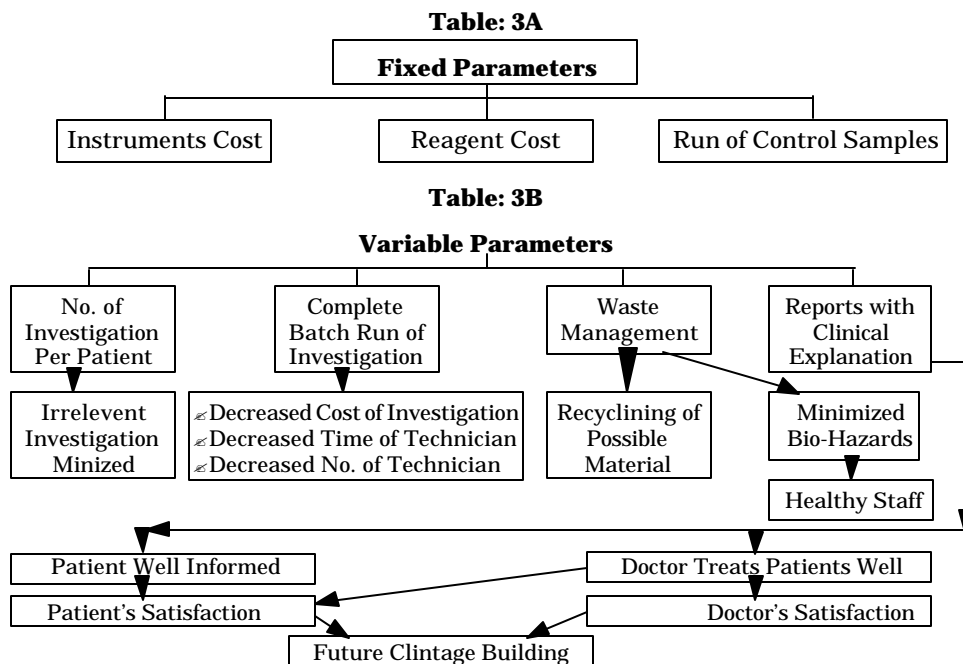
Financial Components of Diagnostics	Ethical Dimensions of Diagnostics
Instruments cost	Patients satisfaction
Technical & non-technical staff salary	Treating clinician satisfaction
Recurring cost	Public accountability
Practitioners decent standard of living cost	Treatment of biohazardous material
Reasonable surplus for future expansions & modernization	Notification of communicable diseases

The role of clinical laboratory scientist has turned more challenging to maintain the balance between quality and cost. Quality is defined as conformance to requirements of patient and treating clinician. Its cost must be understood in terms of cost of conformance and cost of non-conformance as shown in Table 2.



Source: Westgard , J.O Barry 1986.

The cost of conformance can be divided into prevention cost and appraisal cost. Cost added because of calibration is to prevent automated errors. Similarly quality control appraises the performances. Cost of non-conformance consists of internal and external failure costs like repeat run and repeat test required due to low analytical quality. A model has been developed to maintain a balance between ethical practice and high quality diagnostic report. It is shown in Table 3 (A and B).



Among them, the fixed parameters should not be compromised under any circumstances. The instruments and the reagent used should be of the best International Standard. As high technology machines run as closed system where human factor have minimal role and control when once a batch of investigation starts. At very low and high values the linearity of the test has to be tested which in most of the cases gives a freak value. Hence a calibration is must to admire a freak reading and to decide a cut off point where dilution of the sample is needed to achieve accuracy. From time to time a sample with known value(standard) should be investigated to reconfirm the accuracy of the reagent and samples. Such quality control appraises the performance. Thus cost of conformance is the essential expenditure which cannot be compromised, while cost of non-conformance should be avoided.

The Variable parameters in quality policy if intelligently followed reduces the cost of investigation due to wasting of resources. e.g. if the Technician process one particular test of all the patients at a time it reduces the cost of investigation as the control has to be processed only once. Thus the time of Technician and the number of Technicians involved in the activity is minimised. Thus at a optimum cost, quality results are produced.

