Quality Issues in health care management, Nephrology Perspective

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Abstract

Quality is a much more complicated term than it appears. Dictionary definitions are usually inadequate in helping a quality professional understand the concept. There are a variety of perspectives that can be taken in defining quality (e.g. customer's perspective, specification-based perspective). A modern definition of quality derives from Juran's "fitness for intended use." This definition basically says that quality is "meeting or exceeding customer expectations." Deming states that the customer's definition of quality is the only one that matters. Various terms, as, Quality Assurance(QA),Quality Control(QC),Quality Management, and Continuous Quality Improvement(CQI), are used, while discussing quality issues in health care management.

Transition in Indian Health Scenario, because of rapid increase in population, numbers one need to deal with are exceptionally high, and whenever quantity goes up, quality is compromised. This taxes our health care resources, economic resources, but economics is improving faster and literacey and awareness about health is better, therefore, there is quality improvement, and awareness and demand for the same. Chronic Kidney Disease V(CKDV), and End Stage Renal Disease(ESRD), scenario in late seventies, and in 2013, explains this transition clearly.

Quality issues in health care management, can be dealt with two step approach.A.First step is to make quality count, or apply all measures to improve quality in health care: 1.Evidence Based Medicine at bedside,2. Medical Decision & Analysis,3. Regulatory, Statutory and Practice guidelines by regulatory authorities, & professional Societies.,4. ICH- GCP guidelines,5. Health Economics Analysis,6. Complete, or Holistic health care,7. Accredition. B.Second Step is Quality Care Assessment of Services Provided: 1.Death Audit & Medical Audit,2. Survival Analysis,3. Quality of life assessment, QUALYs, DALYs,4. Users or patients feed back and perception,5. External Evaluation. And as follow up, apply, continuous quality improvement, (CQI)

Various instruments, and scales, are used for, quality of life assessment, quality adjusted life years(QUALYs), and disability adjusted life years(DALYs), for feed back and analysis. This is explained by nephrology perspective, specially dialysis.

Key Words

Quality Assurance(QA), Quality Control(QC), Quality Management, Continuous Quality Improvement(CQI), Chronic Kidney Disease V(CKDV), End Stage Renal Disease(ESRD) ,Quality adjusted life years(QUALYs), Disability adjusted life years(DALYs), Quality of life(QOL).

Introduction
Quality is a much more complicated term than it appears. Dictionary definitions are usually inadequate in helping a quality professional understand the concept. There are a variety of perspectives that can be taken in defining quality (e.g., customer’s perspective, specification-based perspective). A modern definition of quality derives from Juran’s “fitness for intended use.” This definition basically says that quality is “meeting or exceeding customer expectations.” Deming states that the customer’s definition of quality is the only one that matters. Quality is defined in the dictionary as “the standard of something as measured against other things of a similar kind; the degree of excellence of something.”

Quality assurance (QA) is a broad concept that focuses on the entire quality system including suppliers and ultimate consumers of the product or service. It includes all activities designed to produce products and services of appropriate quality. QA includes all those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. [Source: ASQ Statistics Division, Glossary & Tables for Statistical Quality Control, 1983]. Eg using good quality well maintained dialysis machines, or dialysis fluid of standard quality as a policy.

Quality control (QC) has a narrower focus than quality assurance. Quality control focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects.

Quality management is the totality of functions involved in the determination and achievement of quality (includes quality assurance and quality control). [Source: ASQ Statistics Division, Glossary & Tables for Statistical Quality Control, 1983]. Eg a supervisor monitors the water conductivity etc daily.

Continuous quality improvement (CQI), like quality assurance, CQI is a way to improve care. The focus of CQI is to see how things are working, take steps to make them better, and prevent future problems. There are specific steps involved in implementing CQI.

Quality problems are reflected today in the wide variation in use of health care services, the underuse and overuse of some services, and misuse of others, variations in services, and disparity in quality. Improving the quality of health care and reducing medical errors are priorities for the Agency for Healthcare Research and Quality (AHRQ). ¹,²,³,⁴,⁵

Why Quality Issues in health care Important: Transition in Indian Health Scenario:

Because of rapid increase in population, numbers one need to deal with are exceptionally high, and whenever quantity goes up, quality is compromised. This taxes our health care resources, economic resources, but economics is improving faster and literacey and awareness about health is better, therefore, there is quality improvement, and awareness and demand for the same.(Fig.1.)
Transition in Indian health scenario is rapid, because of planned attempts by Governmental as well as non governmental organizations, with strong support from International bodies. This is aided by strong health care system, resource development, and excellent medical facilities in public, and private sectors.(Fig.2) Majority of Indians, are now demanding quality care, are more aggressive, informed, and ready to fight for justice.(Fig.3) \(^{3,4,5}\)
TRANSITION INDIAN HEALTH SCENARIO

MAJORITY OF INDIAN PEOPLE WHO WERE LESS EDUCATED, IGNORANT, PASSIVE, DEPENDENT AND FATALISTIC DEMANDING QUALITY CARE, ARE AGGRESSIVE, INFORMED AND READY TO FIGHT FOR JUSTICE

Fig.3. Transition Indian Health Scenario II

TRANSITION EXAMPLE

In late seventies, 75000 ESRDs, were added annually to already existing pool of ESRD patients, out of this, 0.5 to 1% patients had access to Renal Replacement Therapy, (RRT). There was no renal transplant center in and around Nagpur. In 2013, round, 100000-150000, ESRD patients are added annually, however approximately 25-30% patients have access to RRT. There are four renal transplant centers in and round Nagpur.

Quality issues in health care management, can be dealt with two step approach:(Fig.4)

A. First step is to make quality count, or apply all measures to improve quality in health care:

1. Evidence Based Medicine at bedside
2. Medical Decision & Analysis
3. Regulatory, Statutory and Practice guidelines by regulatory authorities, & professional Societies.
4. ICH-GCP guidelines
5. Health Economics Analysis
6. Complete, or Holistic health care
7. Accredition

B. Second Step is Quality Care Assessment of Services Provided:

1. Death Audit & Medical Audit
2. Survival Analysis
3. Quality of life assessment, QUALYs, DALYs
4. Users or patients feed back and perception
5. External Evaluation
And as follow up, apply, continuous quality improvement, (CQI)

**QUALITY ISSUES IN HEALTH CARE MANAGEMENT**

**IMPROVEMENT**
- Evidence Based Medicine at bed side
- Medical Decision & Analysis
- Regulatory, Statutory, & Practice Guidelines
- ICH-GCP guidelines
- Health Economics Analysis
- Complete or Holistic Care
- Accreditation e.g. NABH, NABL

**ASSESSMENT**
- Death & Medical Audit
- Survival Analysis
- QOLA, QUALYs, DALYS
- User’s feedback & perception
- External Evaluation

**CONTINUOUS QUALITY IMPROVEMENT, (CQI)**

Fig.4, Quality Issues in health care management, Step-wise Approach

**IMPROVEMENT**

**A.1. Evidence Based Medicine at bed side**

The requirements for the practice of evidence-based medicine includes a process called, “Critical Appraisal Exercise” (Evidence-Based Medicine Group, 1992) which consists of following steps: 1) defining a patient problem and the information that is required to resolve the patient’s problem, 2) conducting an efficient literature search, 3) selection of the best of the relevant studies, and application of the rules of evidence to determine their validity, 4) should be able to present to colleagues regarding the strengths and weaknesses of the article in an effective manner, 5) extracting the message and applying it to the patient problem. 6,7.

**A.2. Medical Decision Making & Analysis**

Definition: It can be defined as in a clinical context as a method of describing complex clinical problem in an explicit fashion, identifying the available courses of action (both diagnostic and management), assessing the probability and value (or utility) of all possible outcomes, and then making a simple
calculation to select the optimal course of action. Following six steps are involved in decision analysis. 1. Create a decision tree, 2 Assign probabilities to chance nodes, 3 Assign utilities to the outcomes, 4 Calculate the expected utilities, 5 Select the choice, 6 Sensitivity analysis.

A.3. Regulatory, Statutory and Practice guidelines by regulatory authorities, & professional Societies.

This Clinical Practice Guideline document is based upon systematic literature searches last conducted in January 2011, supplemented with additional evidence through November 2011. It is designed to provide information and assist decision-making. It is not intended to define a standard of care, and should not be construed as one, nor should it be interpreted as prescribing an exclusive course of management. Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health-care professional making use of these recommendations is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation. The recommendations for research contained within this document are general and do not imply a specific protocol.