A survey was conducted to analyse the financial constraints and ethical dimensions in medical diagnostics at one of the leading laboratories of India i.e., North Delhi Pathology Clinic (NDPC), which is a reference laboratory of Indian Association of Pathologists and Microbiologists (IAPM) and also ISO 9002 certified. It was found that the diagnostic quality standards observed by the leading ones are favorably comparable to the ones operating in USA and other Western countries, but the fee charged in India are far less than what is prevailing in the foreign countries, e.g., the charges for blood sugar test at NDPC is Rs 50 which is less than one third of what is being charged in USA for the same test. A similar difference exists in other investigations also. Even in India competition has led to lab wise variation in the charges. The use of hi-tech instruments and running of proper control samples raises the cost of the investigations. It was found that to compensate it, some diagnostic centers non ethically use sub-standard instruments, reagents and do not run all the required controls and some times not even the requested investigation is carried out. It has been observed that people prefer to pay a higher amount of fee for quality diagnostic investigation as they feel that it amounts to wasting money if the report is not correct. To quote Benjamin Ruskin - "*It is better to pay too much for something important than too little. If you pay too much you only loose some money, if you pay too little, you still loose money and the things you bought does not serve the purpose which you bought it for.*" (Anand 1998)

It was found during the period of study at NDPC, that the quality of investigation is not compromised at all under any circumstances and that is probably one of the important factor that attracts people from different parts of India even though the fees being charged by NDPC is not on the lower end. Now the question arises as to how quality diagnostic investigation can be ensured uniformly. To fulfil this purpose, innovative techniques are being used. attention should be given right from the stage one - Laboratory request form. It was found that a properly designed form helps the clinician to select the clinical problem directly and minimizes the chances of irrelevant investigation to be ordered and some important ones to be missed. This reduces the burden on the laboratory and minimizes the waste of time, money, and human power.

Similar patterns had been used by Wong and colleagues for Thyroid testing. A sample of such format as followed at NDPC is shown in Table 4.

Table 4: Suggested Disease Oriented Profiles

- ✗ **Amenorrhoea-Primary:** Prolactin, LH, FSH, Estradiol
- ✗ **Amenorrhoea-Secondary:** FreeT3, FreeT4, TSH, Testosterone
- ✗ **Anemia Panel:** Hemogram, Reticulocyte Ct, Comments on Peripheral Blood Smear, CRP, Iron, TIBC, Ferritin, TSH & Hemoglobin Electrophoresis
- ✗ **Arthritis/Joint Pains:** ESR, Uric Acid, Blood Glucose, RA Factor Further- CRP, ANA, Anti dsDNA
- ✗ **Cancer Markers: CA 125:** Ovarian & Endometrial Carcinoma **CA 19-9:** Pancreatic & Colorectal Carcinoma **CA15-3:** Breast Carcinoma **PSA:** Prostate Cancer **hCG:** Embryonal, Choriocarcinoma, Testicular Tumors **AFP:** Hepatocellular & Germ Cell Carcinoma **CEA:** Colorectal, Gastrointestinal, Lung & Breast Carcinoma
- ✗ **Cardiac-Injury:** Troponin T, CPK, CPK-MB, SGOT & LDH First 24 hours-Troponin T, CPK, CPK-MB One to Four days-SGOT, CPK, CPK-MB, Troponin T, LDH Four days or more-LDH, Troponin T
- ✗ **DIC:** CBC with comments, Platelets, Prothrombin Time, APTT, FDP.
- ✗ **Diabetes Evaluation:** Once every fortnight -F, PP Glucose (Post Breakfast & Lunch) Once every three months- HBA1C Once a year-Fasting/ PP Glucose, Urea, Uric Acid, Creatinine, Lipid Profile, HBA1c, Microalbuminuria & Urine Routine
- ✗ **Hemogram:** Hb%, TRBCCt, HCT, MCV, MCHC, RDW, TLC, DLC, Platelet Ct, ESR
- ✗ **Hemolysis:** CBC, Reticulocyte count, Coomb's Test, Bilirubin, Plasma & Urinary Hemoglobin, LDH
- ✗ **Hirsutism:** DHEA-S, 17-OHP, LH, FSH & Testosterone
- ✗ **Hypertension Evaluation:** Hemogram, Urea, Creatinine, Uric Acid, Sodium, Potassium, Lipid Profile, Glucose Fasting/PP, Urine Routine Further- Urinary VMA, TSH & Free T4
- ✗ **Infertility-Female:** Prolactin, LH, FSH, Progesterone & Estradiol
- ✗ **Infertility-Males:** Prolactin, LH, FSH, Testosterone & Estradiol, Routine Semen Examination
- ✗ **Lipid Profile:** Cholesterol, Triglyceride, HDL, LDL, VLDL Cholesterol & Ratios
- ✗ **Lipid Profile-Extended:** Cholesterol, Triglyceride, HDL, LDL, VLDL Cholesterol & Ratios, ApoA1 & B, Lip(a)
- ✗ **Liver Function Tests:** Bilirubin, SGOT, SGPT, GGT, Alkaline Phosphatase, Prothrombin Time, Proteins, Albumin, Globulin & Ratios
- ✗ **Pyrexia of Unknown Origin:** Hemogram with ESR, Hemoparasites, Widal, CRP, ANA, Blood Culture, Urine Routine & Culture Further- Bone Marrow
- ✗ **Pregnancy-Antenatal:** CBC, Blood Group, Blood Urea, Glucose, VDRL, Australia Antigen, Urine Routine Further- HCV, HEV, TORCH Profile, FreeT4, Lupus Anticoagulant, Anticardiolipin-IgG and IgM
- ✗ **Pregnancy -Bad Obstretic History:** Alpha Fetoprotein, Estradiol, betaHCG -Triple Test to Evaluate Risk, Lupus Anticoagulant, Anticardiolipin-IgG and IgM
- ✗ **Renal Function Tests:** Urea, Creatinine, Uric Acid, Sodium, Potassium, Alk. Phosphatase, Calcium & Phosphorus
- ✗ **Rheumatic Fever:** ASO, CRP, CBC, Throat Swab C/S
- ✗ **TORCH Panel IgG & IgM:** Toxoplasma, CMV, Rubella, Herpes