A.4. ICH- GCP guidelines

If there is a element of research, and for informed consent, ICH-GCP guidelines must be strictly adhered to.

A.5. Health Economics Analysis

Money is often a scarce resource for patients who must bear the cost of illness from their savings. The physician may have to forgo expensive diagnostic tests or hospitalization because the patient can not afford to pay. With government stake in an individual patient’s expenses. Thus, the cost of medical care has become a concern of groups of people rather than the individual patient. In this new environment, the physician has been able to act as the patient’s advocate without much concern for the cost to the individual patient. The concerns of health economists are: 1. How best the resources can be utilized? 2. Maximize the efficiency of health care in terms of it’s cost and it’s effectiveness. The are several principles that might be used to allocate a scarce resource: 11,12,13


A.6. Complete, or Holistic health care

Health care facility should be equipped to provide complete or holistic health care, which include medical and physical health, mental health, psychosocial well being, and also occupational rehabilitation. Quality complete health care team will include, doctors, nurses, technicians, paramedics, psychiatrist, psychologist, medico social worker, health economist, and social scientist.

A.7. Accredition
Organizations like, ISO NABH, NABL, have their own standardized system of quality assessment, as well as continuous quality improvement, (CQI). In fact this is now prerequisite by many governmental as well as nongovernmental agencies to get empaneled.

**ASSESSMENT**

**B.1. Death Audit & Medical Audit**

Death is hard outcome of health care management or intervention, therefore needs to studied carefully. Death audit is undertaken by team of experts from all disciplines involved in management of patients. These experts, are unbiased, critical appraisal is undertaken to see, if there was any scope for improved quality parameters in management. In similar ways, medical audit is done. Both these audits are performed, as part of Continuous Quality Improvement.

**B.2. Survival Analysis**

Survival analysis usually for five years, data is studied in the form of Kaplan-Meyer’s graph. This is disease specific and to compare with best available in literature, or where we, stand in comparison and scope for improvement if any.

**B.3. Quality of life assessment, QUALYs, DALYs**

**B.4. Users or patients feed back and perception**

Quality issues: reciever’s perspective, questions need to be asked:
1. Is purpose of his coming to hospital served?
2. Is he/she cured/partially cured/relieved from his illness upto his expectations and satisfaction and to that of his doctor?
3. How happy and satisfied patient is, about overall care and attention received?
4. How will he/she grade the total services received at centre, a. excellent, b. good, c. average, d. poor
5. Given the choice, what more, one will like to have or like to expect from the centre or facility?

Questions asked, are part of questionnaire, prepared for assessment of quality issues.

*These questionnaires are standardised and validated before being used for “instruments of measurement” of quality in health.*

*Some times these questions are scored according to their significance and weight, so that you get numerical evaluation at the end for better comparison.*

**example:** question on relief from medical problem = more wt. = numerical value
psychosocial satisfaction = lesser wt = numerical value

**example:** assigning numbers to functional status

<table>
<thead>
<tr>
<th>scale value</th>
<th>definitions</th>
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<tbody>
<tr>
<td>0</td>
<td>dead</td>
</tr>
<tr>
<td>1</td>
<td>requires assistance at all times</td>
</tr>
<tr>
<td>2</td>
<td>able to perform some acts independently</td>
</tr>
<tr>
<td>3</td>
<td>able to perform all acts independently but slowly and with discomfort</td>
</tr>
<tr>
<td>4</td>
<td>able to perform all acts independently quickly and without discomfort</td>
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Quality adjusted life year: QALYS
The period of time in perfect health that a patient says is equivalent to a year in a state of ill health

Disability adjusted life year: DALYs
The period of time in disability state that a patient says is equivalent to a year in a state of perfect health

Ideal quality intervention is one, which will: qalys are increased and dalys are reduced

B.5. External Evaluation

Most of the “quality issues” assessed, evaluated uses, subjective evaluation, therefore may be, “biased”, hence

- third party or observer evaluation
- independent external evaluation
- designated agency
- where ever possible, “objective assessment”

Such a quality evaluation will be relatively, “unbiased” acceptable and reproducible

QUALITY HEALTH CARE FACILITIES EVALUATION:

1. accessability, 2. infrastructure, 3. expertise, 4. ancillary disciplines, 5. machines & equipments, 6. lab. quality control issues, 7. management guidelines, 8. data storage, follow up, feedback, 9. research element, 10. medical waste disposal