- ∞* **Thyroid Function Tests:** FreeT3, FreeT4, TSH, Thyroid Antibodies
- ∞* **Tuberculosis:** ESR, AFB Staining & Culture, Mantoux Test, Elisa TB for A60-IgG & IgM, FNAC
- ∞* **Viral Hepatitis Screen:** HAV IgM, HBsAg, HBc-IgM, HCV & HEV
- ∞* **Viral Hepatitis 'B' Screen:** HBsAg, AntiHBs, AntiHBc-IgM, HBeAg & AntiHbe
- ∞* **Viral Hepatitis Enteric Origin:** Anti HAV-IgM, Anti HEV-IgM
- ∞* **Viral Hepatitis Blood Borne:** HBsAg & Anti HBc-IgM, Anti HCV-IgG
- ∞* **Viral Hepatitis Immune Status:** Anti HAV-Total (Quantitative), Anti Hbs (Quantitative)

Biohazard management

According to biomedical waste management and handling rules 1997, treatment means a method, process or technique designed to change the physical, chemical or biologic characteristics or composition of any biomedical waste as non hazardous to health and environment. Waste should be properly disinfected either by chemical, thermal, electrical irradiation, biological enzyme, plasma torch, molten glass or molten salt technology. It was found that at NDPC that chemical and thermal methods are used for the routine purpose and storing the radio active substance for three months and then burning them as per the recommendations of Bhaba Atomic Research Center is the strategy followed. Recycling of possible waste materials reduces burden of waste disposal and indirectly reduces financial burden. Besides that, good waste management results in healthy staff adding to human resource.

Reducing the cost of non-conformance, i.e. Internal failure and External Failure cost leads to quality improvement, moral boosting of technical staff and decreased financial constraints on the Lab. W. Edward Deming 1987, developed and internationally promulgated, the idea that quality improvement and reduction in waste lead to improved productivity and competitive advantage.

Every laboratory should establish a systematic process for selecting appropriate quality control procedures. The need for this is illustrated by US CLIA regulations 1998. It was found that NDPC evaluates instruments, reagent stability and operator variance in determining the number, type, and frequency of testing calibrations or control materials and establish criteria for acceptability used to monitor test performance during run of patient's specimen. After calibration of instruments, there is a need for developing a quality control chart. Levy Jennings (1950) chart, The one followed at NDPC is an ideal one in this regard.

Besides the above internal quality control, external quality control program to evaluate once performance is obligatory. At NDPC external quality control program of Indian Association of Pathologist and Microbiologist is followed. From time to time samples are also sent to other countries and received back to compare the performance.