Nephrology Perspective

Quality issues in Nephrology patients management:

Various bodies are present which control and monitor the quality of dialysis in the USA and other countries such as the ESRD Networks and Medicare, Joint Comission on the Accreditation of Healthcare Organizations (JCAHO), The Association for the Advancement of Medical Instrumentation (AAMI) which has standards for dialysis water treatment, dialysis solution preparation, and dialyzer reprocessing, The Food and Drug Administration (FDA) which oversees the safety and effectiveness of all medical devices, National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI™) Clinical Practice Guidelines and many more such guidelines. Recently the Indian Guidelines on Haemodialysis 2012 have been published by the Indian Society of Nephrology on their website.
FIG. 5. CLASSIFICATION OF QUALITY MEASURES IN DIALYSIS DELIVERY SYSTEM

Dialysis services: are carried out according to “Dialysis Outcome Quality Initiative” (DOQI) guidelines which are accepted as standard. Nutrition advise is according to “Handbook of Nutrition in Dialysis” Water quality measurement: Guidelines followed are. “The New AAMI Guidelines” Water treatment for haemodialysis. 2000.

CKD management: Clinical guidelines for management of CKD, issued by, “Indian Society of Nephrology”

Lab. Investigations and quality checks reference lab. Is, Christian Medical College, Vellore, (CMC, Vellore), EQAS

Infection control procedures are carried out according to “Manual of Infection control procedures by N. N. Damani, published by Greenwich medical media ltd. 137 Euston Rd, London NW 1 2AA

Biomedical waste disposal policy, according to “Biomedical waste, (Management & Handling) rules, 1998.

Medical record Keeping and Research Element:The hospital has record of patients since, 1999, and since 2003 it is computerized Some good data is maintained and some presentations and publications have been made out of it.

Quality management system:


Implement the “Plan, Do, Check, Act” Cycle
The last step is to use the plan, do, check, act (PDCA) cycle (see Figure 8). The four steps to the PDCA cycle are:

1. **Plan** – Make a plan to address the problem. Include outcomes, solutions to the problem, a task list for each team member, and a time frame.

2. **Do** – Implement the action plan.

3. **Check** – Monitor the results of the plan, assess results after the plan is done, and assess the plan for any needed changes.

4. **Act** – Adopt the plan in the center on a formal basis and continue to monitor progress.

**FIG.6. PDCA CYCLE**

**Quality of life assessment** — Various tools have been used by individual nephrologists and dialysis programs to assess quality of life of patients. However, there is as yet no mandated use of such tools in dialysis units, and the most appropriate tool and its use in patient care have not yet been clarified. Depression, sexual dysfunction, reduced functional status, and low rates of employment are all relatively common among patients with chronic kidney disease.

Quality of life assessment should begin with the diagnosis of kidney disease and continue until death. Periodic assessment of a patient's quality of life should therefore become as routine as are the current measurements of serum hemoglobin levels and dialysis adequacy. In addition, symptom assessment and treatment in ESRD patients are not routine but integral to quality of life assessment.5,14

**References:**


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BIOGRAPHY

DR.V.L.GUPTA, MD, PhD, BA, MNAMS, FICP, FICE, FISN, is consultant nephrologist at Ashwini Kidney Dialysis Center, and Avanti Institute of Cardiology, Nagpur. He is Ex-Professor & Head dept. of nephrology, Super Speciality hospital & PG Institute of Medical Sciences. He has also been, Director, Clinical Epidemiology Unit, GMC, Nagpur. He has UG, & PG teaching experience of over thirty two years in medicine and nephrology. He has been UG & PG examiner across universities in India. He was postgraduate guide for MD, DNB, and PhD for RSTM university Nagpur.

Winner of research awards & medals, He is recipient of several oration and lecturer ship awards at National level, including “Searle Oration” API 2004. He was awarded, “INCLEN, USAID, fellowship in Clinical Epidemiology, in 1987-88, during which he was part of Master’s program and was trained in Clinical Epidemiology, Research Methodology, at UNC, NC, USA, 87-88, beside he has received several other fellowships at national & international level. Being member over dozen professional bodies, and scientific societies. He has been heading several of them. His name has been included in “Asia’s Who’s Who” of Medicine, 2014. He has authored and published three books, beside contributing to other published monograms & Books, has published over 90 research papers.

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