Patient as a Consumer

The general trend towards greater consumer awareness has created many new expectations from the lab. Previously, The investigation report was for the treating clinician of the patient by the lab. So, Interpretation of investigation was not required. Now the trend has reversed. The investigation reports is of the patient, for the patient requested under guidance of treating clinician. Now mere Biological datas can not and should not be reported, it should be preceded by a note of clinical significance. The patient wants to be constantly informed about the progress of disease. Moreover, Medical Technology demands advancing at fast pace and with little awareness among the clinicians, this has increased responsibilities of clinical lab scientists. Now simply reporting on clinical data can be hazardous.

It was found that every report at NDPC is followed by the interpretations e.g. a report of glycoselated haemoglobin carries the comment as given in Table 5.

Table 5: Hb A1c Level

Suggested Interpretation of Results*	
Hb A1c Level (%)	Degree of Glucose Control
- More than 8.0	Action suggested**
- 7.0 - 8.0	Good Control
- Less than 7.0	Goal for Diabetic
- 6.0 - 7.0	Near normal Glycemia
- Less than 6.0	Non Diabetic
** High risk of developing long term complications such as retinopathy, nephropathy, neuropathy and cardiopathy.	
* American Diabetes Association Diabetes Care 1997.	

By going through such reporting, the patient understands the suitability and progress of his treatment which goes a long way in treatment. Patient's satisfaction resulting from proper diagnosis and cure are the corner stones of medical ethics. Patient's assurance in quality system of lab brings him and his friends to same clinical centre in future and thus eliminates malpractice of commission to referring doctor.

Public Accountability

The entry of substantial public money in medical care has added new dimensions to medical practice. The amount of financial involvement present in preparing a doctor is enormous and proper and fair utilization of talent is must in the interest of the nation and to stick to ethical values is mandatory. Medical ethics are the principles of proper professional conduct concerning the rights and duties of the physicians' action in care of patients and in relation to their families. In this concern Hippocratic oath is demanded from the physician when they are about to enter in the practice of medical profession. By inclusion of medical profession under consumer protection act more physicians are going in for documentation of the diseases rather than blindly treating them. This has further raised the cost and also has forced some ethical values on the diagnostic centers.

Communicable Disease Control

As per recommendations of notifiable disease, it is ethically mandatory for every lab to notify the disease which are infectious like malaria, HIV, plague, etc. This goes a long way in controlling these diseases.

Conclusion

Thus if the ethical values in the profession are ensured, it leads to building up of goodwill of the pathological laboratory and its financial soundness.

In summary it must be mentioned that there are very few diagnostic centers in India which conform to the parameters and scales as outlined above. The situation in many government and private hospital labs is woefully hopeless. However the quality of service and ethical dimensions are observed both in letter and spirit in tertiary diagnostic center both in public and private sector. There is need for proper linkage of primary, secondary and tertiary center.

References

- Anand, R. C. and Sidharth A Satpathy (1998) *Hospital Waste Management - A Holistic Approach*: Jaypee, p. 54-70.
- Burtis, Carl A. and Edward R. Ashwood (1999) *Tietz Text Book of Clinical Chemistry, Third edition*, W.B. Saunders Company, p. 96-99.
- Davis, Brenta G. and Diano Mass Michael L. Bishop (1998) *Principals of Clinical Laboratory Utilization and Consultation*, W.B. Saunders Company, U.S.A.
- Draft Bio-Medical Waste (Management and handling) Rules, (1995). *Gazette of India extraordinary Part-11, Section 3, Sub-Section (11)* 1998.
- Deming, W E, (1987). *Out of the Crises*, Cambridge, M.A., Massachusetts; Institute of Technology Center for Advanecd Study.
- Health care Financing Adminstration, (1998). *Update on CLIA, Clinical Laboratory Improvement Amendment Advisory Committee Meeting*, Jan. 29.
- Levey, S and E R Jennings, (1950). *The use of Control Chart in the Clinical Laboratories*, Am.J.Clinical Pathology, 20, p. 1059-1066.
- Smith, Wyngaarden, (1982), *Cecil Textbook of Medicine, Vol.1*, p. 33-50.
- U.S. Department of Health and Human Service, (1992). *Clinical Improvement Ammendment of 1998, Final Rules and notice*, 42, CFR Part 493, *The federal register*, 57 p. 7188-7288.
- Westgard, J O and P L Barry, (1986). *Cost Effective Quality Control Management - The Quality and Productivity of Analytical Process*, Washington, D.C., AACC Press.
- Wong, E T, (1995). *Improving laboratory testing: Can we get physician to focus on outcome?* *Clinical chemistry*, 41 p. 1241-1247.
-